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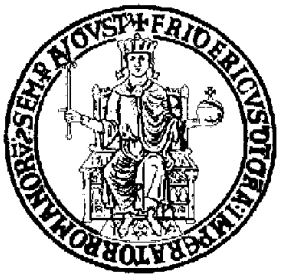

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A SYSTEMIC FUNCTIONAL LINGUISTIC APPROACH TO PATIENT INFORMATION LEAFLETS (PILs)

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A SYSTEMIC FUNCTIONAL LINGUISTIC APPROACH TO PATIENT INFORMATION LEAFLETS (PILs)

DOCTORAL RESEARCH THESIS in ESP

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TABLE OF CONTENTS

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Abstract

Patient empowerment and involvement has become increasingly important within the health sector. There has been a lot of focus on patient information, and a document like the Patient Information Leaflet (henceforth PIL) has been the subject of an ongoing discussion for the last ten years and more. The PIL has often been criticised for its lack of user-friendliness in spite of legal requirements as those outlined by the European Commission Directives. There have, however, been several initiatives to improve their readability, comprehensibility and functionality. In the UK, the Medicines and Healthcare Products Regulatory Agency (MHRA), introduced the 'Always Read the Leaflet Guideline', the 'PIL of the month' issue, and recently, in July 2012, the 'Best Practice Guidance on Patient Information Leaflets'. The aim of the guidelines is to support Pharmaceutical companies and medical experts to enhance the layout, the language and style of PILs and make them 'easy to read, understand, and act upon'. Considered as a genre with potentially seven moves, in this study 60 PILs have been manually analysed based upon a systemic functional linguistic (SFL) framework to evaluate their quality from the levels of the genre, the discourse semantics, and lexico-grammar. The notion of generic structure potential is also elaborated according to frame theory. Furthermore the visual features of layout and design have been examined in accordance with the EU requirements and with the MHRA's recommended guidelines.

FOREWORD

The present study initially arose from my general interest in health information and communication for the lay audience. At first my research was dedicated to the popularization of science texts, then to written information that promotes patient education, and finally, to patient information leaflets (PILs). I embarked on the study of PILs two years ago after reading an article which reported about the changes to wordings on patient medicine labels because they were found to be "confusing and misleading" (Raynor, 2011). Labels are the adhesive instructions added to medicinal packets and bottles by pharmacists in the UK when dispensing a medicine. They give a very brief summary of what the doctor has prescribed for his/her patient. The PIL, on the other hand, is a thin folded piece of paper of different sizes, printed in a small font, and found inside the medicine package.

During the initial part of my research I had the opportunity to contact and receive some important information from Professor Theo Raynor, a researcher at Luto Research Ltd Company, University of Leeds, about patient medicinal written information. He told me to make a clear distinction between 'labels' and 'PILs' because the former are produced by pharmacists, whereas, the latter are issued by Pharmaceutical manufacturers.

I started my research by browsing websites and writing to Pharmaceutical companies for sources. Surprisingly, I found that quite a lot had been written about patient information leaflets accompanying medicinal containers. Of note, a lot of work had been carried out in:

Australia, the U.S.A, the Netherlands, Germany, South Africa, Iran, Palestine, Hungary, Italy, and of course, the UK which is one of the foremost promoters of health education, empowerment and involvement. *Involvement means that the person who receives a medicine needs to become an active reader and participant of the act of taking a medicine*. This aspect of medicine information through a popularised comprehensive text, the PIL, motivated me to take on a study of patient information leaflets and labels issued in the U.K. in the last five/six years.

INTRODUCTION

People expect and are entitled to good quality information about their medicines, whether prescribed (P) or bought-over-the counter (OTC). Informed decision-making by patients and the public about medicines is keenly promoted by the British Department of Health (DH), and is an issue with which healthcare professionals are increasingly becoming familiar.

We live in a society rich in health information sources, and consumers expect to be able to access information in order to make informed decisions about their health and medicines. For many people, the primary or only source of information about their medication is the statutory patient information leaflet (PIL) which, since January1999, has had to be supplied with every medicine packet or bottle. Unlike other sources of health information, PILs are highly regulated on a European level to guarantee a comprehensible document that contains the essential information to enable patients to use medicines safely and gain the most benefit from it. Being set out in European and national legislation PILs must comply with regulatory requirements (the European Commission Directives and Guidelines, 1998, 2001, 2004, 2009). Despite the rules and regulations, the UK Medicines and Healthcare products Regulatory Agency (MHRA) acknowledges that PIL consumers often do not read their leaflet, because they perceive it to be too long or complex (Raynor *et al*, 2007:2). The complexity of PIL production is not only linked to the legal requirements, it is also exacerbated by the knowledge asymmetry between the sender, a medical expert, and the receiver, a layperson. The receiver side of the communication process is very complex for PILs as the potential receiver

group consists of a large heterogeneous group, who, in the reception situation, might feel anxious, stressed or insecure (Albin 1998: 118). Even though text producers might be aware that their potential receiver is a lay person, the receiver of many types of medications can potentially be the entire population, which means that the text producer can never really have a specific receiver in mind, and visualization of the receiver can be extremely problematic for the text producer (Askehave and Zethsen 2003: 26).

Furthermore, research into mass communication concludes that mass communicators use specific cognitive tools to visualize a receiver, and studies from other disciplines such as communication and psychology show that experts, because of their expert status, are often unaware of what poses problems for lay people, and therefore, might overestimate the knowledge of their receivers (e.g. de Jong and Lentz 2007; Lentz and de Jong 2009; Hinds 1999; Nickerson 1999 cited in Askehave and Zethsen 2003: 26). This approach might prove very detrimental to user-friendliness, and may create within the patient an unhappy feeling caused by the amount of information he or she receives about a medication (Harrison and Harwood 2004).

Literature reviews also show that there are a number of readability formulas which have been used to assess the structural elements of PILs which are designed to measure reading difficulties. Formulas, such as FOG, Flesch and SMOG, for example, produce a score or number that indicates how readable a piece of text is, focusing on the premise that long words and/or sentences make text harder. But there are objections to these 'readability' procedures because they are found to be limited. In a paper, Dixon-Woods (2001) for example, argues that the focus on readability arises from conceptions of the purposes of leaflets as well as from

assumptions about the process of communication itself. The dominant conception derives from a biomedical perspective: PILs are a means of patient education and their purpose is to save time and energy and to provide medico-legal security for providers of health care. In this view, the PIL is aimed at effecting cognitive, attitudinal or behavioural changes in patients, who are irrational, passive, forgetful and incompetent. Readability formulas do not take this aspect in consideration, actually they:

> " exclude the voice of patients from the evaluation of printed information, since the value of leaflets can be predicted by a formula about the relationship between syllables and sentence length".
>
> Dixon-Woods (2001: 1426)

By contrast, conceiving of the purpose of PILs as patient empowerment values patients' rationality, competence, resourcefulness and reflexivity. If communication is to be effective, the PIL must be 'noticed, read, understood, believed and remembered' (*ibid*.).

OUTLINE OF THE THESIS

The present research project is structured as follows:

Chapter One opens with a literary review on background information about health communication and literacy. The sections that follow focus on the PIL as regards to its definition, background and rationale. Then an overview of the international and national regulating organizations, that control and provide guidelines for the enhancement of patient leaflets to meet patients' needs, are presented. The legal framework (Directives of the European Community), actually recommends a standard layout (template) which is addressed to all the EU Member States. The following paragraphs of Chapter One, and the rest of this study, concentrate on PILs issued in the UK only. These are highly regulated by criteria standards as regards to language, content and layout. The MHRA, responsible for promoting and ensuring best health information and communication, has issued various guidelines and initiatives to enhance the quality of British patient leaflets. Initiatives such as, PIL user-testing, the 'PIL of the month' for best-practice, and the X-PIL Service for alternative formats for visually or audio impaired users, and/or for people whom English is not their first language, are amongst those issues which are investigated in these paragraphs. The final section is dedicated to the legal classification of medicines in the UK to indicate the differences between leaflets that accompany medicines dispensed only with a prescription (POM), and leaflets accompanying medications that can be supplied without a doctor's prescription over-the-counter (OTC) .

The second Chapter is dedicated to readability processes and to the reading comprehension of PILs. First, a literature review is given as regards to readability mental processes and cognitive factors that are involved when performing the act of reading a text. Then, an overview of readability formulas are mentioned as tools used for assessing readability in general, and in particular for assessing PILs. Flesch, Fry and SMOG formulas, mentioned beforehand, are amongst some of the formulas which have been applied to measure the readability and comprehensibility of PILs. Research, however, consider the drawbacks of these formulas (Lunzer and Gardner,1979; Anderson and Davison, 1988; Halliday, 1998; Dixon-Woods, 2001), and demonstrates that there are parameters which go beyond text lexis and sentence length which involve other factors such as prior knowledge, abilities, preferences, strategies and effective factors. The closing sections of this chapter focus on the concept of word difficulty, sentence length, and the supportive role of prior knowledge.

Chapter Three and Four are devoted to the analysis of the corpus of this research and provide results and discussion. Sixty original PILs are introduced, and analysed in line with Halliday's Systemic Functional Linguistics (SFL). The method of investigation is manual of the corpus and the reason for preferring this procedure to a computerised analysis is that it proves to be carrying a more individualistic character. SFLs views language as a social semiotic resource people use to accomplish their purpose by expressing meanings in context. Patient information leaflets are an important adjunct to verbal exchange between doctor/expert and patient/lay reader. The value of PILs is dependent upon whether they contain useful information and are easily understood. Thus, SFLs has provided me with the possibility to study the corpus within a narrower and

wider context of research. Being the PIL, quite a standard genre (as resulted from the findings) a computerised study would have been limited to few variables. Furthermore, a corpus-based approach is more appropriate for a bigger size corpus, and/or for a diachronic analyses.

Following Halliday's approach, the PILs selected have been analysed within a framework that considers both lexico-grammatical features of language and the discourse-semantics. The overall aim of this study was to assess the quality of current PILs, and find whether they are patient-centered, rather than medical/expert-orientated. The theory applied was a useful and fruitful tool for exploring a full range of relevant textual elements within the corpus in order to identify the writer-reader objectives. Frame theory (Paltridge, 1997), for what concerns the notion of generic structure potential, has also been used to identify how the structural elements of the generic structure of PILs operate.

Referring to the above considerations, my research questions are as follows:

- How stabilized are the text patterns in the corpus, or better, how conventional is the text structure?
- What are the features in a text-based analysis of patient information leaflets to contribute to the fulfillment of writer and reader objectives?
- Is 'patient centeredness' manifested linguistically and how is it manifested?

Within the SFL theory, a series of sub-questions have been selected to assess the quality of PILs in a more detailed manner. The evaluation has considered items which include the overall organizational or generic

structure of the text; the rhetorical elements; the meta-discourse; the clarity of the role relationship between writer and reader; the headings; the lexical density (carried out on section two of the PILs); and specialization of lexis. Finally, although the format is not of linguistic nature but essential for comprehension, the visual aspect of PILs has also been examined. All the design features have been analysed (e.g. general typography, the length, illustrations, format and layout), in accordance with legal design guidelines (European Commission and MHRA), and based upon research literature (e.g. Hartley, 1994; Schriver, 1997; Dowse and Ehlers, 1998, 2005; Piwek *et al*, 2006).

Chapter Four is totally concentrated on the presentation and discussion of the results. Following a step by step method, a wide range of examples, scanned and copied from the original PILs, are presented, and respond to the sub-questions applied within the linguistic framework for assessing the quality of PILs.

The fifth and last Chapter of this project, is dedicated to the new wordings on medicine labels which had remained the same since 1985 in the British National Formulary (BNF), the authoritative textbook that medical experts use for looking up information about medicines. In March 2011, the BNF introduced some important changes following the group of Luto's researchers. The Chapter starts with an overview of the information found on the medicine's dispensing label, continues with the presentation of the recent wordings and its rationale, and ends with an interesting interview which has been trans-scripted by myself. A reporter of BBC Radio 4, interviews Professor Theo Raynor about the changing situation of labels in Britain.

Finally, there is a list of anagrams used in the thesis, the references and an Appendix Section. In Appendix 1, examples of authentic labels are shown with the names of some patients who have given me the permission to use them for my thesis. Appendix 2 includes all the copies of the corpus studied. The PILs attached are copies of the original leaflets examined, where colour, spacing, section separation, features of the headings, sub-headings, and the date of the PILs can be noticed. All the PILs were scanned and saved beforehand, and then copied. However, their dimension has been modified in order to fit the pages appropriately, furthermore some of the parts have not been copied for space reasons in the thesis. The original copies in their complete version may be viewed in the CD that has been enclosed, or downloaded in their updated versions in the electronic medicine compendium (see 3.4).

CHAPTER ONE

PATIENT INFORMATION LEAFLETS (PILs)

"*Everyone needs written medicines information at some time*".
(Raynor *et al*; 2007: 1)

1.1 Overview of Chapter

This chapter will attempt to explain how health communication has developed in the last decades to inform users about health matters, and the importance of health literacy. The following paragraphs are concerned with the presentation of the patient information leaflet: its background and rationale; the main regulating responsible agencies which control PILs; the standard layout of a PIL; the rules and regulations within the European Community; the patient medicinal leaflet in the UK; what user-testing is; the PIL of the Month initiative; other formats of PILs. Finally, the classification of medicines in the UK and the difference between P medicines and OTC medicines and their relevant package PILs.

1.2. Health communication and literacy

Health communication has developed over the last thirty years as a vibrant and important field of study concerned with the powerful roles performed by humans and mediated communication in health care delivery and health promotion. Health information is the most important resource in health care and promotion because it is essential in guiding strategic health behaviours, treatments and decisions (Kreps, 1988).

Health communication examines many different levels and channels of communication in a wide range of social contexts. The primary levels analysis include: intrapersonal, interpersonal, group, organizational, and societal communication. Intrapersonal health communication inquiry examines the internal mental and psychological processes that influence health care, such as health beliefs, attitudes, and values that predispose health care behaviours and decisions. Intrapersonal health communication inquiry examines the relational influences on health outcomes, focusing on the provider/consumer relationship, dyadic provision of health education and therapeutic interaction, and the exchange of relevant information in health care interviews. Group health communication inquiry examines the role communication performs in the interdependent coordination of members of collectives, such as health care teams, support groups, ethics committees, and families, as these group members share relevant health information for making important health care decisions. Organizational health communication inquiry examines the use of communication to coordinate interdependent groups, mobilize different specialists, and share relevant health information within complex health care delivery systems to enable effective multidisciplinary provision of health care and prevention of relevant risks. Jackson and Duffy (1998) stated that societal health communication examines the generation, dissemination, and utilization of relevant health information communicated via diverse media to a broad range of professional and lay audience to promote health education, health promotion, and enlightened health care practice.

Health literacy comes in very importantly for the comprehension of the health material supplied. Health literacy is a concept in health research that goes beyond general literacy, which defines the reading ability of the individual, because it integrates comprehension and incorporation of health

material into use. Healthy People 2010 cited in Ngoh (2009: 47), defines health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions". Boswell *et al*., (2004) argue that a person's functional health literacy may be significantly poorer than his or general literacy and that health literacy is: "the ability to read, understand and act on health information" (Boswell *et al*., 2004: 62).

The increased focus on the importance of health communication, especially with the general public, shows that the demand for patient information and involvement comes from both the patient and the societal push to involve patients in their own health. This is the why UK government policy is to provide patients with health information that is accessible and of high quality as:

> "quality information empowers people to make choices that are right for them"
>
> (Department of Health. The information standard and accreditation, 2010)

Patient information leaflets (PILs) as a medium of communication, play a crucial role in patient empowerment and involvement (Holmstorm & Roing, 2010) and are considered the most important source of information about a medication for the patient (Bjerrum & Foyed, 2003: 58). The leaflet must not replace a full discussion between a doctor and a patient but it is actually thought of as a consistent basis of information which doctor or patient may wish to expand upon.

1.3 What is a PIL?

A PIL, short for 'patient information leaflet', is a document enclosed in the sales package of a medicinal product and is written in the national language(s) of the country where it is sold. Other names may be found, for

example: ‘consumer medicine information’, ‘instruction leaflet’, ‘package insert’, ‘consumer insert’.

PILs are issued by pharmaceutical companies and have to meet the requirements of the medicine regulatory agencies in the country where the PIL will be issued. For the European Community countries, these leaflets are tightly regulated both by the European Medicine Agency (EMEA) and, by the country’s own medicine regulatory agency (see paragraph 7).

PILs are summarised and simplified versions of summaries of product characteristics (SPCs). The Summary of Product Characteristics is a specific document required within the European Commission before any medicinal product is authorized for marketing. This summary is the description of the product both in terms of its properties, chemical substances, pharmacological and pharmaceutical use, and the clinical use that can be made of the product. The EU provides guidelines on the use of this document for applicants. The Summary must be completed and submitted as an application to the EMEA before marketing is authorized. Therefore, the document is an intrinsic part of the authorization, and cannot be changed following approval. The SPC is not intended to give general advice about treatment of a condition but states how the product is to be used for a specific treatment. It forms the basis of information for health professionals to know how to use the specific product safely and effectively. SPCs are produced for the approval and development of medicines and are intended for professionals and experts. A PIL, on the other hand, is an adapted version, simplified, popularized, and intended for the lay audience.

1.4 Background and rationale of PILs

The need for readily available and useful written patient information on medicines was highlighted by a retrospective study on evaluation of emergency room visits in the United States (Department of Health and Human Services, 2000: 4). The study indicated that a large number of visits and hospitalization were a result of simple non-adherence to instructions related to prescribed medicines. The questions at this point are: Were the patients aware of the consequences of not taking their medication as prescribed? Were they supposed to inform the doctor of side-effects or medicine interactions experienced? Who was responsible for a negative therapeutic outcome? Did the system fail to provide sufficient information to enable patients to protect themselves? The Department of Health and Human Services stated that the problem to be addressed was that the desired therapeutic outcomes were not achieved, or that patients could be adversely affected as a result of their ignorance regarding the medicine to take (Department of Health and Human Services 2004: 4).

In a research project carried out by Mary Dixon-Woods (2001) on the publications of discourses about the use of patient information leaflets, numerous reasons are given for the motivation of using patient information leaflets. For example, leaflets are seen as a possible source of advantage to health care providers. Proposed benefits include saving time in the consultation, and relieving staff boredom. Leaflets have also been proposed as a possible source of medico-legal advantage, as a means of achieving cost-benefits in the national Health Services, or as a substitute for expensive professional time, (Dixon-Woods, 2001: 1419).

As in the case of the Department of Health and Human Services, 2004, another powerful motivation for using patient information leaflets derives from a discursive construction of patients as irrational, passive, forgetful,

and incompetent. These assumptions themselves draw on a body of work in cognitive psychology carried out by Phillip Ley and collegues (e.g. Ley, 1973, 1977, 1988). Again Dixon-Woods (2001: 1423) refers to Hjelm-Karlsson (1989), who notes:

> "[...].these findings clearly demonstrate that giving oral information to patients in many cases is equivalent to not giving information at all".
>
> (Dixon Woods, 2001: 1423)

The verbal advice (patients) are given is often forgotten (Ley, 1979), and the medical terminology may be confusing (Boyle, 1970, Baker *et al*., 1991: 525)

These considerations characterise patients as being unreliable witnesses to their consultation. Patient leaflets are therefore used to compensate for patients' inadequacies and to bring their knowledge into line with what is medically "correct" (Dixon-Wood, 2001). In the words of Savage (1992):

> "It is crucial to back up verbal advice with written material, as the average adult forgets half of what is told within a few minutes".(1992: 24)

In general, people may only retain about 20% of what they hear, but this may increase by 50% if there is additional visual or written input. (Kenny *et al*., 1998)

Do patient information leaflets effect cognitive, attitudinal, or behavioural changes in patients? According to researchers (Ley, 1979; Hjelm-Karlsson, 1989, cited in Dixon-Woods, 2001, 1423) they do, and their role is to improve compliance, because non-compliance is the result of incompetence. There is the need to consider patients as active participants in their care rather than passive recipients. Health professionals must take account of patients' views and preferences and share decision-making in appropriate ways (*ibid*.).

Hence, PILs have the goals of promoting the health of the population, educating about health problems, stimulating and optimising the use of a medicine and "ensure safe, effective and appropriate use when the decision has been made to take it (Raynor, 2009). In other words, PILs are to meet the consumer's demand for information about their medicine, condition and general health matters (Ley and Morris, 1984; Kay and Punchak, 1988) and to strengthen the (verbal) information given during a GP consultation.

1.5 Responsible Agencies

There are various national or international organizations that regulate medical information. In the United States there is the Food and Drug Administration (FDA) which determines the requirements for patient package inserts and labels. Other organizations that regulate medical information include the European Medicine Agency (EMEA), which from 1995 to 2004 was known as the European Agency for the Evaluation of Medicine Products. It is based in London and was set up after more than seven years of negotiations among EU governments. It replaced the Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products, though both of these were renamed as the core scientific advisory committees. The Japanese Ministry of Health, Labour, and Welfare (MHLW) is responsible for Japan. Other country-specific agencies, especially in the case of EU (European Countries) countries and candidates, plus countries of South America and many in Asia and the Far East, rely heavily on the work of these three primary regulators. The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods. They carry out a range of assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard with the aim of

ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.

The first patient package insert required by the FDA was in 1968, mandating that an inhalation medication was to contain a short warning explaining that excessive use could cause breathing difficulties. Then in 1970 a patient package insert was required for combined oral contraceptive pills which had to contain information for the patient about specific risks and benefits about that medicine. In the UK, the first patient information leaflets accompanied inhaled medicines and others that required detailed instructions for use, by patients self-medicating outside the healthcare environment at the end of the sixties and during the early seventies. In other European countries, such as Italy, Germany and the Netherlands, information leaflets in medicine packets were already used during the sixties.

1.6. Layout of a PIL

The contents and structure of PILs has not remained the same in the course of time but has undergone many changes, and is still facing changes to meet the requirements of the authorities and, most importantly, the patient's needs. At the end of the eighties, the European Commission started to standardize patient information. Before that time, the individual European countries each had their own laws regarding the documentation of patient information.

The Directive requires that the PIL is drawn up in accordance with the Summary of Product Characteristics and that it contains specific information in a specific order.

Detailed information on the medicines and the leaflet is available in all EU/EE languages on the European Medicines Agency website at: http://www.ema.europa.eu.

The Directive prescribes the following seven sections within a PIL:

- **Identification of the medicine**

  Name of the product, the active substance and details of the other ingredients, the pharmaceutical form, contents within the pack, the name and address of the marketing authorization holder and the manufacturer and the way in which the medicine works.

- **Therapeutic indications for the product**

  The conditions for which the medicine is authorized.

- **Information which patients need to be aware of prior to taking the medicine**

  Situations when the medicine should not be used, any precautions and warnings, interactions with other medicines or foods, special patient populations such as pregnant women or nursing mothers, and any effects the medicine may have on the patient's ability to drive.

- **Dosage and usual instructions for use**

  How to take or use the medicine, how often the dose should be given, how long the course of treatment will last, what to do if a dose is missed and, if relevant, the risk of withdrawal effects.

- **Description of side effects**

  All effects which may occur under normal use of the product and what action the patient should take if any of these occur.

- **How to store the product**

- **Date on which the leaflet was prepared**

(Always read the leaflet – getting the best information with every medicine, 14-15).

The PIL must be written in the official language of the member state and must also be written in clear and understandable terms for the users.

1.7 Rules and regulations in Europe

Written medicine information for patients was introduced no earlier than the late 1970s in Europe, according to Koo (2005). Until the eighties, European countries each had their own regulation, and an important step forward was taken by Belgium which, as a pioneer introduced a law in 1984 stating that package leaflets had to be written in such a way as to be legible for adults who had the educational level of compulsory school, which was sixteen in Belgium at the time. Following the example of Belgium, Europe decided that henceforth medicine packages had to contain a comprehensible patient information leaflet.

In 1992 the then EEC issued Directive 92/27/EEC to standardise patient information for all EU countries. Article 8 of this Directive stipulates that:

> "[…] the package leaflet must be written in clear and understandable terms for the patient and be clearly legible in the official language or languages of the Member State where the medicinal product is placed on the market. This provision does not prevent the package leaflet being printed in several languages, provided that the same information is given in all the languages used"
>
> (Directive 92/27/EEC)

The fact that the then twelve member states of the EEC were obliged to comply with this directive, created the need for a multilingual glossary in the nine languages spoken in the former EEC at that moment (EN, NL, FR, DE, ES, PT, IT, EL, & DA). This was the immediate cause for setting up the Multilingual Glossary of Technical and Popular Medical Terms in 1993, which was completed two years later in 1995. The multilingual

glossary containing, 1,830 technical medical terms and their popular equivalents in the nine languages was put on the web at: http://users.ugent.be/~rvdstich/eugloss/welcome.html at the disposal of the general public, where it can still be consulted (Vanopstal and Van Wiele, 2009).

As for Directive 92/27/EE, after a phasing-in period, it came into effect across the EU in January 1999 (Dickinson, Raynor & Duman, 2001: 148). In 2001, this Directive was revised by Directive 2001/83/EEC and in 2004 by Directive 2004/27/EEC. The Directive describes the conditions for which all PILs brought onto the European market must comply with. According to article 59 of Directive 2004/27 EEC, a package leaflet should be drawn up in accordance with the Summary of Product (SPC). The Economic Commission validated their Council Directive by stating that the purpose was to:

> "provide guidance on how to ensure that the information on the labeling and package leaflet is accessible to and can be understood by those who receive it in order to guarantee safe and appropriate efficacy".
>
> (Directive 2004/27 EEC)

The characteristics to be included, are as follows:

(a) identification of the medicinal product

1. name, strength and pharmaceutical form, and, if appropriate, if it is intended for babies, children or adults. The common name shall be included where the product contains only one active substance and if its name is an invented name;
2. pharmaco-therapeutic group or type of activity in terms easily comprehensible for the patient;

(b) the therapeutic indications;

(c) list of information which is necessary before the medicine is taken:

1. contra-indications;

2. appropriate precautions for use;
3. forms of interaction with other medicines and other forms of interaction (e.g. alcohol, tobacco, foodstuffs) which may affect the action of the medicine;
4. special warnings;

(d) the necessary and usual instructions for proper use, and in particular:

1. the dosage;
2. the method, and, if necessary, the route of administration;
3. the frequency of administration, specifying if necessary the appropriate time at which the medicinal product may or must be administered; and, as appropriate, depending on the nature of the product:
4. the duration of treatment, where it should be limited;
5. the action to be taken in the case of an overdose (such as symptoms emergency procedures);
6. what to do when one or more doses have not been taken;
7. indication, if necessary, of the risk of withdrawal effects;
8. a specific recommendation to consult the doctor or the pharmacist, as appropriate, for any clarification on the use of the product;

(e) a description of the adverse reactions which may occur under normal use of the medicine, and. if necessary, the action to be taken in such a case; the patients should be expressly asked to communicate any adverse reaction which is not mentioned in the package leaflet to his doctor of pharmacist;

(f) a reference to the expiry date on the label, with:

1. a warning against using the product after that date;
2. where appropriate, special storage precautions;

3. if necessary, a warning concerning certain visible signs of decoration;
4. the full qualitative composition (in active substances and excipients) and the quantitative composition in active substances, using common names, for each presentation of the medicine;
5. for each presentation of the product, the pharmaceutical form and content in weight, volume or units of dosage;
6. the name and address of the marketing authorization holder, and, where applicable, the name of his appointed representatives in the Member States;
7. the name and address of the manufacturer;

(g) where the medicine is authorized in accordance with Articles 28 to 39 under different names in the Member States concerned, a list of the names authorized in each Member State;

(h) the date on which the package leaflet was last revised.

(Directive 2004/27/EC of the European Parliament and of the Council 136/48-136/49).

The Directive, as a legal instrument, binds upon each Member State to which it is addressed. However, the national authorities in each Member State (such as the Agenzia Italiana del Farmaco -AIFA- in Italy and the MHRA in the United Kingdom) are allowed to adapt the Directive into a form they consider most suitable for achieving the objectives in their country (according to the EU Pharmaceutical Legislation).

In 1998 the Pharmaceutical Committee of the European Commission published: "**A Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use** (more commonly known as "Guideline on readability") which was especially aimed at the readability of PILs and was to supplement the existing Directive

92/27/EEC. In this document, requirements with regard to contents, structure, design and style of PILs were drawn up. It provides advice to marketing authorization holders (MAH) and does not have legal force; the definitive legal requirements are those outlined in the Directive and national rules of the Member States. However, this guideline should be considered as a "harmonized Community position" which will simplify the assessment, approval and control of PILs. Marketing authorization holders (MAH) and manufacturers of medicines are allowed to take alternative approaches regarding the readability of PILs, but they need to justify their procedures. The Guideline on readability consists of the following directions (summarized):

- The print size and type should be 8 points Didot.
- The spaces between lines should measure at least 3 mm.
- Words in full capitals/upper case should be avoided.
- Colours may be used but must be distinguished from the background.
- Simple punctuation should be used.
- Sentences over 20 words or 70 characters should be avoided.
- The rules concerning bullet point lists should be obeyed. A group of bullet points should be introduced with a colon and a single full stop should be placed at the end of the group. A list of bullet points should begin with the uncommon and specific case and end with the common or general case, unless this is inappropriate for the product.
- A minimum number of words should be used in the bullet points and never more than one sentence. There should be no more than nine items where the bullet points are simple and no more than five when they are complex.

- Abbreviations should be avoided.
- When possible ‘it' should be used for reference to the medicine, avoiding repetition.
- The paper size should be A4/A5 for long leaflets. The paper weight should be no less than 40g/m2.
- (Sub)headings should be made conspicuous (e.g. by colours) and also, headings should be numbered. No more than two levels of headings should be used.
- Sentences should be formulated in an active and direct style.
- Pictograms should only be used when they make the message clearer.
- Red colour print should only be used for very important warnings.
- Capitals should not be used indiscriminately.

(European Commission Guideline on the readability of the label and package leaflet of medicinal products for human use, 1998: 3, 4, 11, 12).

The report on readability supplements the Directive on some aspects very well, but fails to give good advice on other key aspects of PILs. For example, “the text must be readily understandable for the patient” is vague and can be interpreted in many different ways. The guideline fails to give concrete advice on this aspect. For this reason, several EU countries have published additional reports on PILs’ readability, in order to supplement the guideline of the European Commission.

Included in the Guideline on readability, in1998 the European Commission designed a model leaflet in which an example PIL had been drawn up (Guideline on the readability of the label and package leaflet of medicinal products for human use 13-7). Until November 2005, PILs could be set up in two ways: either according to the Directive, or according to the

example of the model leaflet. The Directive is not very specific about how a PIL should be set up because, as mentioned before, the only concrete information the Directive gives, is about a PIL's content and structure. Until November 2005, PILs that were not designed according to the model leaflet (as recommended by the Directive) had to be tested.

In 2004, the revision of the European medicinal law, called the Quality Review of Documents (QRD) 2001, was rounded off. The date of implementation of this review was 1 November 2005. From this date onwards, manufacturers and registration holders of medicines that were to be registered for the first time or that had changed drastically were obliged to have their PIL's readability tested. The Guideline on readability includes information on testing PILs' readability but again, the report is not very specific about what the test should entail and, moreover, the '16 out of 20' norm (16 out of 20 consumers must be able to answer each test question correctly) caused much discussion as this norm was considered too light (Guideline on the readability of the label and package leaflet of medicinal products for human use 1998: 24-6). Therefore, the individual Member States, again, set up their own additional reports in which the tests (user-testing) were set on (see 1.9).

1.8 Patient information in the United Kingdom

Patient information with medicines has been regulated in the United Kingdom since 1977. Although few medicines at that time were supplied with leaflets, those leaflets which were produced had to comply with certain legal requirements, such as inhaled medicines. As already mentioned, in 1992, the European Commission issued Directive 92/27/EEC and implemented it into UK legislation in 1994. In 1993, the then Medicines Control Agency produced a guidance document that elaborated

on the Directive: "Guidance for the pharmaceutical industry on the labeling and leaflets regulation," and this guidance caused the European Commission to publish the Guideline on readability.

In the United Kingdom, the Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency which is responsible for ensuring that medicines and medicinal devices work, and are acceptably safe. The Patient Information Quality Unit is part of the Vigilance and Risk Management of Medicines Division. The Unit is responsible for policy and regulation of all types of product information and assesses labels and PILs provided by the pharmaceutical industry for compliance with the Directive. In 2005, the MHRA published guidance on the Guideline on readability: "Always Read the Leaflet – getting the best information with every medicine". In this document it was stated that the Guideline on readability had had a great impact on the quality of the information in PILs because many PILs started to contain a better balance of the risks and benefits of a medicine. However, there is much more which could be achieved within the current regulatory framework and therefore the Working Group redrafted the Guideline on readability.

The guideline: Always Read the Leaflet – getting the best information with every medicine (2005) contains the following adaptations and additions to the Directive and the Guideline on readability:

- Improvement of risk communication: annex 10 of Always read the leaflet, gives extensive information on how risk information should be communicated. Attention is being paid to: key points as a summary at the start of the section, giving information on the benefits of taking the medicine, and guidance on presenting statistical information (149-65).

- Improvement of usability of PILs: annex 6 of Always read the leaflet gives extensive information on how the accessibility and readability of a PIL can be improved. Attention is being paid to: writing style, typeface, design and layout, headings, use of colour and use of symbols and pictograms (97-101). Information on these aspects is much more extended in the annex, than in the Guideline on readability.
- Attention is being paid to patients with special needs: annex 6 provides information on people who need PILs in a different format (102-111).
- Improvement of how to undertake user testing: annex 5 and its appendix gives extensive information on how user testing should be accomplished. Attention is being paid to: the legal basis, reasons for user testing, when to undertake tests, implementation and an illustration of one way of undertaking a test (89-96).
- Lay terms: in annex 8 of Always read the leaflet. The MHRA has produced a list of acceptable lay versions of medical terms in the package leaflet (123-8).

Furthermore, the MHRA proposes an extra section, a headline section, with *key information* or *general information* at the beginning of the leaflet, especially designed for people that would consider a leaflet too long or complex to read. It is the independent variable and can be defined as: "summarizing a few key messages for safe and effective use" (MHRA, 2005). The key information is presented as a short series of bullet points and includes the following information:

- benefits of the product
- maximum dose or duration of treatment
- potential side effects or withdrawal reactions

- contraindications
- important drug interactions
- circumstances in which the drug should be stopped
- what to do if the medicine does not work
- where to find further information
- stimulation for reading the rest of the PIL
- latest update of the PIL

(Always read the leaflet – getting the best information with every medicine, 151).

As for information concerning the *benefits of medicines*, the MHRA (2005) states that the risks of a treatment should be placed in the context of the potential benefits and this could be achieved by including some general information on how the medicine works. According to the Directive, a PIL already needs to have the section '*What is your medicine and how does it work?*' and according to the MHRA, this section could be complemented with the following information:

- "why it is important to treat the disease and what the likely clinical outcome would be if the disease remained untreated?
- whether the treatment is for short term or chronic use;
- whether the medicine is being used to treat the underlying disease (i.e. curative) or for control of symptoms;
- if the latter, which symptoms will be controlled and how long will the effects last?
- whether the effects will last after the medication is stopped;
- where the medicine is used to treat two or more discrete indications, all should be succinctly described as above;
- where to obtain more information on the condition"

(Always read the leaflet – getting the best information with every medicine, 158).

Items which are most relevant to the patient, for example the impact of the medicine, should be given prominence by means of using specific font sizes or types (This is part of the layout which is developed in Chapter Four).

Information about *side effects* follow the guidelines below:

- The scientific term of a condition should be placed in brackets after the lay term.
- In case of serious side effects the action that is to be taken by the patient must be described.
- The duration of risk must be stated.
- A doctor should be consulted if side effects that are not mentioned in the section occur.
- Serious side effects should be mentioned first, then other possible side effects grouped by frequency (most frequent first). Body System Order Class grouping should only be used when frequencies are not known.
- Verbal descriptors should only be used if accompanied by the equivalent statistical information of which only the upper bound should be referred to, e.g. use ’fewer than 1 in every 1,000’ rather than ‘between 1 in 10,000 and 1 in 1,000.’
- If severity of side effects is known, this should be included in the PIL.
- If a side effect is dose-related, this should be included in the PIL.
- Providing links/details of further information sources on side effects should be considered.
- Conveying imprecision of point estimates using terms such as ‘approximately’/’about’/’around’ when referring to estimates for major safety issues.

(Always read the leaflet – getting the best information with every medicine, 160-64).

1.9 Readability user-testing of PILs

Readability user-testing is another compulsory intervention concerning patient information leaflets which became a mandatory step in November 2005 (in the UK in July 2005). Simon Andriesen, the Managing Director of **MediLingua**[1] based in the Netherlands, refers to the European Directive 2004/27/EC which defines that leaflets should be "legible, clear and easy to use", and that the manufacturer has to deliver a readability test report (with a positive conclusion) to the authorities (Andriesen, 2007). This means that every PIL must be tested

and pass the test before being approved. The idea for user testing derived from an Australian initiative (Koo, 2005, Dickinson, Raynor and Duman, 2001). It has been in act in Australia since 1994 (Sless and Wiseman, 1997, Koo 2005). It is a performance based, flexible development tool which identifies barriers to people's ability to understand and use the information presented and indicates problem areas which should be rectified. It is particularly useful as part of a leaflet development process and aims to identify whether or not the information, as presented, conveys the correct message to those who read and should understand it. The user testing according to Professor David Sless from the Communications Research Institute of Australia (1997) is a "performance based" testing and therefore

[1]**MediLingua** provides professional medical translation services. It is based in the Netherlands and offers 40+ of the world's major languages. The work concerns both medicines and medical devices. Their customers are pharmaceutical companies, CROs, medical publishers, national and international medical and regulatory organizations, and manufacturers of medical devices, instruments, in-vitro diagnostics and medical software. They translate regulatory dossier information (SPCs, PILs, labeling), general information about medicines, health and treatment, clinical trial documents, and instructions for medical devices. Our services also include pre-translation source text editing, translatability assessment, international review management, translation validation, harmonization of language versions, user-testing (cognitive debriefing), readability testing, and back translation and reconciliation. Simon Andriesen can be contacted at simon@medilingua.com. The website is http://www.medilingua.com.

differs from the "content based" approach used in the past, where a checklist is applied to ensure that the correct information is present. If testing reveals barriers to understanding, carefully considered changes to the leaflet will be needed to improve it (MHRA, 2005). Readability user-testing is used for changing patient information leaflets so that people can understand them better; increase public awareness of medicine and prevent misuse. According to the understanding of David Sless, the text of a medicine information has three main functions – headings for navigation, instructions on what to do and explanations to help understand why to do it. When issuing a label or package leaflet, the designer must approach the writing and the presentation of each of these functional elements as one integrated task because readers do not separate content and form (Sless and Wiseman, 1997).

Sless and Wiseman (1997) argue that usability and usability testing is too easy to consider the "scientific" nature of this activity as a validating principle in itself. However, when looking at the outcome rather than the means, usability testing is an expression of respect for others and a social desire to be friendly and helpful to others, which explains the often used phase "user friendly". Taking the latter into consideration, usability testing can be much more clearly seen as an act of courtesy, involving people who will have to use the material in the process of developing and refining that respective material, i.e. the package leaflet in this regard. Therefore, user testing is legitimated by its social purpose rather than the methods it uses. This is done by asking participants questions about the leaflet.

The EU published a method for testing the readability of the leaflet in the 'Guideline', however there isn't a consensus on the test criteria to be used, so providers of test services have extracted their own test method.

The readability test project begins with a preparation phase, during which the test of the leaflet is carefully edited and checked; spelling or grammatical errors are corrected and sentences are rephrased. This is an important step and according to Andriesen (2007), approximately 70% of all changes in the leaflet are made during the preparation phase. The leaflet must comply with the template, available in 25 European languages, published by the Quality Review of Documents (QRD) group of the European Medicines Agency (EMEA).

For the test, a list of about 15 questions are prepared that cover the most important parts of a leaflet (especially safety aspects). The MHRA (2005), requests that each question must perform satisfactorily and considers it inappropriate for data to be accumulated and for one or more key messages not to be found and understood by participants. Hence, each single question of the test protocol has to be listed separately for each patient concerning legibility, i.e. finding of information, and comprehensibility and understanding of the content. Thus, in case one single question is not adequately found by 2 out of 20 patients tested, the user test would have already failed. There are, however, differences amongst some PILs for example, Schikel (2007), argues that the sort of approach above mentioned, does not seem to be helpful or adequate as a general binding rule, especially when considering the enormous differences in terms of the length and levels of difficulty of different PILs depending on their indication and mode of application (e.g. when comparing a package leaflet for an analgesic such as aspirin OTC medicine, with an anticoagulant such as a powder inhaler to medicate patients suffering from asthma, POM medicine).

The readability guideline requires that a range of different categories of people who might possibly use the medicine, are included in the test

procedure. In case of testing medicines for rare diseases, the people included should preferably have or have had the respective illness. In addition, further demands on subjects to be interviewed are detailed as follows with regard to the fact that the information which can be used by the least able will be beneficial for all users:

- Particular age groups such as teenagers and the elderly (especially if the medicine is particularly relevant to their age group, i.e. the target age groups are preferred).
- New users or people who do not normally use medicines, simply members of the general public.
- People who do not use written documents in their working life.
- People who find written information difficult (users who have poor eyesight or are dyslexic).

In fact, selection of adequate test persons for the user testing is rather challenging especially with regard to the target group for the respective indication and, even more difficult, in case the medicinal product has multiple indications. To find a reasonable balance, it might be helpful to select participants according to the patient populations chosen for the clinical trials as part of the marketing authoritative application (MHRA, 2005).

In a number of cases, the target group of test people is discussed with the competent authority, i.e. the EMEA or the reference member state (RMS). This is of particular value and necessity in case of medicinal products which can be applied by health care professionals only as the choice of the population consulted has to be defined and explained in the final test report submitted to health authorities.

The readability guideline states that:

> "The people who are likely to rely on the package leaflet for a particular medicine will depend upon a number of factors and may include carers (e.g. parents, partners, friends, as well as nursing assistants) rather than patients if the medicine is generally intended for administration by someone other than the patient…"
>
> (Guideline, 2005)

In a test group there is always a young person (around 18-22 years of age) and two or three older people (over 60).

Before starting a test participants are given an explanation of what the test entails. The aim of the readability test is to assess whether certain information can be found and understood. The testers are told that it is unnecessary to learn the text by heart, and that they can refer to it when answering the questions, just as they would do at home. The interviewers stress the fact that they are testing the leaflet for readability and not examining the tester's memory or reading skills. If there is something that the tester cannot find, or does not immediately understand, then it is likely that there is a problem with the text (or layout) of the leaflet (and not with the tester). If a single tester gives an incorrect answer, that does not inevitably lead to changes in the leaflet. However, if a number of testers have the same problem finding or understanding the information, it is a clear indication that there is probably something wrong with the text. A readability test consists of at least two test rounds with a test panel of 10 testers each. In order not to bias the results by training effects of the patients participating in user tests, an appropriate time period is ensured between the attendance of different user tests. The MHRA (2005) suggests that participants should not be used more frequently than once every six months.

Once having fulfilled the inclusion criteria and being selected as a participant for a user testing, the patient and the recruiting person (doctor,

pharmacist etc.) will normally receive approximately from £20 to 50€ for compensation purposes.

Since data security is an issue, every participant has to sign a declaration of confidentiality agreement. However, the participant's personal data are made anonymous as it is done for clinical trials. In addition, a fully operational database helps to effectively manage interview dates and to keep the usually tight project timelines for user testing.

A leaflet only passes a test round if for at least 90% of the questions the information is located and if in at least 90% of these cases the information in understood (Sless and Wiseman, 1997). After the PIL has passed its user test in its original language, it can be translated into any other European language without additional testing. In the UK the result of such user testing must be submitted to the MHRA. Any other official European language is allowed and sufficient, however, most applicants decide to perform their user tests in the United Kingdom for the following reasons:

The United Kingdom has been a pioneer in developing additional guidelines and publishing details on the performance of user tests and has been rather strict and demanding concerning the necessity of (additional) local user testing and the basic need for user testing.

In the centralised, decentralised and mutual recognition procedure, only the English language version of the package leaflet is agreed during the scientific assessment of the EMEA and the competent authorities involved in the procedure, respectively. The quality of translations into the various languages, however, should be the focus of a thorough review by the applicant or marketing authorisation holder (AH) once the package leaflet has been properly tested. Consequently, it lends itself to use the English version of the package leaflet for performing user testing.

The MHRA requires all marketing authorizations submitted to comply with user testing. Hence, not surprisingly a large number of contract research organizations (CROs) offering services for user testing are located in the United Kingdom.

Manufacturers are happy that the Directive requires only one language version to be 'readability-tested' because of the cost of a single test. However, Andriesen (2007). Argues that a leaflet that has gloriously passed the test in one language may be poorly translated into any or all of the other EU languages.

Amongst the leading companies which carry out user testing, very important in the UK is **Luto Research Ltd**[2] which was created as a spin-off company of the University of Leeds. The work team led by Professor Theo Raynor and Dr Peter Knapp try to localize potential

problems people may encounter when reading the leaflet in 'real life' and improve the consumer's ability to handle the PIL.

In conclusion, although there are still aspects to renew in PILs, they are improving in quality as a result of new legal obligations on manufacturers to test the documents on potential patients. Testing makes sure that the presentation of the information enables patients to find and understand key messages for safe use of the medicine and thereby enable them to use the medicine "safely and effectively" (Raynor, 2005).

[2]**Luto Research Ltd** is a company of the University of Leeds, created in 2004, which works with clients to enhance the clarity of information created by its patients. Since its inception, it has carried out more than 15,000 individual participant interviews to ensure that patient information materials are fit for purpose. Visit: www.luto.co.uk

1.10 The 'PIL of the month'

In 2008 the MHRA in the UK came up with an initiative that consisted of putting **best-practice**[3] examples of PILs on their website. The initiative was and is still called: 'the PIL of the month'. The MRHA also published the quality criteria for assessing the PILs of the month (see website references). The quality criteria includes a wide range of relevant parameters (such as font, size, grouping of side-effects, headlines, the use of capitals, etc.) which all need to be taken in consideration to constitute best practice.

These parameters should have a huge impact on the user-friendliness (readability, comprehensibility and functionality) from a linguistic point of view, however, there are still doubts regards to user-friendliness of PILs, and, as mentioned beforehand, the overall aim of this research is to assess the quality of PILs in order to encounter features which may entail a more user-friendly approach compared to former PILs.

A study carried out by Askehave and Zethsen (2010: 103) reports, that the assessors of PILs are not linguists but scientists who tend to applaud the good layout, and a good graduation of side-effects for example, but do not evaluate and appreciate the linguistic aspects such as syntactical issues. The MRHA cannot refuse leaflets as long as they comply with the regulations concerning content and structure. Thus, according to Askehave and Zethsen (2010) it seems that the overall legislative EU requirement that PILs must be easy to read, understand and act upon, does not hold any power in practice.

[3]**Best practice** is a method or technique that has consistently shown results superior to those achieved with other means, and that is used as a benchmark.

1.11 Other formats for PILs

In November 2005 the X-PIL Service was launched in the UK. The web site X-PIL ensures that patient information leaflets supplied with medicines are accessible to everyone, including those with sight impairment. It is a leading source of reliable and up-to-date information on UK medicines. All package leaflets on the web site are supplied and updated regularly by UK pharmaceutical companies. They can be viewed in different sizes on the screen by clicking on the font size-menu. In addition, the website details a single national phone number (free to use and operating day and night) of the Royal National Institute of the Blind (RNIB), where the leaflets can also be requested in audio, Braille or large prints. This free service is supported and promoted by pharmacists and the NHS. It is a venture by the Royal National Institute of the Blind (RNIB) and the national Library for the Blind and Datapharm Communications.

Furthermore, recently a new guidance was issued on behalf of the MHRA, on 7th July 2012, which stated that it will become compulsory for all companies to supply alternative formats for the readers, and that the information about the alternative formats must be written inside the PIL. In other words:

> "The PIL is the most obvious way for companies to make people aware of the availability of alternative formats of the leaflet such as Braille, CD, audio or large print for example. Place this prominently in the leaflet in at least 14 point bold text".
>
> (Point 1.9; PIL Guidance, 7/12)

Possible wordings inside the PIL include:

"Is this leaflet hard to see or read? Phone 0123 456789 for help"

"Reading or sight problems? Call 0123 456789 for help"

"For information in large print, tape, CD or Braille, phone 0123 456789"

"Call 0123 456789 for a leaflet in large print, tape, CD or Braille"

"Hard to read? Call 0123 456789 for help".

The legal provisions require Manufacturer holders (MA holders) to provide the statutory information in a format suitable for blind and partially sighted medicine users. This can be achieved in a number of ways and what is provided will depend on user preference. MA holders should ensure that they are able to provide the statutory information in any format which may be requested on behalf of the user. The alternative formats as required by the guidance are:

Large print versions of the leaflet to help many people with sight loss, and also for some people with learning difficulties. Individuals have different preferences, so there should be the facility to print in a range of font sizes rather than have only a single option. The usual range of font sizes is 16-24 using a clear font which is either roman, semi-bold or bold.

CD, MP3 versions of the leaflet can help people with sight loss, those with limited command of English who can understand the spoken word better than written text and people with reading or learning difficulties.

Braille versions are useful for the approximately 20,000 Braille readers in the UK. Separate guidance on the provision of leaflets in Braille is available from the European Commission, and the UK will develop its own supplementary guidance to help MA holders meet this obligation nationally.

Electronic versions of the leaflet include email and Microsoft Word documents which can be sent on data stick, attached to an email or downloaded from a website. These can be useful for blind or partially sighted people and others who use a computer with text-to-speech or screen

magnification software, or other 'access technology' devices. Website standards are available to ensure that the format of the material is suitable for use with the access technologies referred to above (PIL Guidance 7/12/2012).

The PIL supplied in alternative format must be identical to the currently approved PIL. To avoid confusion, companies may need to have in place measures to explain why there may appear to be differences if a PIL has recently been updated.

Medicine users' individual requirements and preferences differ, so MA holders are asked to have the resources available to prepare PILs in alternative formats on demand rather than holding a store in several different formats which would become obsolete whenever any change is made to the PIL. Furthermore companies must supply the patients with copies of the leaflets requested for their medicines in a timely manner so that they have access to the information whilst they are taking the medicine.

Before designing an additional leaflet, website or audiovisual material companies should identify whether the desired outcome can be achieved by simplifying the existing PIL without loss of information or by providing additional information in the PIL that would be of use to patients and carers. Companies should also consider the benefits of working with a patient organisation to ensure that the proposed materials meet their needs.

In the past, companies had often provided additional patient support materials to prescribers to pass on to their patients, this relied on memory and availability of materials at the time of consultation, but much was forgotten, (as already seen). Information in the PIL provides an alternative source to help overcome forgetting important medicinal information.

There is also further material, apart from the PIL to help patients administrate their medication. Again the recent PIL Guidance (2012: 24) refers to what further material may be provided as follows:

Additional leaflets which consist in reference leaflets for children or carers of patients. These additional material may be placed in the PIL, but must always be non-promotional.

Simplified leaflets are leaflets written in an easier way to help people with literacy learning difficulties or a limited command of English. They may also help older children to understand how to use their medicine.

Videos are produced to help explain complex instructions such as how to take an inhaled medicine or prepare a complex product.

Booklets are also available to provide additional information, such as disease awareness material or information targeted at particular groups. The guidance says that it is, however, preferable to include the information in the PIL because that is more likely to reach the user.

Magazines are issued too to help support people who use a medicine long-term, for example for people who suffer from diabetes.

Help lines are available as well**,** which may take the form of recorded information or a live advice service, and can also help most people with special access needs. Where a helpline is publicized in a PIL, a copy of the script or the recorded information should be provided to the MHRA

Product Information Unit in advance to ensure that the content complies with the legal requirements.

A leaflet in another language may also be requested by people with limited command of English. It is an option which is particularly relevant in certain ethnic groups that have a prevalence of a particular disease. Patients must obtain a faithful translation of the English version, which does not need to ' verbatim' but must adequately convey the intended messages.

1.12 Classification of medicines in the UK

One of the responsibilities of the MHRA is to enforce the provisions of the Medicine Act 1968 and associated secondary legislation. The law regulates the sale, supply and administration of all medicines available in the UK. Each medicine is assigned to one of three legal categories: POM, P and GSL. The following classifications determine how medicine can be supplied to the public (MHRA: Availability, prescribing, selling and supplying of medicines, 2 September, 2005). See *Tab. 1.1*

Prescription only medicine	**POM**	**Requires a prescription from specified health professional/s**	**'In the dispensary'**
Pharmacy medicines	**P**	**Must be sold by, or under the supervision of, a registered pharmacist**	**'Behind-the-counter**
General sales list medicine	**GSL**	**Available from any sales outlet, e.g. garage, newsagent**	**'Off-the-shelf'**

Tab 1.1 Classification of medicines in UK

The P category requires supervision by a pharmacist, and might be thought of as the 'behind-the-counter' category to differentiate it from the 'off-the-shelf' medicine (Fenichel 2004, cited in the **Report** prepared by the Board of Science of the British Medical Association, 2005)[4]. The OTC market includes the P and GSL categories, and also herbal and homeopathic medicines, which are currently not regulated under the same system. In the UK, medicines in the P category can only be sold 'under the supervision' of a pharmacist, from registered pharmacy premises, whereas the GSL products can be sold both from pharmacies, without the supervision requirement, and from any retail outlet. The pharmacy supervision requirement has been interpreted in its strictest sense with a requirement for the pharmacist to be both present in the pharmacy and aware of all such sales. To some extent this has limited the pharmacist from taking on other duties and thus has led to a review of alternative arrangements as part of a wider consultation on making the best use of the pharmacy workforce (Department of Health 2004).

1.12.1 Use of OTC medication

Over-the-counter medicines have traditionally been used to treat self-limiting minor ailments. The scope for treating such conditions has been extended by the switch from prescription to OTC status of effective treatments.

Like all treatment interventions, OTC medicines bring both benefits and risks. Potential benefits to the public include enabling people to take control of their own illnesses and rapid and convenient access to treatments. Potential risks include adverse effects and the possible misuse

[4] The **Report** (2005) concerning OTC medication on behalf of the BMA (British Medical Association), is available at: www.bma.org.uk

of certain medicines. Potential benefits to the healthcare system include more efficient use of the doctor capacity through the transfer of consultations about minor ailments to pharmacists and nurses, as well as increased individual responsibility and empowerment in the context of minor ailments. Baker and Shaw (2004) suggested the term 'Involved Patients' to denote active involvement in treatment choices and self-management of health.

It is estimated however that there is as many as 80% of patients with chronic daily headache (CDH) who overuse pain medications (Dowson, *et al*, 2004). Less people are reading the instructions on the OTC package leaflet, and researchers report that this may be due to the increased confidence in self-treatment, and/or people's belief that OTC and non-prescription medicines are safe and without serious side effects.

In a nurse bulletin issued by the National Prescribing Centre in 1999, some important points were stated for Pharmacists to consider when recommending an OTC therapy for self-medication: the mnemonic **WHAM**:

W Who is it for?

W What are the symptoms?

H How long have the symptoms been present?

A Action taken so far?

M Any other medication?

As for the choice of product to give the patient, the mnemonic **EASE** should be considered:

E How effective is the product?

A Is it appropriate for this patient?

S How safe is it?

E Is the product cost-effective?

In the past OTC PILs were not regulated like the P PILs, actually they were defined as being shorter and carrying less information. But being the only source of information of that medicine, the patient was and is required to take even more responsibility for using it.

In recent years, in fact, following the work of the Better Regulation of Over-the-Counter Medicines Initiative (BROMI), the Patient Information Quality Unit (PIQU) has extended the notification scheme for changes to all medicine leaflets regardless of legal category in relation to the packaging components for all medicines subject to a marketing authorisation (product license). Hence, OTC PILs are currently much more similar to the P medicinal leaflets.

CHAPTER TWO

READABILITY OF PILs

> *The reading process is not simply a matter of extracting information from the text. Rather, it is one in which the reading activates a range of knowledge in the reader's mind that...may be refined and extended by the new information supplied by the text.*
>
> (H.G. Widdowson 1979: 7)

2.1 Understanding PILs

PILs are still regarded to be difficult and hard to understand by many people. In a study by D.K Raynor *et al* (2007) on the quantitative and qualitative review of leaflets tested, findings showed that most people do not value the written medicines information for the poor quality in terms of content and layout. Anna Lewcock, (03-April-2007)wrote an article called: **Patient info leaflets found lacking**, in which she reported that the working group actually found that some patients considered PILs as merely serving to fulfill legal and regulatory requirement and protect manufacturers from medico-legal actions, rather than give any benefit to the consumers themselves. The article may be downloaded at:

http://www.in-pharmatechnologist.com/content/view/print/156811.

(Site visited on 18/01/2012).

Obviously, as many studies have shown, the 'same' message often needs to be framed or presented in different ways in order to be communicated most effectively and most persuasively to different people.

But what are the factors that make patient leaflets difficult? Or more generally, what is a hard text? What is a hard word? And when is a sentence difficult to understand? Before a literature review is presented to answer these questions, it is essential to understand the cognitive process of information processing. By so doing the theory about word difficulty, sentence length and prior knowledge will be put into a relevant perspective.

2.2 Text processing

What happens when people read a text? A mental process takes part to build up a coherent meaning. Sanders and Gernsbacher (2004) argue that text processing is a dynamic process during which the reader constructs a cognitive representation of the information in the text. Even though readers' representations are not identical to the information they read, texts contain many linguistics signals that guide comprehension. Reading involves many cognitive processes. First, you need to be able to identify the printed characters as letters and the letters as words. Secondly, you need to hold individual words in memory so that you can understand a complete sentence and relate it to previous sentences. You also need to be able to comprehend the text and integrate new information conveyed in the sentence you are currently reading with information acquired from previous portions of the text. Hence, reading involves object recognition, immediate memory, long-term memory, semantic memory and many other processes.

Despite the involvement of so many complex cognitive operations, reading seems effortless and is usually very accurate. It differs from spoken language in several ways. First, reading is visual and spatial whereas spoken language is auditory and time-dependent, and while readers can speed up, slow down or pause, listeners cannot do this as listening is dependent on the speaker (although it is possible in some cases to ask

someone to repeat themselves). Furthermore, reading involves understanding word units that are separated by white spaces, but speech is continuous and many words are co-articulated. The meaning of the words can be augmented in speech through the use of stresses and accents, but this is not possible with printed words (except with the use of italics, for example, to emphasise certain words). Reading involves concerted attention and controlled eye movements and it is usually difficult to do something else while reading. As for the cognitive steps needed to transform signs on a piece of paper into letters into a coherent text there is a model discussed by Sanders & van Wijk (2002), cited in Dolk (2009: 11), who gives a simplified version of a complete model.

The following figure illustrates that model:

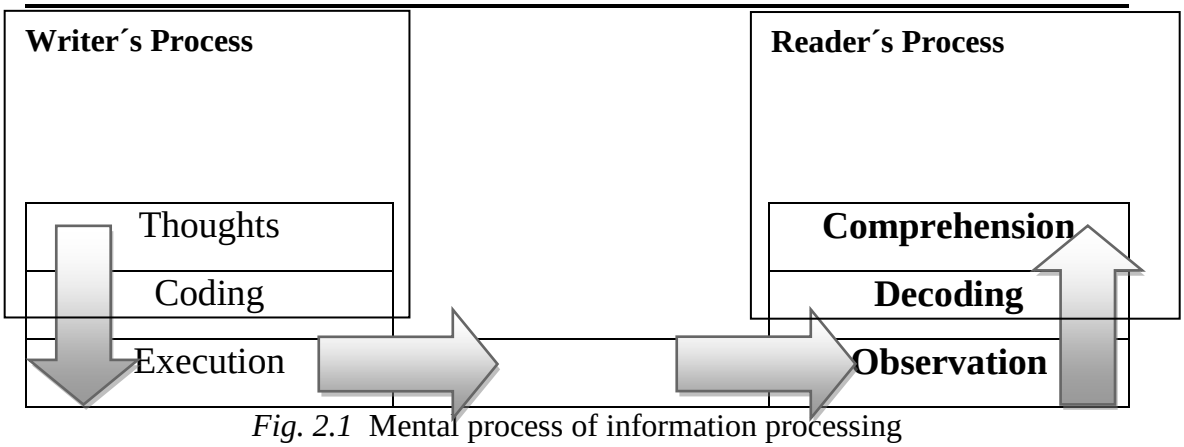


Fig. 2.1 Mental process of information processing

The left hand side of this model represents the steps that the writer has to go through to produce a text. Whereas, on the right hand side of the model, the information processing of the receiver of the information is presented. In short, the reader sees a text by sensory activities of the eyes (observation), this message is decoded (decoding) and linked to prior

messages and world knowledge (comprehension). The first step is physical, and the latter two are conceptual.

2.3 Psychological research in text comprehension

Reading texts serves a variety of purposes such as getting information about the world, performing certain actions, or escaping into fictional worlds. Text comprehension researchers agree that highly complex cognitive mechanisms underlie the skill of comprehending texts. Text comprehension is an instance of cognitive information processing based on the interaction between the text structure and the recipient's cognitive structure. It is only successful if the reader is able to convert a sequence of sentences into a coherent text, i.e. to identify semantic relations among the text ideas and to build a mental representation that shows connectedness (Holler & Eckardt, 2005: 2). The reader is challenged to create a coherent story from the individual sentences he/she reads. This is done by inspecting linguistic cues to link words and sentences to each other. Connectives, such as 'because' and 'but', and referential links facilitate this process. This search for these linguistic cues is referred to as micro process. Hence, this process takes place on a textual, literal base. Consecutive parts of the text are connected to each other on a local level: this leads to a superficial text comprehension. During this stage of text processing, these signals are related to the reader's knowledge of the world. The reader makes inferences at this moment; he/she adds information to the literal information from the text. To create an overall coherence, the reader needs a macro process to integrate the information from the text with prior knowledge and knowledge about texts' macro (global) structure.

When the reader has successfully fulfilled this process, a mental representation of the text has been created, and according to Britton, Gülgöz & Glynn (1993) a well written text facilitates this process.

Kintsch and van Dijk (1978 and Kintsch, 1998) offer an influential theoretical framework of text comprehension, the construction-integration theory. They assume that the processing of text involves two sets of sub-processes: a set of discourse processes such as word retrieval and grammatical parsing and a set of discourse processes that relate to the output of the lower-level processes to the actual linguistic and situational context by deactivating contextually inappropriate concepts. The processes of the first set are active during the so-called integration phase. Construction-integration cycles may be repeated. If successful, this results in a coherent multilevel text representation consisting of three levels of representation: a) a mental representation of the actual wording of the text, the so-called surface structure (this entails actual words and phrases, and is stored in the short-term memory); b) a mental representation of the explicitly stated semantic information, the so-called text base, (understanding the information presented in a text, hence, the propositional content of the text is integrated with the reader's prior knowledge), and c) a mental representation of the state of affairs denoted in a text, the so-called situation model or scenario (Kintsch, 1998). The situation model supplements the surface level with the reader's prior knowledge. Zwaan (1999) states that "comprehension is first and foremost the construction of a mental representation of what that text is about: a situation model." The mental representations of single events are the building blocks of situation models. Readers keep track of at least five situational dimensions during comprehension: space, causation, objects, intentionality and time. A

situation model is stored in the long- term memory, and can be updated in case new information becomes available (Zwaan and Radvansky, 1998).

2.4 Can readability be measured?

Lunzer and Gardner (1979) view reading comprehension as an active process, not as a passive process: it involves a triangular relationship between reader, author and text, hence, a text must be readable. But can the readability of a text be measured? A well-known way of assessing whether a text can be read and understood easily is a readability formula. Research into readability began in the 1920s, and an array of metrics have been designed since then and have been made use of in different fields. In fact, more than a hundred readability formulas have been developed which are based on some combination of the number of words per sentence, word length and word familiarity. In general, a readability formula is intended as a quick and conventional measurement which usually takes into account only easily measurable aspects of a text such as word difficulty and average sentence length. A weighted combination of these measurements yields a number for each text. Some readability formulas produce estimates that represent grade levels; others range over a 100 point scale where higher numbers indicate greater readability For example, the Fry Readability Formula (Fry 1967) applies a simple formula based on the ratio of words of three or more syllables in 100 word excerpts from the beginning, middle and end sections of a text. A similar approach is taken in SMOG (Simple Measure Of Gobbledegook) and the FOG index. More complex formulae are employed in two of the most commonly used measures, the Flesch Reading Ease score and the Flesch-Kincaid Reading Grade Level (FKRGL). These were designed principally to assess reading texts for schools, but are also frequently used for other kinds of text (Fulcher, 2007).

The Flesch formula is based on the English language and takes the average number of syllables per word and number of words per sentence into account.

In 1996 Ley and Florio provided an informative summary of a number of readability tests and reported that there was a high correlation between the results obtained in a range of texts using different methods. Their general conclusions, as far as readability is concerned, was that 'much of the literature produced for patients, clients and the general public is too difficult'(1996: 25).

In a research work concerning patient information leaflets, Garner *et al* (2011*:* 9), opine that "these tests have considerable limitations". At a purely practical level, the validity of a readability score requires a minimum word count (e.g. 100 words of continuous text), which are in excess of those in many PILs, such as those that accompany over-the-counter medicines. More fundamentally, these tests ignore factors such as the nature of the topic, the ordering of ideas, choices of sentence structure which do not affect length, and the reader's background knowledge and stylistic and personal expectations. Anderson and Davison (1988:25) point out that "scholars of readability are aware of the impossibility of reducing all text properties to formula variables" and that the formula values should not be taken as "anything but rough predictions of the text ease or difficulty" (*ibid.*:25). Objecting to readability formulas on the grounds that reading difficulty may be affected by the purpose and background of the reader and the inherent difficulties of the subject matter, Davison and Kantor (1982) opine that the popularity of readability formulas is attributed in part to the fact that they are generally quick and easy to apply. Most contemporary word-processing software packages do, in fact, include a readability measure facility which are expressed as a clear numerical value.

So while a formula and an index scale may sound like useful tools to evaluate a text, a number of actual problems have been identified because they take no account of non textual dimensions such as context (prior knowledge, purpose for reading), cultural differences (Bruce and Rubin, 1988), and visual element. Text related factors, such as sentence structure and the legibility of print, e.g. the layout, typographical features, and the reading conditions (Johnson, 1998: 1)are not taken in consideration. Proponents of readability formulas claim to be measuring text difficulty or comprehensibility but they do not involve a broader range of parameters than those offered by readability formulas only. Contrary to those formulas, Bruce and Rubin (1988) argue that:

> "The concept of readability concerns many different factors including 'reader specific factors, such as motivation, interest, values, or purposes…"

Thus, they conceive:

> "[…] a readability formula as a method of assigning a numerical estimate of readability to a text".
>
> (Bruce and Rubin,1988: 8)

Readability is, therefore, a multifaceted concept, and is mainly concerned with the problem "of matching between reader and text" (Johnson, 1998: 1).

Role-relationship between author and reader (Halliday, 1996), the structure or organization of the text are essential for understanding written text used for the development and evaluation of doctor-patient written information. Although word difficulty and sentence length *look* like factors that have a negative influence of the readability of a text, their actual contribution is a point of discussion according to some scholars like Anderson and Davison (1988: 25).

2.5 Word difficulty

Long words and long sentences have not been considered to be imperative for a hard and unreadable text. So what is a hard word, and when are sentences difficult to understand? The subsequent paragraphs will elaborate on this matter.

Word difficulty as referred to in readability formulas is defined as: "the percentage of words that do not appear on a list of words familiar to children, the length of words in syllables or the length of the words in letters" (Anderson and Davison, 1988: 27). This might sound like a solid definition to assess the difficulty of a text. However, most long, infrequent words are clear derivatives and compounds. Additionally, words that are unknown to the reader do not cause comprehension challenges per se. An exception is a text that is full of difficult words (Stahl, 2003, Anderson and Davison, 1988).

Words can be conceptually difficult or lexically difficult (Anderson and Davison, 1988:28). Lexically difficult words represent a concept that is familiar to the reader, but the word itself is not known. The meaning of a lexically difficult word can often be retrieved from the text's context. Lexically difficult words may effect text comprehension on a text base level. Stahl, *et al* (1989) conclude in their article 'Prior knowledge and difficult vocabulary in the comprehension of unfamiliar text' that (lexically) difficult words influence recall on three levels: the sequence of information, central and supporting information. This micro-process of information processing deals with the literal, textual structure of the text leading to the text base level.

Conceptually difficult words, on the other hand, represent a concept that is unfamiliar for the reader. This makes it hard to link a correct meaning to the word. Conceptually difficult words are often related to a

certain scheme. Schemata are mental representations of stereotypical situations (Zwaan and Radvansky, 1998). Often these words are (only) known to a certain group of people who are considered the experts of a certain sector. For example, a financial manager might encounter a profound amount of conceptual difficult words in a PIL, whereas a doctor might have difficulties reading a publication about a banking business. Conceptually difficult words impede the comprehension process on a higher level: the readers cannot integrate the new information with his/her prior knowledge. Hence, conceptually difficult words have an impact on the higher levels of text comprehension, whereas lexically difficult words influence the text base level.

Concrete and abstract words also have an effect on comprehension. For concrete words there is a 'direct sensory referent' and their mental images are easily accessible (Schwanenflugel and Stowe, 1989). Sentences with abstract words take longer to read (Schanenflugel and Shoben, 1983). Moreover, processing abstract words takes longer than concrete words due to a lack of prior knowledge. However, when both are presented in a supporting context there is not a lot of difference in processing time (Schwanenflugel and Stowe, 1989). Written text has less contextual support, therefore, communication is more dependent on words, and especially on the precision of word choices.

When we relate this knowledge to PILs, we can say that they potentially entail a relative high amount of conceptually difficult words. The question is whether conceptually (and lexically) difficult words can be avoided in PILs. Being of medical genre, difficult words are bound to be present, however, it is essential not to isolate these words but embed them in a comprehensible context. Most likely, formulations like these can be found in the sections where '*Taking X with other medicines*' and '*possible*

side effects' are stated. For example; the (abstract) word 'beta-blockers ' could mean anything for most laymen. However, if this word is imbedded by the following information 'a type of medication used to treat high blood pressure, irregular heart rhythm', the exact meaning of the word loses its importance. The word 'beta-blockers' is explained on a lexical and conceptual level, which should facilitate text processing, as supported by Schwanenfluger and Stowe (1989).

2.6 Sentence length

Another factor that was used in readability formulas was the length of the sentences. Gibson (2000) provides insight in the way sentences are processed. The process of assembling sentence structures is called sentence parsing. The two components in this process are: words are connected into a structure for the input so far (integration) and the structure as a whole is also tracked to integrate incomplete dependencies (storage). Nested and multiple nested structures require a lot of resources during the processing. This would support the readability formula assumption that singular sentences are more easily understood. However, two short sentences are not always more easily comprehended than one long sentence. As discussed before, connectives can make relationships explicit and this facilitates text comprehension. Anderson and Davison (1988: 25) give three illustrating sentences:

1. *I moved the switch. The lights went off.*
2. *I moved the switch, because the lights went off.*
3. *The lights went off because I moved the switch.*

Sentences 2 and 3 are longer than 1, but contain a connective to make the meaning of the relationship between the clauses explicated. The

ambiguity and vagueness of sentence 1 is cleared in 2 and 3; in two different ways. Pearson (1954-1975, as cited in Anderson and Davison, 1988:26) showed that children prefer sentences containing an explicit connective and also comprehend those sentences better. This result was confirmed by Irvin and Pulver (1984). Thus, connectives facilitate the comprehension process even though they increase the lengths of the sentence.

In a PIL, (multiple) nested structures, as explained above, should be avoided whereas, connectives can effectively be used to make clausal relationships explicit.

2.7 Prior knowledge for PIL comprehension

In literature another factor that facilitates the reading process is prior knowledge. Prior knowledge plays a supportive role in comprehending a written message. Patients' ability to participate in their care and decision making depends largely on their knowledge and literacy skills. It is a reader's variable and cannot be measured by means of a readability formula. According to studies (e.g. Ngoh 2009; Pander and Lentz, 2009) there is a gap between what patients ought to know to use dispensed medications appropriately and what they actually know. In a country like the UK, the effects of low literacy is especially found in the elderly, non completers of Secondary school, immigrants and those who have a lower cognitive ability. Cognition is the portion of a person's comprehension, memory, and recall is used to perform tasks that require some knowledge, skills, or ability. The implication therefore is that patients must understand what they are supposed to do before they can follow medical recommendations. Thus, as previously discussed, prior knowledge helps the reader/patient to create a situation model, a schemata, and according to

their pre-existing schemata, before initiating a therapy, patients should know :

1 what their main problem is;

2 what they need to do;

3 why it is important to do that.

The patient leaflet structure needs to follow reader's schemata and in the schema theory, background knowledge serves as a scaffold to help encoding information from a text (Stahl *et al*, 1989). Conventional patterns are the basis for the expectations about the coherence relationships between the different parts of the texts (Sanders and Spooren, 2010). For the 'taking medication' schema the information is grouped in three groups: *identification of medication*, *adherence with medication* and *outcomes* (Morrow, Leier, Adrassy, Tanke and Stine- Morrow, 1996, cited in Walgalter and Vigilante, 2003:340). From the definition stated, we can derive that background knowledge facilitates the process of information processing.

CHAPTER THREE

HALLIDAYAN LINGUISTICS APPLIED TO PILS

A PIL for every ill?
(Kenny *et al*, 1998)

In the following chapter a manual analysis of a corpus of 60 original PILs is conducted based upon a systemic functional linguistics (SFL) approach. Michael A. K. Halliday, the 'father' of systemic functional linguistics, saw the need to have a linguistic system that was more sociological in orientation. Since there have been many changes and revisions to improve patient information leaflets in order to make them more user-friendly for the recipient hence, promoting patient centeredness, (thanks to user-testing, for example, see Chapter One), Halliday's theory seemed as most appropriate and adequate for exploring a full range of relevant textual elements within PILs. This idea is also consolidated by the fact that:

> "SFL is a dynamic system: it keeps changing in step with the environment in which it is operating. In this way, it has been remarkably stable since its beginning in the 1960s; it has remained stable because it has kept changing, thus a meta-stable system. SFL is also an open system: as it changes, new features are added in response to new needs".
>
> (Matthiesen, 2009: 12)

To analyse the main characteristics of PILs in line with Halliday's theory, and assess whether they currently address the consumer in a more

user-friendly manner, the following questions are taken in consideration for the analysis:

What are the features in a text-based analysis of patient information leaflets, to contribute to the fulfilment of writer and reader objectives?
How stabilized are the text patterns in the corpus, in other words, how conventional is the text structure, considering the corpus analysed?
Is 'patient centeredness' manifested linguistically and how is it manifested?

Bearing in mind both the discourse-semantic and lexico-grammatical level, the following linguistic features are studied: the generic structure of the text; the rhetorical elements; the specialization of lexis; the meta-discourse; the role relationships; the use of headings, and lexical density. Although not of linguistic consideration, the visual aspects of PILs is considered as well since it is an integrated factor of readability and understanding..

3.1 PILs within the SFL theory

The framework is based upon the theoretical construct of systemic functional linguistics (Halliday, 1994). Systemic theory considers how people use language to make meaning and how language is organised to enable meaning to be made. According to the theory, language is viewed as a pattern of interlocking systems, from the smallest unit (e.g. words or phrases) up to the largest (e.g. a paragraph or longer piece of text) (Halliday, 1994: 23). In order to approach a text, we need to break it down into smaller, more manageable units, for example, into sentences (those units of the writing system beginning with a capital letter and ending with a full-stop), which in turn can be broken down into clauses, (which combine with each other to form a text), which then can be broken down into groups of words, and so on. This sort of analysis looks at the units of grammar in a

more systematic way to identify the functions of language and foreground the role of grammar as a resource for construing meaning (*ibid*.).

The interaction between text and context is the means by which the reader constructs meaning, so any model of text needs to take context into account. The two types of context identified in this analysis are context of culture and context of situation (Halliday and Hasan, 1989). (see Table *3.1*.) Context of culture refers to knowledge, beliefs, ideologies worldviews and value systems that have an impact upon the language used in a text. This shapes the way the text is organized at the macro-level (Martin, 1992), that is, the macrostructure of the text. Paltridge (1997) quoting Van Dijk (1980), notes that macrostructure refers to the 'higher level semantics and conceptual structure that organise the 'local' micro-structures of discourse interaction and their cognitive processing" At the highest level within context of culture is the *genre*, which considers the organization or structure of the overall text with respect to its specific purpose (Swales, 1990). Patient information leaflets in this case, may be regarded as a subset of the genre of healthcare materials. The comprehensibility of this information will be affected by expectations of what is considered to be a conventional text structure for this particular type of genre (Swales, 1990). The next context level, context of situation, refers to the non-verbal environment in which the text is actually functioning (Halliday and Hasan, 1989). The key situational aspects impact on the type of language used. Three of these can be described as variables of the context of situation which have consequences for language: what is being talked about -*field*-, who is involved –*tenor*-, and the channel of communication –*mode*- whose function is accorded to the text and to the rhetorical aim, that is to say, "what part the text is playing" , (Halliday 1994: 76).

These three variables of context define the *register* to which the text belongs. Register is the:

> "set of meanings, the configuration of semantic patterns, that are typically drawn upon under the specified conditions along with the words and structures that are used in the realization of these meanings."
>
> (Halliday, 1995:248).

There is an inextricable, systematic association between context and text (the extra-linguistic situation and the linguistic/verbal realizations) and vice versa: the context activates the meanings (i.e. the semantics) that are realized in and by the grammar (i.e. lexico-grammar). Hence, a register may be defined as a "culturally specific text-type which results from using language to accomplish something" (Gerot & Wignell 1994 cited in Freddi, 2007: 14). To develop a register description of patient information leaflets, it is necessary to identify what is most fruitful to examine, hence, the field, the tenor and the mode, (see *Table 3.1*). Texts reflect these key situational aspects, in that they deal with experience of the world, express interpersonal relations and are 'knitted together' so that they can be understood. The degree to which a given text is understandable to a reader is dependent upon: the nature of the topic that is being communicated; the reader's expectations; prior knowledge, (as mentioned in the previous chapter); and the perceived role relationship between writer and reader. Other aspects important for comprehensibility include the organization of the text and density of information. To create a patient information leaflet as an effective functional text, a writer needs to structure the text in such a way that it is appropriate to readers' needs. Frame theory predicts a certain commonality between individuals in the way they approach a particular type of text (Paltridge 1997). Thus, for the PIL, the patient frame may be, for example, 'doctor using knowledge to assist patient with information

that will guide behaviour and help prevent any adverse events' (Clerehan & Buchbinder 2006: 45).

The Table below shows the model of systemic functional text evaluation for PILs:

Context of culture	**Context of situation**		
Genre	Register		
	Field (What is being talked about).	Tenor (Who is involved).	Mode (Channel of communication)
Schematic structure of text: PIL	Use of medicine: side effects, etc.	Professional relationship: expert 'informing' lay person.	Leaflet handed-out with medicine.

Tab 3.1 Systemic functional text model for PIL evaluation.

3.1.1 Organisation of the text (*generic structure*)

The notion of generic structure potential is elaborated by Paltridge, (1997), drawing on Hasan (1989), to present how the structural elements of a given text operate: what elements can or must occur, where they can/must occur, and how often they occur. Different types of text with their characteristic overall 'generic' structure consists of a series of sections or 'moves'. Holmes (1997: 325) defines, a move as*: "*a segment of text that is shaped and constrained by a specific communicative purpose*".*

Each move consists of a number of elements or steps that are combined to constitute information in the move, which makes sense for a particular audience in a given situation (Hasan, 1989; Swales, 1990; Paltridge, 1997). Written patient information about a medicine should provide instructions

about the contents, dosage, interaction with other medicines, storage and accounts of its potential benefits and side-effects.

The comprehensibility of a text will be affected by expectations of the 'moves' included, and how these are organised, i.e. their order or sequence. For example in PILs logical background information about the medicine appears nearer to the beginning of the text than the end, because research shows that patients scan the text but wish to have basic information about the medicine before going on with the reading, *if* they continue reading. Thus, there are some 'moves' which are considered essential and some that are considered useful, but not essential.

3.1.2 Function of each 'move' in relation to the reader (rhetorical elements*)*

The function of each 'move' in relation to the reader may be *to define/explain, inform or instruct* the reader. These functions are called rhetorical elements and their purpose is to influence the reader. For example, background information about the medicine in a PIL is apparently *to inform* the reader, whereas, in relation to the medicine dosage, it may be more appropriate *to instruct* the reader. If the relations between the writer and reader are not clear from point to point, it may not be obvious to the reader what to do with the information that is presented. For example, the reader may be informed that the dose of a medicine may need to be increased, but who is expected to monitor and vary the dose?

Hence, at a rhetorical level, there is *a procedure* for taking the medicine; this procedure comprises a *goal* (taking a tablet) and a *method*, which consists in turn of a sequence of *steps*. These are all rhetorical concepts/moves which are part of the message no matter how it is expressed.

In PILs, according to layout formats, there are about seven sections and 'moves' accordingly, and they all signify distinct communicative purposes.

3.1.3 Meta-discourse (*Purpose of the text)*

Meta-discourse is often presented as the writing that we do about our writing, rather than about our topic. This brings to a more complex understanding of meta-discourse: the linguistic strategies that we use to manage the evolving relationship between writer, reader, and text. Hyland and Tse point out that:

> "[…] meta-discourse is the range of devices writers use to explicitly organize their texts, engage readers, and signal their attitudes to both their material and their audience".
>
> (Hyland and Tse, 2004:156)

This definition offers a valuable description of what can be accomplished through writing choices, and bases the view of writing as a social engagement.

Documents which are designed to support readers in making decisions or following procedures make use of 'meta-discourse' - language about the text itself that explains its purpose and assists the reader's movement around the text (e.g. '*The main purpose of this leaflet is to*...'). These are instructive texts which are theme-centered because the text answers a number of questions about the act that is to be performed (Pander Maat 1994). Apart from learning a procedure, which is based on declarative knowledge, instructive texts should also contain conceptual information. Before users of an instructive text can carry out procedures and instructions, they need to know why they are going to carry out certain acts. For instructive texts like PILs, this means that procedural and declarative information needs to be merged into a recognizable and readable unity. In a study about the sequence of information, Ummelen (2005) defines

procedural information as text that needs to support the execution of the task in a direct manner. It is all the information that instructs users on what to do. This information does not only include the action itself, but also the condition for an action and the consequences of an action., which can concurrently be a condition for a following action. Ummelen (2005: 330) calls this sequence an action-centered sequence. The linguistic form in which procedural information should be shaped is as follows:

- action verbs
- imperative
- relatively short action steering sentences
- step-by-step presentation of items
- direct style
- if…then constructions.

Declarative information should contribute to factual knowledge and insight (*ibid.:*331).

Within a readable unity a PIL, should try to answer two questions: is this medicine suitable for the patient, and how does he/she use the medicine safely and correctly? The single steps are the instructions that are communicated to the reader which then need to be followed up. The reader wants to know, for example, *how often*, *how much of*, and *in which way the medicine is to be used*, The text must convey this sort of information, thus, supporting the purpose.

In updated versions of PILs there should be a clear description of the purpose/function of the text because readers should be helped to connect, organize, interpret, evaluate and develop attitudes towards that material (Kopple 1997 cited in Wang, 2012: 105).

3.1.4 Role relationships *(author-reader identities and status elations)*

The concept of role relationships is made possible by the fact that in any communicative event there should be in principle more than one participant, and therefore there must be a role for each of them to play. These roles are of two kinds, social roles and interactional roles. The former, referred to by Eggins (1994: 63) as *Tenor*, is dependent on the participants' relatively static social statuses, and it starts from these social statuses to predict on the use of certain forms of the language. The latter kind of role relationships, on the other hand, is more dynamic since the participants can play the different roles interchangeably, and it is often through the choices of the language that participants play their roles. This kind of role is firmly tied to the immediate interactional, rather than the more permanent social, statuses of the participants. An important common feature of both kinds, however, is that they are generally more tangible in an event of speaking since the participants are typically present and can play their roles simultaneously. In written discourse, writers and readers also adopt such roles and modify their language accordingly, but the interactions are separated from each other and, this is less obvious than speaking.

Halliday (1994) refers to the interactional role relationships as "speech roles" and explains what he means by this term as follows:

> "In an act of speaking, the speaker adopts for himself a particular speech role, and so doing assigns to the listener a complimentary role which he wishes, him to adopt in his turn".
> (Halliday, 1994:68)

Hence, we use language to interact with other people, to establish and maintain relations with them, to influence their behaviour, to express our own viewpoint on things in the world, and to elicit or change theirs

(Thompson 1996, 2000 cited in Ming, 2007: 78). The interactional role relationships can be accounted for both spoken and written discourse ; an interrogative, for example, raises the question of who demands the information (the questioner) and who is supposed to provide the answer (the addressee). It is therefore not surprising to think of the written communication as an exchange between the writer and the reader, and to explore this structure underlying the written interaction. Although writing may be viewed as a "monologic activity, it is nonetheless dialogic in its communicative structure" (Nystrand, 1986: 36). Nystrand argues, in fact, that the writer makes choices among the options available which are determined by his/her reader's need, not only by the meaning the writer wants to convey (*ibid.*). There is no turn taking or overt exchange, in terms of giving and taking, between the writer and the reader, but there is an underlying structure that indicates the writer's awareness of the presence of the reader and the modification of the message to accommodate his/her needs, reactions and expectations.

The sort of interaction may be referred to as *negotiation of meaning*, which in broad terms means "the skill of communicating ideas clearly" (Bygate, 1987: 27). An important point to be considered, as noted by Bygate, is that:

> "[...] it is this aspect of spoken interaction which contrasts most sharply with position of reader and writer in the written word"
>
> (*ibid.*:28)

The 'sharp' contrast about the position of the two participants in the written interaction means that there is no *direct* negotiation between the two. Negotiation is in fact an intrinsic feature of any kind of communication; what makes it different in written language is that the participants are physically not present during the interaction which rules

out the possibility of 'direct' negotiation. Likewise, Nystrand (1987) indicates this difference explaining how negotiation in written discourse, as compared to spoken discourse, can be brought about:

> "In talk this negotiation is comparatively conspicuous, manifesting itself in turn taking, querulous glances plus rephrasing, etc. In writing, however, this negotiation is more abstract: the writer must create a text that will effect an exchange of meaning in a context of eventual use...".
>
> (Nystrand, 1987: 210)

Writers need to take into account different situational variables of the context in which their writings will be read, who is going to read them, at what time, what their readers want to know and what they do not need to know, and so forth. As an example from a formal essay, Nystrand argues that a review of literature does not only serve "argumentative purposes" but also "communicative function"; it is meant to establish a "communicative footing", i.e. "shared knowledge of common ground with readers" (Nystrand, 1987: 203).

Despite the fact that negotiation underlies all kinds of communication, there are clear differences among written genres in how negotiation is being carried out. Moving from genres like the formal essay used by Nystrand above, to more interactional discourse, we can find instances of relatively overt negotiation between writers and readers which are sometimes no less explicit than what is normally found in conversational exchanges. For example, simple forms of the exchange structure can be found in sequences of questions and answers (as shall be seen in the PILs examined); the reader's voice can clearly be heard by means of the writer putting words in his/her mouth, and the interaction might be sometimes changed according to the reader's participation; readers and writers do not only jointly work out experiential meanings. These aspects of the negotiation process are necessary in patient information leaflets.

Although most of the linguistic accounts of medical discourse have focused on face-to-face communication between doctors and patients (e.g. Coulthard & Ashby, 1975; Cicourel, 1985; Tannen & Wallat, 1987; Fisher & Croce, 1990; Soyland, 1991, cited in Sultan Al-Sharief, 1996: 9), there have been several studies regarding the specific type of written medical discourse in medicinal leaflets.

Medicinal leaflets are in some respects dramatically different from the other kinds of medical written discourse. There is no 'real' doctor-patient communication as in the face-to-face communication, like negotiation and dialogue, as discussed before. This is the reason why the text needs to be made as explicit as possible and give an authentically interactional message, it cannot be just a mere description of the symptoms and treatment of the disease. Patient leaflets show concern with the human values as with the bare facts. Rather then the writer who "plays wholeheartedly the role of dispassionate scientific observer*"* (Thompson, 1996 quoted in Sultan Al-Sharief, 1996: 11), in medical leaflets the writer's main task is to interpret the scientific facts in terms of their social and psychological effects on the reader/patient. This can be seen in how appropriate it is for medical-expert writer to be assertive/directive or conciliatory/collaborative in their 'advice', and make it clear to who should carry responsibility in the world of action.

3.1.5 The use of headings

Headings in documents, while related to 'field', may be considered as instances of macro-themes and thus, related to 'mode', following Martin (1992). Their role is particularly important in any assessment of communicative effectiveness within a functional text. According to Nielson (1999), the main heading on the page should provide an overall view of

what the text will state in detail. The main function carried out by descriptive headings is to be a sort of keyword and allow readers to easily identify what each section is about.

For PILs, the MHRA (see Chapter one, paragraph 7) actually proposed the inclusion of a headline section to "ensure that patients are aware of key information on the safe and appropriate use of a product" (2005). The reason for this being is that some patients do not read their leaflet at all. By including the headline section the MHRA wants to convince the reluctant patients to read at least the headline section. Research, in fact, indicates that readers using texts to make informed decisions do not usually read through the information in a linear way, but ask a series of questions and scan through the document to look for answers (Wright, 1999).

In PILs, however, the inclusion of a headline section, may also be risky and this is due to the fact that patients might only read the headline section and forget about the rest. This means that they are still not fully aware of the risks and benefits of that particular medication. Another issue is whether the headline section could have a negative effect on the reader's comprehension and usability of the information. It is quite difficult, therefore, to predict what effect the headline section may have on those who read it. See example of headlines in *Fig. 3.5*.

3.1.6 Specialization of lexis

Specialization of lexis is included under 'field' as it is a way of encoding "what is going on", Halliday (1994: 56).

The connection can also be seen, however, with elements of participant role relationships. In other words, lexical choices are made by the writer of a medical information document in an expectation of the level of technicality required to achieve the communicative objectives. Biber (1988) claims that

lexical specificity seems to be correlated with the production of differences between speaking and writing. A higher *lexical specificity* seems to be associated to formal written genre, marking a high density of information, by reflecting a precise word choice and an exact presentation of informational content. The technicality of the vocabulary used in a PIL refers to the degree of complexity of the medical terminology and/or other vocabulary used. Thus, the writer needs to select and employ words and phrases which are understandable to the general public rather than resorting to the specialist terminology known from the medical context.

3.1.7 Lexical density

As already stated in Chapter Two, language is made up of what may be called 'content' words, with its lexical or conceptual value (e.g. tablets, patches, acetate, symptoms, uncoated), and 'non-content' words, also called 'empty words' which have no lexical or conceptual content, they only have their grammatical function, (e.g. and, in, whether). The density of information in a portion of text or 'lexical density' refers to the average number of content words per clause.

According to Halliday (1985), one of the differences between written language and spoken language is the density with which information is presented. The average lexical density for spoken English is between 1.5 and 2, and for written English between 3 and 6, "depending on the level of formality of the writing" (Halliday, 1985:80). In the PILs selected for this study, the lexical density is performed on the second section regarding the strength of the medicine and what it is used for (*What X is and what it is used for*).

3.1.8 Visual aspects of the texts

The visual presentation also needs to be taken into account when assessing the quality of texts (Hartley, 1994; Shriver 1997; Paul *et al*. 2004).

In documents, readability, clarity, order, and reliability of information are fundamental aspects. The special organization of graphics and text can direct reader's attention and make the interaction more effective. A good graphic design creates a visual logic and a positive optical impact. The length, format, layout and graphical aspects of the information are all part of the visual organization. In the reviewed PIL Guidance of July 2012, the MHRA discusses some important information regarding this aspect. It discusses that:

> "Before writing the information and setting it out on the page you will need to consider where the medicine is going to be used, who will be taking it and what particular issues will need to be resolved. Involving potential patients at an early stage in the drafting of the PIL should ensure success in the testing later on. There is scope to consider the needs of older people, those whose first language may not be English, people with learning difficulties or those with a condition (for example diabetes) which may affect their vision". (PIL Guidance 07/12 p. 5)

Furthermore, using upper-case font sub-heading: 'information architecture', the following is stated about document design and development:

> "How the information is set out in the document is an important feature of information design. It provides order and structure to the document as well as looking at navigation tools within the document. Very little information is read from beginning to end (with the exception of novels) and the way in which the information is arranged is important in ensuring that readers can find their way around it. Making the information easy to use is an important output from this.
>
> A well written and clearly designed leaflet can maximise the number of people who can use the information to make decisions about their medicine so that they can use it safely and

> effectively. Information design essentially makes complex information easy to use and easy to understand. It is a particularly important aspect of document development where the risk of misunderstanding is likely to come with a cost – highly likely in the field of medicines information. This is an iterative process and in deciding on a design for a particular PIL there are likely to be a number of different designs and modifications in the development process".
>
> (PIL Guidance 07/12 p. 6)

Therefore the design and layout of the information is crucial in helping patients to find and understand the important messages for safe use within the PIL. As stated in Chapter one, leaflets undergo user-testing trials, hence, before submitting a leaflet, manufacturers are asked to review the way in which the information is set out within the document and to take account of best practice to comply with the new article 59 of Council Directive 2001/83/EC. Layout is important because it enhances plain text by introducing various graphical devices like indented lists, tables, boxes, footnotes, along with extra character formatting (italics, bold face, small type, etc.). There is not a sharp distinction between 'plain text' and 'text with layout', unless by 'plain text' we mean literally a string of words, with no punctuation at all. Devices like semi-colons, full stops, and parentheses serve as graphical aids as much as bulleted lists or bold face (Bateman *et al*., 2001; Power *et al*., 2003).

As required by the PIL Guidance (2012, p.15):

> "manufacturers need to follow a common design and layout, firstly because it must be accessible for the reader and secondly, because it becomes important that it is easy to re-enter the text after looking away, in order to retrieve the next turn".

The Guidance defines the following aspects to consider in the layout:

- Font style and font size
- Headings and sub-headings including consistency of placement

- PIL dimensions including whether the document is laid out in portrait or landscape format and number of columns
- Use of colour and choice of colour
- Style of writing and language used
- Layout of critical safety sections of the PIL
- Use of pictograms

And, some of the key points that manufacturers must note which help patients to navigate the information are:

1. Headings must be placed consistently and stand out by using either a larger font or by emboldening the text;
2. Judicious use of colour can help but it must not make a contrast;
3. Patients like an index, so this is very important if a booklet format is being used which is known to be more difficult to navigate. The reason, presumably, is that an indented list represents an exchange of clarity for depth. The crucial points can be found more easily, but since space is wasted, there is less room for giving additional explanation. Some readers will thank the author for easing their task; others will perceive the leaflet as an insult to their intelligence. Similar differences are probably found between academic fields: while common in scientific articles, bulleted lists are rare in humanistic fields like philosophy, literary criticism, and history, where the dignity of the material seems to demand long paragraphs of continuous prose and to preclude anything so vulgar as a list (Bateman *et al*., 2001; Power *et al*., 2003).

4. The text size used should be as large as possible and there should be a good use of white space. Dense text means patients lose concentration and therefore cannot find the information required.
5. Long lists of side effects are frightening and short bullet points have been found to be helpful. The side effects should be grouped according to seriousness and allow patients to immediately distinguish when to take urgent action.
6. Related information should be located together and not split over different columns or sides of the leaflet.
7. Information should not be repeated as this is known to confuse.
8. Information which appears before the index or in a box is overlooked by patients so these devices should not be used.

All of the above goes to show that continuous on going work is carried out to make PILs more acceptable for the intended audience and the layout is one of the fundamental factors because:

> "No matter how well written the text is in the PIL if it is set out in a typography which is difficult to read it is unlikely that patients will take the time or be encouraged to read it".
>
> (PIL Guidance 07/12, p. 5)

3.1.9 The use of pictures

Many documents, whether they are meant to be seen on paper or on a computer screen, contain more than just formatted text. In addition to formatting, they may contain such graphical elements as formulas, diagrams, and pictures. A considerable amount of research has been done on the meaning and use of diagrams, for example: Kerpediev and Roth, (2000). My concern in this part of the study is on the use of pictures. Pictures are sometimes distinguished from other graphics by the fact that they are 'iconic': the meaning of a picture arises mainly by its similarity to

what it depicts (Hartshorne and Weiss, 1958). Photographs are pictures, and so are the more stylised sketches found in PILs. In the following we shall see: (a) how pictures contribute to the meaning of a document, (b) how they affect the style of the document, and (c) how they can affect the wording of the document.

It is not easy to say in general terms what the meaning of a picture is. An interesting exploration of this question can be found in Levesque (2003:84), who claims that pictures tend to convey "vivid information: information that contains no logical structure beyond predication and conjunction". A picture might say, for example, that a person shook hands with another person: it cannot say that they *either* shook hands *or* beat each other up. The notion of *vivid information* is an important concept in artificial intelligence, and pictures are sometimes seen as a prime example. Here, pictures will be viewed as basically expressing existential information: A picture of two men shaking hands can be argued to mean that at *some* point in time, *two men* shook hands in a particular way. Photographic' pictures of this kind convey a wealth of information, and would be difficult to generate automatically.

The picture just discussed, for example, shows in detail *how* the handshake took place. This 'how' would be difficult to capture in words or mathematical symbols: any symbolic representation would tend to leave out something that the picture depicts. This is different with the kinds of pictures that are used in instructional texts like PILs where pictures are employed to convey 'discrete' information of the kind that might also have been conveyed by text. Piwek *et al*, (2006: 13) give an example of the illustrated versions of a document followed by the verbal instructions (see *Fig.3.1* and *3.2*):

Fig. 3.1 Illustration of medicine storage

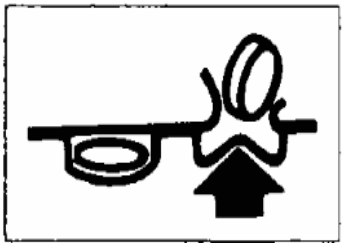


Fig. 3.2 Extracting of tablet from the blister

To take a tablet, you should first remove it from the foil and then swallow it with water. Your doctor will tell you the dosage. Follow his advice and do not change it. If you are unsure of your dosage or when to take it, you should ask your doctor. If you take an overdose, you should inform your doctor immediately or go straight to your hospital's emergency ward. Store the medicine out of the reach of children.

The picture shows someone storing away the medicine. The person is shown as a woman with longish hair; the cabinet has a specific size and a medicinal cross on each of its doors. Little of this has anything to do with the meaning of the picture in its current setting. In other respects, the picture is rather poor in information. For example, it does not show what the woman is doing; there is no medicine in sight! Clearly, the picture denotes both more and less than what is depicted: it denotes a person (whose gender and appearance are irrelevant) storing away a medicine in a place where children cannot reach it. This is the kind of information that is conveniently represented using a representation language that allows us to represent atomic propositions (involving one or more arguments), existential quantification, and conjunction.

In other words: 'There is a person ***x*** and a medicine ***y*** such that ***x*** stores away ***y*** away from children.' Something similar is true for the other picture, which shows how to obtain the tablet (*Fig. 3.2*). There is a person ***x*** and a

tablet ***y*** such that ***x*** removes ***y*** from the foil by pushing a finger to the back of ***y***.' (Piwek *et al*, 2006: 14).

Even though pictures and text can express similar kinds of information, they do not have the same strengths and weaknesses. One strong point of pictures, for example, is the immediacy with which they tend to be understood (Pineda, 2000). Certain aspects stand out with much more clarity and immediacy than others: headers, for example, have a high perceptual salience, and the same is true for pictures. A related strength of pictures is that they are language-independent, making them especially suitable for conveying information to linguistic minorities.

Another strong point of pictures, relating to their iconicity is their suitability for indicating information relating to the relative locations of objects. Consider the first of the two pictures above, for example. It can be expressed textually, but to express everything that the picture conveys would tend to be cumbersome:

> Take your tablet by removing it from the foil by pressing your finger against the back of the tablet…
>
> (Piwek et al, 2006: 14)

An informal study of leaflets in the Association of the British Pharmaceutical Industry (APBI 1997 cited in Piwek *et al*, 2006: 16) has shown that pictures are used in about 60% of the leaflets, and that they are used heavily to depict:

- complex pieces of equipment (anti-asthmatic inhalers, inoculators, etc.) whose spatial layout of the document is important for the patient to understand.
- actions, such as the steps that need to be taken to clean an inhaler. Often, entire sequences of actions are depicted.

- continuous quantities – e.g., when creams and ointments are used, one frequently sees depictions of the required quantity, sometimes positioned on a finger or juxtaposed to a coin to show the relative size of the blob.
- parts of the human anatomy e.g., eye drops, inhalers, thermal patches.

There are several examples of pictograms and illustrations in the corpus of study which are presented in the **Results** (e.g. *Figures 4.6; 4.7; 4.8*).

3.2 Sub-questions for the evaluation of PILs within the SFL framework

To assess the corpus of the PILs within the SFL framework, the following sub-questions have been applied:

1) Overall organizational or generic structure of text:

What identifiable sections of text or 'moves' are present ?

Are all the essential moves included?

What is the sequence of moves and is it appropriate?

2) Rhetorical elements:

What is the function of each move in relation to the reader?

Are these functions clearly defined and appropriate?

Is there clear guidance about what to do with the presented information?

3) Meta-discourse:

Is there a clear description of the purpose/function of the text?

Are the objectives of the PILs defined appropriately?

Does the text convey a clear message to allow compliance?

4) *Relationship between writer and reader (medical expert to lay person):*

Is the relationship between writer and intended reader clear and consistent?

Is the person who is expected to take responsibility for any action clear?

5) Headings (signposting for the reader):

Are headings appropriate?

6) Specialization of lexis:

How technical is the vocabulary used in the texts?

Is it appropriately presented?

7) Lexical density:

What is the average content density of the text? (analysis of the section concerning the route of administration of the medicine).

8) Format:

What is the length, layout, font/type size and other visual aspect of the document?

Are there pictures and do they aid comprehensibility?

3.3 The Corpus (PILs) selected for the study

The corpus of PILs selected for this analysis covers a good variety of products - some for serious and some for less serious illnesses, both for prescribed (P) and over-the-counter OTC medications . The dates of revision (last approval on behalf of the authoritative committees) go from February 2008 to February 2012. The PILs are the original medicinal leaflets (see index section including copies of the corpus), which were

supplied to me by friends residing in the UK. They may however, be downloaded, in their updated versions, from the electronic medicine compendium at : http://www.medicines.org.uk/emc/

The sixty PILs analyzed are those that accompany the following medicines with indication of the therapies and the date of revision of the leaflet:

Name of medication	*Treatment uses*	*Last revision of leaflet*
Adenuric tablets	(gout)	Aug 2010
Advodart capsules	(prostate)	Mar 2010
Alendronic Acid	(osteoporosis)	Nov 2010
Amlodipine	(high pressure)	Sept 2010
Aspirin Enteric Tablets	(antiplatelet)	May 2009
Aspirin tablets	(anti-inflammatory)	Nov 2010
Atarax Tablets	(urticaria)	Sept. 2008
Azathioprine Tablets	(immunosuppressant)	July 2008
Benadryl Plus	(hay fever)	Sept. 2008
Benylin	(children's chesty cough)	April 2008
Buscopan tablets	(antispasmodics)	Oct 2010
Butrans Trans. patches	(analgesics)	Jan. 2009
Cefalexin Capsules	(bacterial infections)	Oct. 2009
Celluvisc eye drops	(eye irritation)	Nov 2011
Citalopram	(anti-depressant)	July 2010
Clopidogrel Tablets	(thrombi)	July 2010
Coaprovel	(hypertension)	Jan. 2010
Co-codamol Tablets	(moderate pain)	Feb. 2011
Detrusitol	(anti-muscarinics)	Sept 2010

Dulcolax tablets	(laxative)	Feb 2011
Ezetrol tablets	(high blood pressure)	Mar 2010
Finasteride	(prostate)	July 2010
Flecainide Acetate tablets	(fast heartbeats)	Jan 2011
Flucloxacillin Capsules	(penicillin antibiotic)	Jan. 2009
Half Sinemet CR Tablets	(Parkinson's disease)	Nov. 2009
Hydrocortisone ointment	(skin inflammation)	Sept. 2009
Istin	(chest pain)	March 2010
Lamictal tablets	(epilepsy)	June 2011
Lercanidipine Tablets	(high blood pressure)	Feb. 2009
Lipitor	(cholesterol)	March 2011
Liquifilm tears	(dry eyes)	Feb. 2009
Lisinopril tablets	(high blood pressure)	Aug 2010
Losartan Potassium	(hypertension)	Jan 2010
Macrodantin	(infections)	Feb 2012
Metoprolo Tartrate	(high blood pressure)	Jan. 2009
Multaq	(anti-arrhythmics)	Dec. 2009
Naproxen tablets	(steroidal anti-inflammatory)	Feb 2010
Neurpro transdermal patch	(Parkinson's disease)	Nov. 2010
Nurofen for children	(anti-inflammatory)	Mar 2010
Nystatin Oral Suspension	(anti-fungal)	Aug. 2008
Omeprazole capsules	(stomach acid reducer)	Nov 2010
One- Alpha Capsules	(osteodystrophy)	Feb. 2009
Paracetamol caplets	(anti-inflammatory)	Mar 2010
Phenergan Tablets	(allergic conditions)	March 2008
Phorpain gel	(anti-inflammatory)	July 2010

Piriton tablets	(allergy)	May 2010
Prednisolone tablets	(cortisone for a variety of ailments)	July 2010
Premique Tablets	(hormone replacement)	April 2010
Propranolol tablets	(high pressure)	Sept 2010
Ramipril capsules	(heart failure)	Sept 2010
Simvastin	(cholesterol)	Nov 2011
Temazepam Tablets	(insomnia and anxiety)	April 2009
Tritace Tablets	(hypertension)	Feb. 2009
Ventolin Evohaler	(asthma symptoms)	June 2009
Viscotears	(ocular lubricator)	Dec. 2008
Voltarol thermal patch	(muscle relaxation)	July 2010
Warfarin Tablets	(anticoagulant)	April 2008
Xalatan eye drops	(ocular hypertension)	Nov 2010
Zoton Fas Tab	(stomach acid reducer)	July 2011
Zovirax	(cold sores)	Nov. 2008

Tab. 3.2 Corpus of study

CHAPTER FOUR

PRESENTATION AND DISCUSSION OF RESULTS

The corpus was approached by reading all the 60 PILs thoroughly first, and then by reading each PIL separately. In the first part, the macrostructure was identified, then each macro-structural section was studied to detect the move structure. The moves were then put in relation to what the text was rhetorically trying to achieve. The findings from the analysis were then divided into features, and finally, the results identified in all the PILs were compared in order to answer the research questions: writer/reader objectives fulfilment; patterns in the text; features likely to further user-friendliness (patient-centeredness) and/or likely to hamper user-friendliness. Being the PIL a highly functional text, divided into seven mandatory functional sections (established by the EU guideline/template) and being the challenge of writing user-friendly PILs very much associated with the function of each section, it was essential to see how the purpose of each section was or was not successfully fulfilled.

In what follows, a number of examples are provided to illustrate formulations identified in the leaflets that, according to previous research on accessibility and written patient information (see former Chapters), are considered to be user-friendly, thus, patient orientated and understandable to the general public.

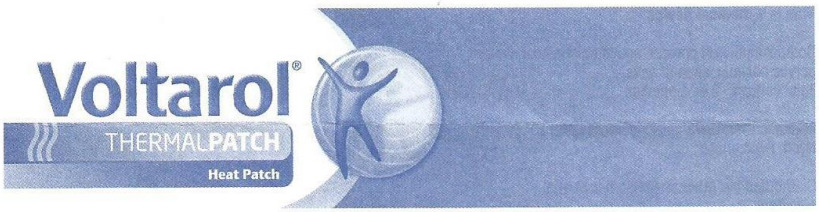
4.1 Organization of the text and the rhetorical functions

All the PILs analysed were printed on single sheets but had a wide range of dimensions. The seven sections were identified in all the leaflets except for one -Voltarol Thermal Patch-, (see *Fig. 4.1*), hence, making them rather conventional in their genre. The sections followed this order:

a) introduction to *inform* the consumer;
b) background of the medicine to *define/explain/describe in general;*
c) warnings and precautions to *inform/instruct/explain;*
d) constraints on patient behaviour -including information about medicine interaction- to *instruct/explain*;
e) account of side-effects to *explain/describe/instruct*;
f) storage instructions to *instruct* ;
g) further information to *describe* the medicine in detail and *offer* the consumer clinical contact.

There was not a large degree of variability between the leaflets as regards to the incidence and sequence of the moves. Only three PILs slightly differed from the rest: Voltarol Thermal Patch which contained five short sections and a brief boxed opening section introducing the name and strength of the medication; Prednisolone (see *Fig.4.6*) which also included a headline section; and Ventolin Evohaler which also added the Asthma Control Test and its score at the bottom of the leaflet to be cut out and kept (*Fig.4.2*)

The sections in Voltarol were divided as follows: what the medication is for; how to use the patches; when not use the patches (precautions); what not to do with the medication; storage of the leaflet till the medication has ended and further information on the next page of the PIL to inform about the composition, manufacturer, distributer and the last revision date of the leaflet:



Voltarol® Themal patch effectively and naturally provides pain relief and deep muscle relaxation for muscle pain, back, neck and shoulder pain.

Voltarol® Thermal patch is applied directly to the skin, on the site of your muscular pain. You feel the heat and relief instantly. The patch provides **10 hours** of penetrating heat that works to unwind tight, aching muscles and increases circulation to help soothe pain away. Thin, discrete and designed to work on your body where it hurts, the patch helps you to get active again soon and take your mind away from pain.

Using the heat patch
- Make sure your skin is clean, dry and non-greasy.
- Carefully tear open the sachet (start tearing by notch).
- Remove the patch from the sachet only at the time of use.
- Immediately take the protective film off the adhesive part of the patch, and apply the heat patch onto your skin at the site of your muscular pain.
- The patch will gradually warm up to a comfortable, soothing level (approximately 40°C).
- For optimum results, leave the patch to act for 10 hours. However, do not apply for longer than this time on the same area. However, if needed you can apply another patch on the same area 24 hours later.
- The patch stays in place and is easily removable.
- The patch can be used alone or with other pain relief medicines,except for medicated products applied on the skin and on injection sites (see Precautions)
- If you sweat excessively, remove the patch.
- The patch is for **external** and **single use only.**

Precautions
Do not use the Voltarol® Thermal patch:
- on irritated, cracked or damaged skin.
- on children under the age of 12.
- on people who are unable to remove the patch themselves (e.g. the elderly, handicapped or disabled), unless supervised by a responsible adult.
- if the wearer is unable to remove the patch or to feel the heat of the patch: for example if you have areas on your body you cannot feel.
- if your perception may be impaired by e.g. sedative medicines, alcoholic drinks.
- on an injection site.
- straight after an injury – heat may make swelling or bruising worse.
- over medicated products applied to the skin, or with any other sources of heat (such as infrared light).
- while bathing or showering.

Talk to your pharmacist or doctor before using the patch if you:
- have poor circulation, diabetes or arthritis or any other serious medical condition.
- have skin conditions like eczema or psoriasis, or have very sensitive skin.
- are pregnant.

For your safety
- Do not cut, tear or damage the patch. Do not use the patch if it is torn or damaged.
- The patch contains iron powder, which could be harmful if ingested. Consult a doctor straight away if this happens.
- If the skin or eyes come into contact with the powder, immediately rinse the affected area well and consult a doctor.
- Do not lie on the heat patch, even when in bed, or apply strong pressure during use (e.g. under a waistband).
- As with any heat product, this product has the potential to cause skin irritation or burns. If the patch feels too hot or your skin becomes irritated (swelling, eruption or prolonged redness), remove the heat patch straight away.
- Remove patch before medical scans
- If the pain does not improve, contact your doctor.
- Keep out of the reach of children and pets, both before and after use.
- Do not microwave or reheat the patch after use.
- Dispose of the patch in a waste bin.
- Avoid exposure to direct sunlight.
- Store the patch in a cool dry place. Do not store it in the freezer.

Keep the leaflet until all the patches contained in the box have been used !

This is a medical device

Composition: Iron powder, activated charcoal, water, acrylic polymer, sodium salts.
Total content: 2 or 4 patches

Manufacturer: Novartis Consumer Health S.A., Nyon, Switzerland

Distributed by: *Novartis Consumer Health*
Horsham
RH12 5AB, UK.

Text revised on: 15.7.10

CE 0459

Fig.4.1 Voltarol Thermal Patch PIL (front page and back page).

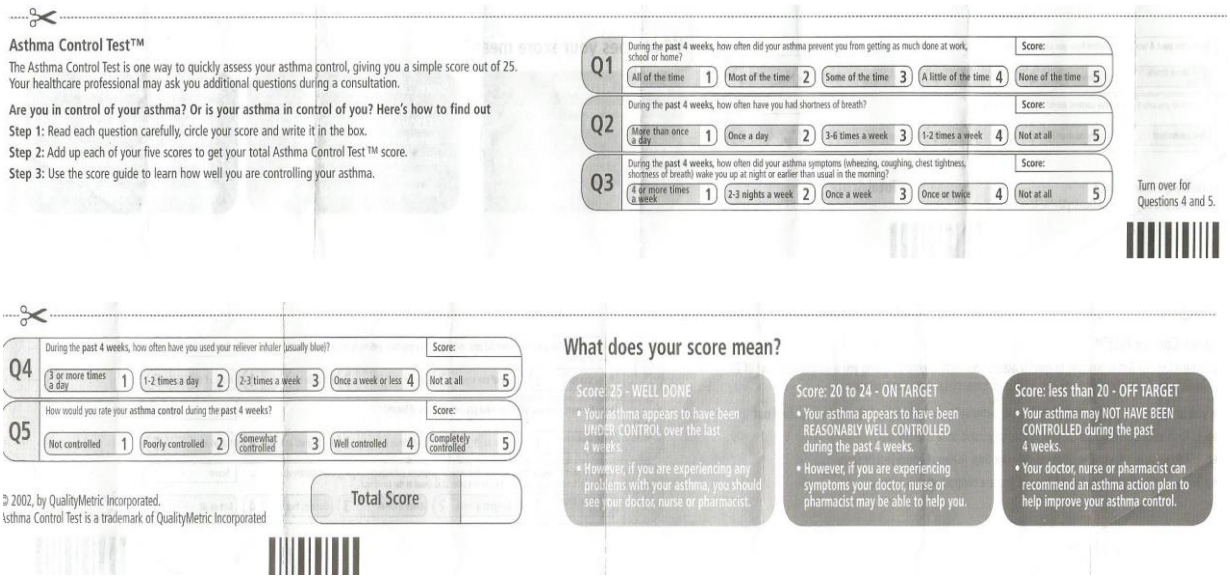


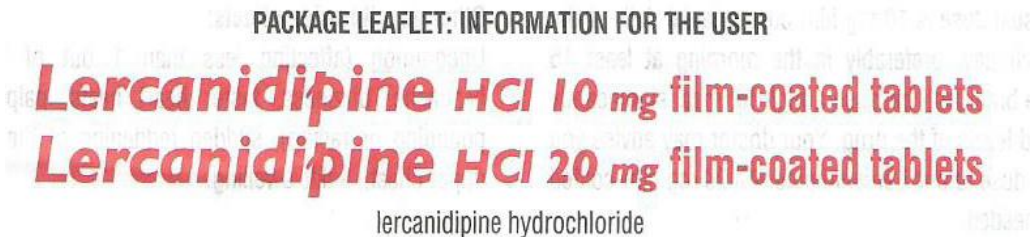
Fig. 4.2 Ventolin Evohaler PIL (bottom of front page and bottom of back page)

All the other 57 PILs of the corpus contained seven identified sections, and the ordering of information was quite consistent between the documents. The sections are now presented one by one.

Section 1

The leaflets opened with the section that presents the name, the strength, pharmaceutical form, and active substance of the medicine, as in the following:

Example 1:



(Lercanidipine)

Only 1 PIL, Istin, included the pictures of the packets available with the active substance, instead of stating the strength and pharmaceutical form verbally:

(Istin)

Straight after, there is also a preamble which instructs the consumer on how to engage with the leaflet and with the medicine s/he is about to take and to contact the doctor if there happen to be any doubts. This is defined as the bullet point section at the beginning of all PILs as shown in the example:

Example 2

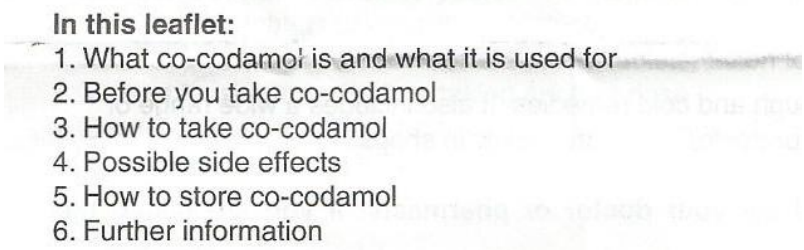
Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

(Zoton Fas Tabs)

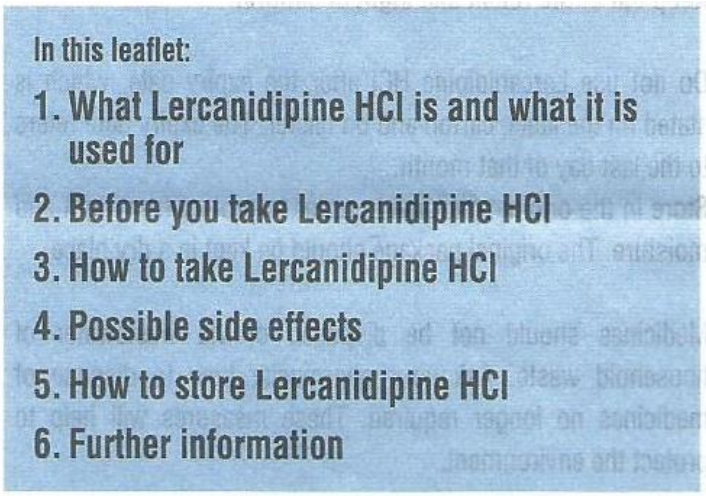
Finally, in this first section there is a table of contents, from 1 to 6, as an introduction to the whole leaflet:

Example 3

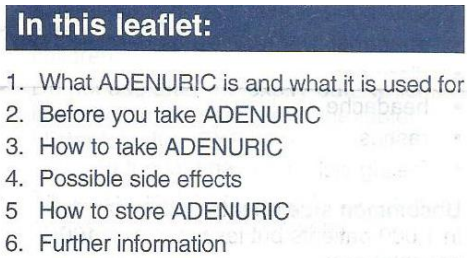

In this leaflet:
1. What co-codamol is and what it is used for
2. Before you take co-codamol
3. How to take co-codamol
4. Possible side effects
5. How to store co-codamol
6. Further information

As mentioned in 3.1.8, the guidelines recommend judicious use of colour which may help to emphasise some key messages. The following are other examples of contents listed in coloured shaded boxes, or coloured print on white background:

Examples 4


In this leaflet:
1. What Lercanidipine HCl is and what it is used for
2. Before you take Lercanidipine HCl
3. How to take Lercanidipine HCl
4. Possible side effects
5. How to store Lercanidipine HCl
6. Further information

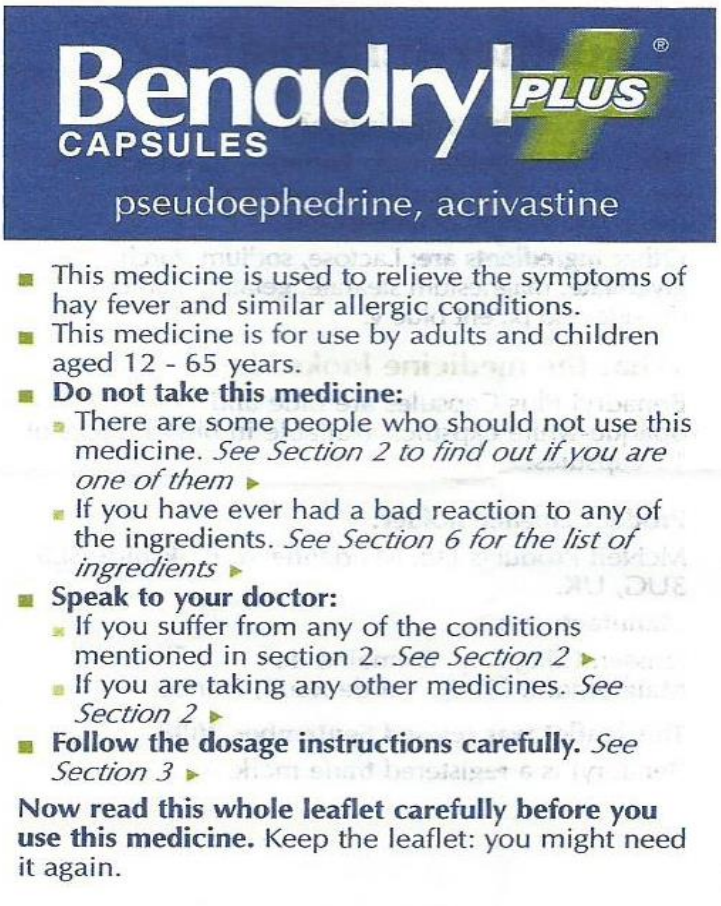
(Lercanidipine)


In this leaflet:
1. What ADENURIC is and what it is used for
2. Before you take ADENURIC
3. How to take ADENURIC
4. Possible side effects
5 How to store ADENURIC
6. Further information

(Adenuric)

Most PILs followed the above examples where the contents are presented as a list, not necessarily in shaded coloured boxes, or blue print, but with numbers to give an overview of what the leaflet will explain after. Only 4 of the leaflets did not have a table of contents: *Aspirin Gastro-resistant Tablets, Benadryl Plus Capsules, Benylin and Lisinopril tablets* (see index section). In the example that follows, the patient/reader is asked to read the leaflet carefully before taking the medicine but the list of contents is left out,

Example 5



Benadryl® PLUS
CAPSULES
pseudoephedrine, acrivastine

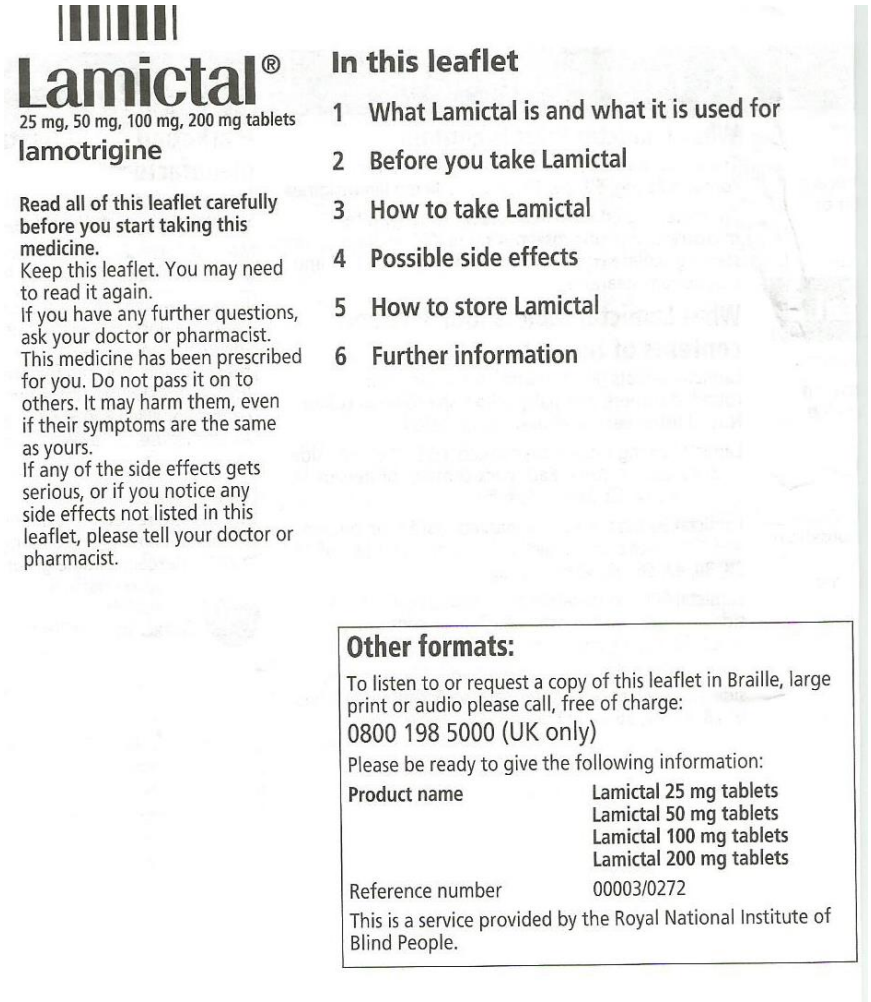
- This medicine is used to relieve the symptoms of hay fever and similar allergic conditions.
- This medicine is for use by adults and children aged 12 - 65 years.
- **Do not take this medicine:**
  - There are some people who should not use this medicine. *See Section 2 to find out if you are one of them* ▸
  - If you have ever had a bad reaction to any of the ingredients. *See Section 6 for the list of ingredients* ▸
- **Speak to your doctor:**
  - If you suffer from any of the conditions mentioned in section 2. *See Section 2* ▸
  - If you are taking any other medicines. *See Section 2* ▸
- **Follow the dosage instructions carefully.** *See Section 3* ▸

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

(Benadryl)

Most of the text in the introductory section consists of standard phrases taken from the EU template and there is little variation between the leaflets. However in the Lamictal PIL there is an instruction to call a hotline, if the consumer finds the leaflet difficult to see or read, straight after the list of contents. The consumer is asked to give specific information about the strength of the tablets and the reference number so that a reply may be given appropriately:

Example 6



Lamictal®
25 mg, 50 mg, 100 mg, 200 mg tablets
lamotrigine

Read all of this leaflet carefully before you start taking this medicine.
Keep this leaflet. You may need to read it again.
If you have any further questions, ask your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK only)
Please be ready to give the following information:

Product name	**Lamictal 25 mg tablets** **Lamictal 50 mg tablets** **Lamictal 100 mg tablets** **Lamictal 200 mg tablets**
Reference number	00003/0272

This is a service provided by the Royal National Institute of Blind People.

It is also made clear that this service is only reserved for residents in the U.K. free of charge.

Section 2

The next section *describes* what the medicine is (the group of medicines which the product belongs to), *explains* what the medicine is used for, how it works, and/or what is expected from it.

Example 1 (What the medicine is)

LIQUIFILM TEARS is a substitute for tears and contains a lubricant called polyvinyl alcohol.

(Liquifilm Tears)

Examples 2 (What the medicine is used for)

BUSCOPAN Tablets are used to relieve cramps in the muscles of your:
- Stomach
- Gut (intestine)
- Bladder and the tubes that lead to the outside of your body (urinary system)

It can also be used to relieve the symptoms of Irritable Bowel Syndrome (IBS).

(Buscopan)

Prednisolone tablets are used in a wide range of inflammatory and auto-immune conditions including:
- allergies, including severe allergic reactions
- inflammation affecting the: lungs, including asthma, blood vessels and heart, bowel or kidneys, muscles and joints, including rheumatoid, arthritis, eye and nervous system
- skin conditions
- some infections
- some cancers, including leukaemia, lymphoma and myeloma
- to prevent organ rejection after a transplant

Also:
- to make up the difference when the body's production of cortisone is too low to maintain good health.
- to treat high calcium levels.

(Prednisolone)

Examples 3 (How the medicine works and its expected effect)

It works by controlling the uneven beating of your heart (called 'arrhythmias'). Taking the tablets helps your heartbeat to return to normal.

(Flecainide Acetate PIL)

EZETROL works by reducing the cholesterol absorbed in your digestive tract. EZETROL does not help you lose weight.

EZETROL adds to the cholesterol-lowering effect of statins, a group of medicines that reduce the cholesterol your body makes by itself.

(Ezetrol)

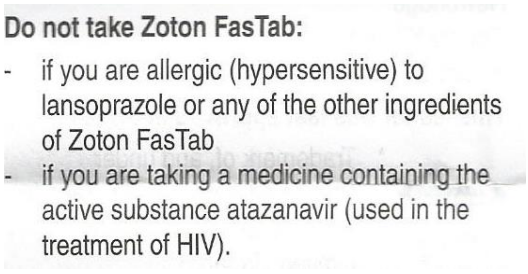
Section 3

Section three regarding 'constraints on patient behaviour' is a warning to consumers who are about to take the medicine. According to Sless and Wiseman (1997: 42), this section is a 'safety net for cases where consumers have not informed their doctor about important conditions that might affect their use of a medicine'. Thus consumers are instructed to avoid taking the medicine and to contact the doctor if certain conditions apply to them, e.g. if they are allergic to the active ingredient, belong to a certain category of users (the elderly, children, pregnant, breastfeeding), have pathological conditions, operate machinery, take other medicines, alcohol and foodstuffs, which may interact negatively with that medicine. This section tends to be one of the longest and the one with most information in it (the heavy section of the PIL). The information about effects consists of conceptual information which is split up into modules, meaning that the information is transferred into relevant questions of the user, that is, from the perspective of the patient. The linguistic means used to convey risk conceptual information uses clear signal words with a warning character,

sometimes pictograms as well. Because this part of the PIL is dense and full of information, often the patient is at risk for missing essential information because of its overload. This is the reason why, as recommended by research, current PILs tend not to exaggerate on risk matters. In general there is a lot of recognition of the importance of informing people about the risks, as well as benefits of their treatment, but the information must not frighten the consumer who may give up taking the medicine after all. In this section the imperative form is used to realize instructions such as: '*Do not take this medicine and/or tell your doctor if...*'. The patient is addressed directly through the second person pronoun and this is another way of promoting patient-centeredness, so as to give the text a less formal tone.

Other features include lay terms and colloquial everyday language, simple active syntax, and bullet points that highlight key messages (i.e. special conditions and precautions which may apply to the individual consumer):

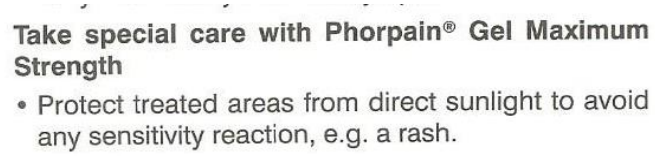
Examples 1



Do not take Zoton FasTab:

- if you are allergic (hypersensitive) to lansoprazole or any of the other ingredients of Zoton FasTab
- if you are taking a medicine containing the active substance atazanavir (used in the treatment of HIV).

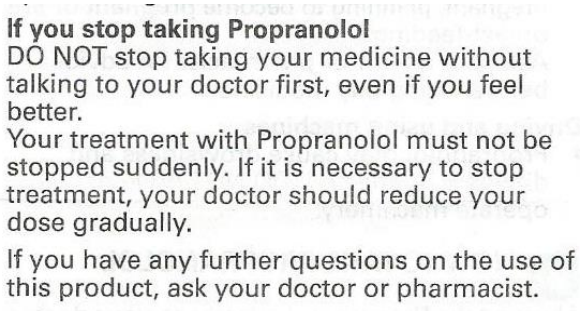
(Zoton FasTabs)



Take special care with Phorpain® Gel Maximum Strength

- Protect treated areas from direct sunlight to avoid any sensitivity reaction, e.g. a rash.

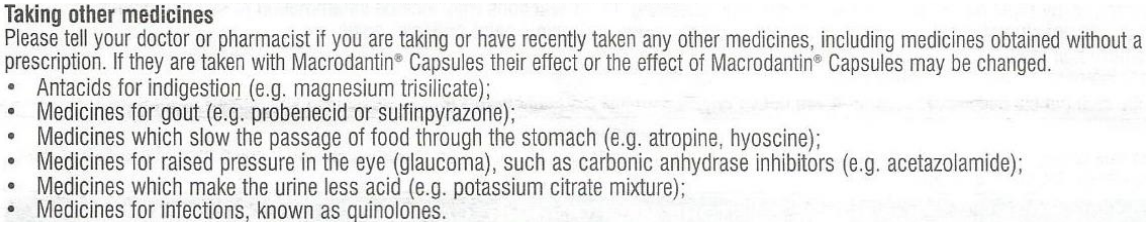
(Phorpain Gel)



If you stop taking Propranolol
DO NOT stop taking your medicine without talking to your doctor first, even if you feel better.
Your treatment with Propranolol must not be stopped suddenly. If it is necessary to stop treatment, your doctor should reduce your dose gradually.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

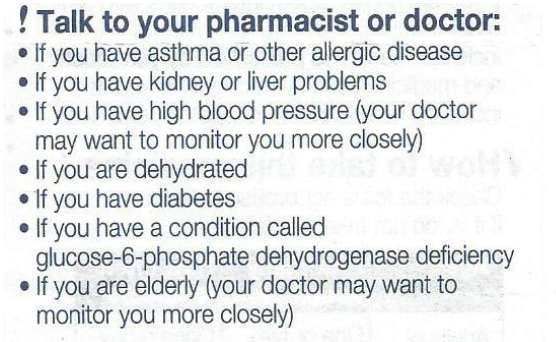
(Propranolo)



Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If they are taken with Macrodantin® Capsules their effect or the effect of Macrodantin® Capsules may be changed.

- Antacids for indigestion (e.g. magnesium trisilicate);
- Medicines for gout (e.g. probenecid or sulfinpyrazone);
- Medicines which slow the passage of food through the stomach (e.g. atropine, hyoscine);
- Medicines for raised pressure in the eye (glaucoma), such as carbonic anhydrase inhibitors (e.g. acetazolamide);
- Medicines which make the urine less acid (e.g. potassium citrate mixture);
- Medicines for infections, known as quinolones.

(Macrodantin)



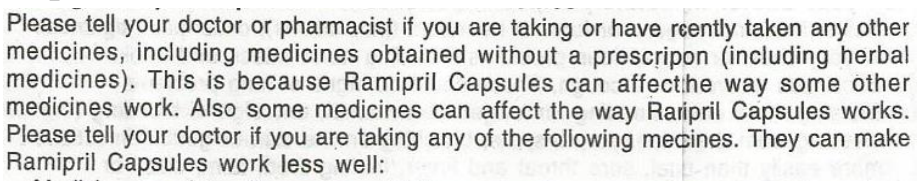
! Talk to your pharmacist or doctor:

- If you have asthma or other allergic disease
- If you have kidney or liver problems
- If you have high blood pressure (your doctor may want to monitor you more closely)
- If you are dehydrated
- If you have diabetes
- If you have a condition called glucose-6-phosphate dehydrogenase deficiency
- If you are elderly (your doctor may want to monitor you more closely)

(Aspirin Enteric)

There are many examples of direct instructions with an easy-to-understand explanation of *why* the patient should inform the doctor about other medicines. The following piece of text taken from Zoton Fas Tabs, illustrates the positive trend of trying to provide consumers with information which is relevant for their compliance:

Example 2



Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescripon (including herbal medicines). This is because Ramipril Capsules can affecthe way some other medicines work. Also some medicines can affect the way Ranipril Capsules works. Please tell your doctor if you are taking any of the following mecines. They can make Ramipril Capsules work less well:

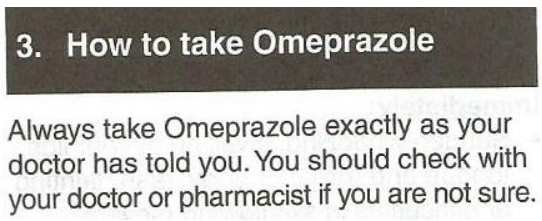
(Ramipril)

Section four

The purpose of section four is to *instruct* the patient on how to take the medicine correctly and how to act in case he/she does not take the medicine correctly, or perhaps has any doubts on the use of the product.

Information in this section includes dosage (often in relation to certain categories of users), method and frequency of administration, the duration of treatment, the expected effect, instances of forgetting a dose, over dosage and the way treatment should be stopped. Positive features in this section include imperative clauses for realizing straightforward instructions (e.g. how to take the medicine) and simple and short sentences (often in bullet points) which *explain*, in a colloquial and direct way, how the medicine should be taken and what may happen if procedures are not being followed:

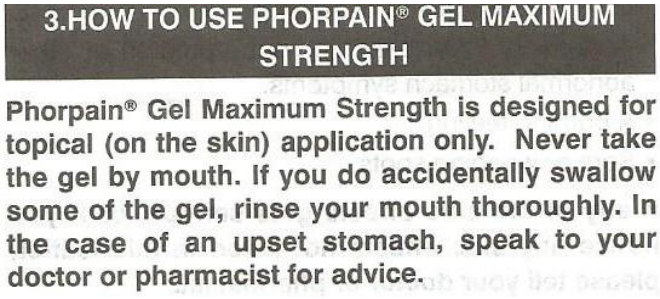
Examples 1



3. How to take Omeprazole

Always take Omeprazole exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

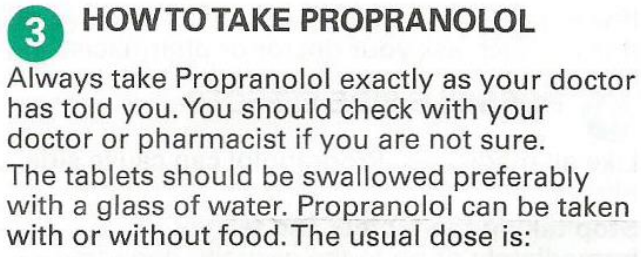
(Omeprazole)



3.HOW TO USE PHORPAIN® GEL MAXIMUM STRENGTH

Phorpain® Gel Maximum Strength is designed for topical (on the skin) application only. Never take the gel by mouth. If you do accidentally swallow some of the gel, rinse your mouth thoroughly. In the case of an upset stomach, speak to your doctor or pharmacist for advice.

(Phorpain)

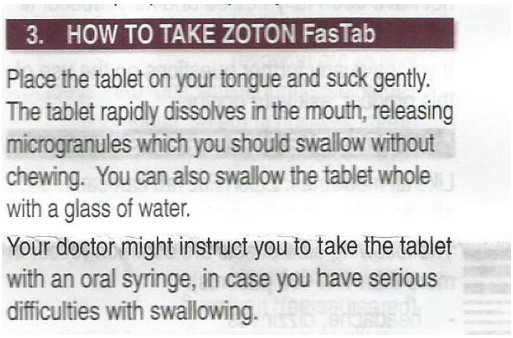


3 HOW TO TAKE PROPRANOLOL

Always take Propranolol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed preferably with a glass of water. Propranolol can be taken with or without food. The usual dose is:

(Propranolol)

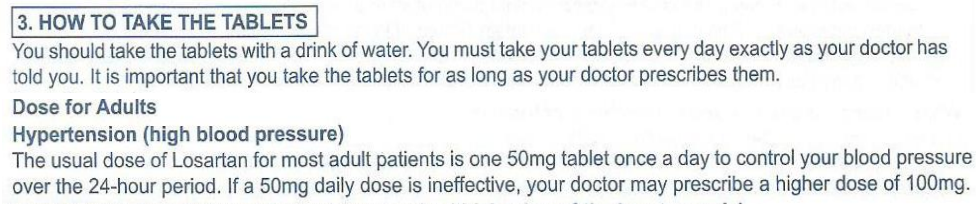


3. HOW TO TAKE ZOTON FasTab

Place the tablet on your tongue and suck gently. The tablet rapidly dissolves in the mouth, releasing microgranules which you should swallow without chewing. You can also swallow the tablet whole with a glass of water.

Your doctor might instruct you to take the tablet with an oral syringe, in case you have serious difficulties with swallowing.

(Zoton Fas Tabs)



3. HOW TO TAKE THE TABLETS

You should take the tablets with a drink of water. You must take your tablets every day exactly as your doctor has told you. It is important that you take the tablets for as long as your doctor prescribes them.

Dose for Adults

Hypertension (high blood pressure)

The usual dose of Losartan for most adult patients is one 50mg tablet once a day to control your blood pressure over the 24-hour period. If a 50mg daily dose is ineffective, your doctor may prescribe a higher dose of 100mg.

(Losartan Potassium)

Section five

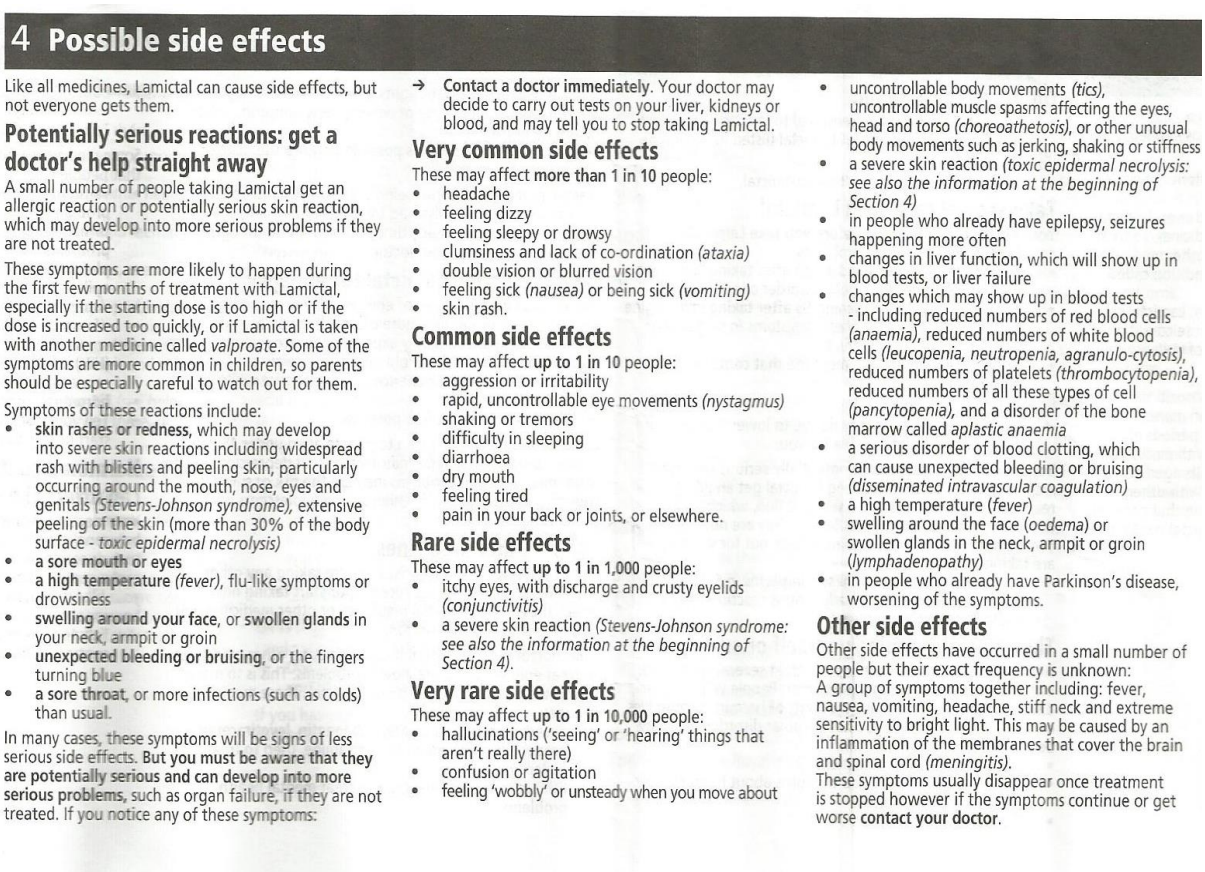
The purpose of section five is to *describe*, *explain*, and *grade* some of the undesirable side effects that may occur, and to *instruc*t the consumer to take action if a side effect occurs (e.g. to contact the doctor or pharmacist). The information about effects consists of conceptual information which is split up into modules, meaning that the information is transferred into relevant questions of the user, that is to say, from the perspective of the patient. The linguistic means used to convey risk conceptual information uses clear signal words with a warning character, sometimes pictograms as

well. This section also entails the risk that perhaps the patient will miss essential information because of information overload. In general there is a lot of recognition of the importance of informing people about the risks, as well as benefits of their treatment. There is, however, growing evidence from both everyday experience and empirical studies, that people's interpretations of risk messages are also significantly influenced by the particular way in which the information is presented. The information given about side effects is very important for the patient who wants to satisfy his/her hunger to be further informed of what possible effects may occur. The ability of the writer (expert) is to provide patients with sufficient information, but at the same time, that information will not lead to increased anxiety about their illnesses or treatments. Good information leaflets should reduce anxiety and should not result in an increase of side effects, but aid patients to participate more actively in their own treatment. In most current PILs presentational factors for describing probability information is presented both verbally and numerically. The grading of side effects may be a potential source of confusion but changes have been made and two common ways of presenting risk probabilities are applied: verbal labels, such as '*common*' or '*rare*', and numerical terms such as '*1 in a 100'* are mostly used now. In fact, the European Commission (2001), specifically recommended the use of five such descriptors -'very common, common, uncommon, rare, and very rare'-. Before the introduction of natural frequencies, such as: 1 out of 100, or 1 out of 1000, to describe probabilities of risk, the use of percentages showed to give rise to particular difficulties because people would over-estimate risk, thinking for example that 10% meant much more than what it really related to (Berry, Raynor and Knapp, 2003). Thus, positive framing has shown to affect people's

treatment preferences and improve their understanding of the information presented (Armstrong, Shwartz, Fitzgerald, cited in Berry, 2006: 122).

About 32 of the PILs analysed have shown to carry a successful grading as regards to probability information, where a division into *very common, common, uncommon, rare and very rare* side effects including a graduation of frequency (by number of persons affected) was presented in a straightforward colloquial manner (see examples):

Examples 1



4 Possible side effects

Like all medicines, Lamictal can cause side effects, but not everyone gets them.

Potentially serious reactions: get a doctor's help straight away

A small number of people taking Lamictal get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated.

These symptoms are more likely to happen during the first few months of treatment with Lamictal, especially if the starting dose is too high or if the dose is increased too quickly, or if Lamictal is taken with another medicine called *valproate*. Some of the symptoms are more common in children, so parents should be especially careful to watch out for them.

Symptoms of these reactions include:

- **skin rashes or redness**, which may develop into severe skin reactions including widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals *(Stevens-Johnson syndrome)*, extensive peeling of the skin (more than 30% of the body surface - *toxic epidermal necrolysis)*
- **a sore mouth or eyes**
- **a high temperature** *(fever)*, flu-like symptoms or drowsiness
- **swelling around your face**, or **swollen glands** in your neck, armpit or groin
- **unexpected bleeding or bruising**, or the fingers turning blue
- **a sore throat**, or more infections (such as colds) than usual.

In many cases, these symptoms will be signs of less serious side effects. **But you must be aware that they are potentially serious and can develop into more serious problems,** such as organ failure, if they are not treated. If you notice any of these symptoms:

→ **Contact a doctor immediately**. Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking Lamictal.

Very common side effects

These may affect **more than 1 in 10** people:

- headache
- feeling dizzy
- feeling sleepy or drowsy
- clumsiness and lack of co-ordination *(ataxia)*
- double vision or blurred vision
- feeling sick *(nausea)* or being sick *(vomiting)*
- skin rash.

Common side effects

These may affect **up to 1 in 10** people:

- aggression or irritability
- rapid, uncontrollable eye movements *(nystagmus)*
- shaking or tremors
- difficulty in sleeping
- diarrhoea
- dry mouth
- feeling tired
- pain in your back or joints, or elsewhere.

Rare side effects

These may affect **up to 1 in 1,000** people:

- itchy eyes, with discharge and crusty eyelids *(conjunctivitis)*
- a severe skin reaction *(Stevens-Johnson syndrome: see also the information at the beginning of Section 4)*.

Very rare side effects

These may affect **up to 1 in 10,000** people:

- hallucinations ('seeing' or 'hearing' things that aren't really there)
- confusion or agitation
- feeling 'wobbly' or unsteady when you move about
- uncontrollable body movements *(tics)*, uncontrollable muscle spasms affecting the eyes, head and torso *(choreoathetosis)*, or other unusual body movements such as jerking, shaking or stiffness
- a severe skin reaction *(toxic epidermal necrolysis: see also the information at the beginning of Section 4)*
- in people who already have epilepsy, seizures happening more often
- changes in liver function, which will show up in blood tests, or liver failure
- changes which may show up in blood tests - including reduced numbers of red blood cells *(anaemia)*, reduced numbers of white blood cells *(leucopenia, neutropenia, agranulo-cytosis)*, reduced numbers of platelets *(thrombocytopenia)*, reduced numbers of all these types of cell *(pancytopenia)*, and a disorder of the bone marrow called *aplastic anaemia*
- a serious disorder of blood clotting, which can cause unexpected bleeding or bruising *(disseminated intravascular coagulation)*
- a high temperature *(fever)*
- swelling around the face *(oedema)* or swollen glands in the neck, armpit or groin *(lymphadenopathy)*
- in people who already have Parkinson's disease, worsening of the symptoms.

Other side effects

Other side effects have occurred in a small number of people but their exact frequency is unknown:
A group of symptoms together including: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover the brain and spinal cord *(meningitis)*.
These symptoms usually disappear once treatment is stopped however if the symptoms continue or get worse **contact your doctor**.

(Lamictal)

The following side effects have been reported. Tell your doctor if any of these side effects become troublesome:

Very common side effects (probably affecting more than 1 in 10 patients)

- infections (in kidney transplant patients)
- feeling and being sick (nausea and vomiting)
- reduction in number of white blood cells which makes infections more likely
- loss of appetite (anorexia).

Common side effects (probably affecting less than 1 in 10 patients):

- liver disease
- increased infections in patients with bowel inflammation
- reduction in blood platelets which increases risk of bleeding or bruising
- decrease in red blood cells in the blood (anaemia)
- inflammation of the pancreas, which causes severe pain in the abdomen and back.

Certain types of cancer (lymphomas, cancer of the cervix, vulva and skin (especially on areas of the skin exposed to the sun)) are common in patients after kidney transplant.

Uncommon side effects (probably affecting less than 1 in 100 patients):

- allergic reactions including dizziness or feeling unwell, low blood pressure, fever, feeling cold , feeling severely sick and vomiting, diarrhoea, rash, rigors, kidney problems, muscle pain (myalgia), pain in the joint (arthralgia), inflammation of blood vessels (vasculitis), high number of liver enzymes
- increased infections in patients suffering from rheumatoid arthritis
- blood disorder after transplant surgery
- foul smelling stools which are bulky, loose and greasy
- hair loss (alopecia).

Rare side effects (probably affecting less than 1 in 1000 patients):

- paleness or fatigue or feeling short of breath caused when the body's bone marrow is not producing enough blood cells (aplastic anaemia)
- cough and fever caused by pneumonia or inflammation of the lung
- stomach ulcer and disease which may cause heartburn, vomiting, general discomfort in the stomach.

Very rare side effects (probably affecting less than 1 in 10,000 patients):

- blood disorders (including acute myeloid leukaemia and myelo-dysplastic syndromes)
- very serious allergic reaction.

(Azathioprine)

Uncommon side effects (less than 1 out of 100 but equal or more than 1 out of 1,000 patients):

- nausea;
- vomiting
- irritation or inflammation of the gullet (oesophagus the tube that connects your mouth with your stomach) or stomach
- black or tar-like stools
- rash;
- itching;
- redness of the skin

Rare side effects (less than 1 out of 1000 but equal or more than 1 out of 10,000 patients):

- allergic reactions such as hives; swelling of the face, lips, tongue and/or throat, possibly causing difficulty breathing or swallowing
- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth
- stomach or peptic ulcers (sometimes severe or with bleeding)
- narrowing of the gullet (oesophagus the tube that connects your mouth with your stomach)
- jaw problems associated with delayed healing and infection, often following tooth extraction
- blurred vision, pain or redness in the eye
- rash made worse by sunlight
- severe bone, muscle and/or joint pain
- mouth ulcers when the tablets have been chewed or sucked
- transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment

Very rare side effects (less than 1 out of 10,000 patients):

- severe skin reactions

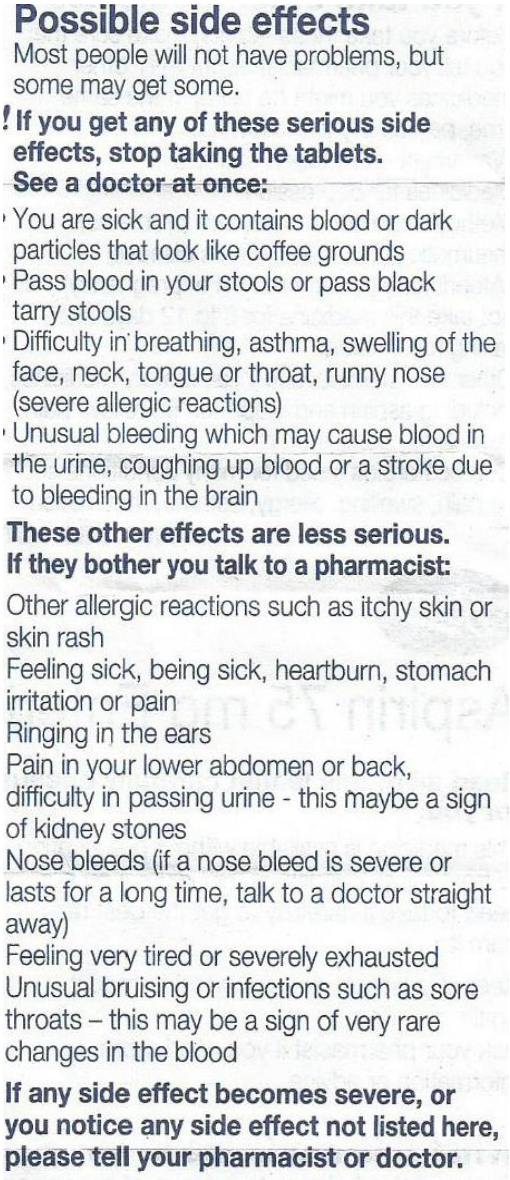
During post-marketing experience the following side effects have been reported (frequency unknown):

- dizziness
- joint swelling
- tiredness
- swelling in the hands or legs

(Alendronic Acid)

In Aspirin Enteric Tablets (see example below), Omeprazole, Phorpain gel, Paracetamol caplets, Piriton allergy tablets, Flecainide, Naproxen, Propranolol tablets, Lisinopril tablets (see PILs in appendix), and Voltarol (see *Fig. 4.1*), neither verbal nor numerical descriptors, of side effects were present:

Example 3



Possible side effects

Most people will not have problems, but some may get some.

! If you get any of these serious side effects, stop taking the tablets. See a doctor at once:

- You are sick and it contains blood or dark particles that look like coffee grounds
- Pass blood in your stools or pass black tarry stools
- Difficulty in breathing, asthma, swelling of the face, neck, tongue or throat, runny nose (severe allergic reactions)
- Unusual bleeding which may cause blood in the urine, coughing up blood or a stroke due to bleeding in the brain

These other effects are less serious. If they bother you talk to a pharmacist:

Other allergic reactions such as itchy skin or skin rash
Feeling sick, being sick, heartburn, stomach irritation or pain
Ringing in the ears
Pain in your lower abdomen or back, difficulty in passing urine - this maybe a sign of kidney stones
Nose bleeds (if a nose bleed is severe or lasts for a long time, talk to a doctor straight away)
Feeling very tired or severely exhausted
Unusual bruising or infections such as sore throats – this may be a sign of very rare changes in the blood

If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.

(Aspirin EntericTablets)

Two PILs, Finasteride and Nurofen for children, carried the verbal descriptors but not the numerical ones (see examples):

Examples 4

4. Possible side effects

Like all medicines, Finasteride 5mg Tablets can cause side effects, although not everybody gets them. You should promptly report to your doctor any changes in your breast tissue such as lumps, pain, enlargement of the breast tissue or nipple discharge as these may be signs of a serious condition, such as breast cancer.

Common side-effects include: impotence (inability to maintain an erection); a reduced desire to have sex; producing a reduced amount of semen

Uncommon side-effects include: Swelling and/or tenderness of the breasts; problems with ejaculation; skin rashes

Rare side-effects include: Allergic reactions including itching, hives or swelling of the face and lips; pain in the testicles and a rapid and irregular heart beat

(Finasteride)

Other side effects which may occur are:

Uncommon:
- headache

Rare:
- diarrhoea, wind or constipation. Tell your doctor if these last for more than a few day or become troublesome

Very rare:
- kidney problems may occur with Ibuprofen
- stroke or heart problems may occur with Ibuprofen. This is unlikely at the dose level given to children
- worsening of colitis and Crohn's disease
- high blood pressure.

(Nurofen for children)

Section six

Section six has the 'move' which *instructs* the consumer on how to store the product safely and effectively, and how to dispose of the medicine

in a safe and environmentally friendly way. It also instructs the consumer on how to act if the product has reached its expiry date or shows visible signs of deterioration:

Example 1

How to store

Keep out of the reach and sight of children.
No special precautions for storage.
Do not use Citalopram tablets after the expiry date stated on the label/carton/ bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

(Citalopram)

Much of the text in this section of the leaflet, draws on standard phrases from the EU template as: '**keep out of reach and sight of children**'. The PILs in the corpus do, in fact, follow that template, except for Paracetomol that has reformulated the phrase above and also carries a symbol representing storage measures beside the verbal instructions:

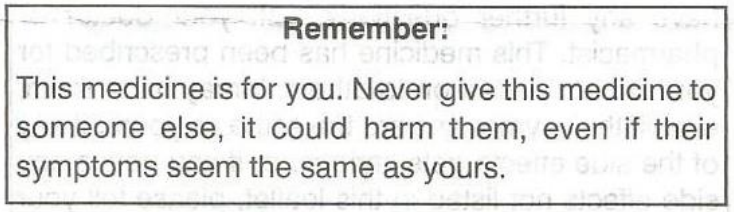
Example 2

5. STORING YOUR MEDICINE

Keep your medicine in a safe place where children cannot see or reach it.
Do not store above 25°C. Store in the original packaging to protect from light and moisture.
Do not use this medicine after the expiry date printed on the packaging.

The Phorpain PIL has also added a boxed warning as follows:

Example 3



Remember:

This medicine is for you. Never give this medicine to someone else, it could harm them, even if their symptoms seem the same as yours.

Section seven

Section seven concerns further information.

The purpose of this final section is to *describe* what the medicine contains, what it looks like and to list the content of the package. It also includes the name and address of the marketing authorization holder (MAH) and manufacturer, product licence number and the date of the last PIL revision (see Chapter One).

All the PILs analysed contained the details stated above. The following are some examples:

Examples 1

What Flucloxacillin Capsules BP contain

Active ingredient: flucloxacillin as flucloxacillin sodium
Other ingredients: Sodium starch glycollate, magnesium stearate, red iron oxide (E172), yellow iron oxide (E1
black iron oxide (E172), titanium dioxide (E171) and gelatin.
Please see further information on sodium in section 2.

What Flucloxacillin Capsules BP look like

250mg Capsules are opaque caramel and grey printed with 'FXN 250' in black ink. The capsules contain a gra
off white powder.
500mg Capsules are opaque caramel and grey printed with 'FXN 500' in black ink. The capsules contain a gra
off white powder.

Both strengths are available in the following pack sizes:
Securitainers are available in pack sizes of 15, 18, 20, 21, 28, 30, 50, 100, 250 & 500 capsules.
Blister packs are available in pack sizes of 15, 18, 20, 21, 28, 30, 50, 100, 250 & 500 capsules.
Not all pack sizes may be marketed.

The licence holder and manufacturer is:

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

(Flucoxacillin)

Lipitor and BuTrans also include the pharmaceutical companies which distribute that medicine with the same or different name in other countries of the Member States:

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Bulgaria, Czech Republic, Estonia, Germany, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia	Sortis
Belgium, Cyprus, Finland, Greece, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Sweden, UK	Lipitor
Denmark, Greece, Iceland, Portugal, Spain	Zarator
Finland	Orbeos
France	Tahor
Germany	Atorvastatin Pfizer, Liprimar
Greece	Edovin
Hungary	Obradon
Italy	Torvast, Totalip, Xarator
Portugal	Atorvastatina Parke-Davis, Texzor
Spain	Cardyl, Atorvastatina Nostrum, Atorvastatina Pharmacia, Prevencor

This leaflet was last approved in 03/2011.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	*Norspan®*
Belgium	*Norspan®*
Czech Republic	*Norspan®*
Denmark	*Norspan®*
Estonia	*Norspan®*
Finland	*Norspan®*
Germany	*Norspan®*
Hungary	*Norspan®*
Iceland	*Norspan®*
Latvia	*Norspan®*
Lithuania	*Norspan®*
Luxembourg	*Norspan®*
Netherlands	*BuTrans®*
Norway	*Norspan®*
Poland	*Norspan®*
Portugal	*Norspan®*
Republic of Ireland	*BuTrans®*
Slovak Republic	*Norspan®*
Sweden	*Norspan®*
United Kingdom	*BuTrans®*

Two PILs, Multaq and CoAprovel, supplied the local representatives of the Marketing Athorisation Holder (MH) in other countries of the EU, and support the information with the inclusion of the EMEA website:

Examples 3

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

België/Belgique/Belgien
sanofi-aventis Belgium
Tél/Tel: +32 (0)2 710 54 00

България
sanofi-aventis Bulgaria EOOD
Тел.: +359 (0)2 970 53 00

Česká republika
sanofi-aventis, s.r.o.
Tel: +420 233 086 111

Danmark
sanofi-aventis Denmark A/S
Tlf: +45 45 16 70 00

Deutschland
Sanofi-Aventis Deutschland GmbH
Tel: +49 (0)180 2 222010

Eesti
sanofi-aventis Estonia OÜ
Tel: +372 627 34 88

Ελλάδα
sanofi-aventis AEBE
Τηλ: +30 210 900 16 00

España
sanofi-aventis, S.A.
Tel: +34 93 485 94 00

France
sanofi-aventis France
Tél: 0 800 222 555
Appel depuis l'étranger : +33 1 57 63 23 23

Ireland
sanofi-aventis Ireland Ltd.
Tel: +353 (0) 1 403 56 00

Ísland
Vistor hf.
Sími: +354 535 7000

Italia
sanofi-aventis S.p.A.
Tel: +39 02 393 91

Κύπρος
sanofi-aventis Cyprus Ltd.
Τηλ: +357 22 871600

Latvija
sanofi-aventis Latvia SIA
Tel: +371 67 33 24 51

Lietuva
UAB sanofi-aventis Lietuva
Tel: +370 5 2755224

Luxembourg/Luxemburg
sanofi-aventis Belgium
Tél/Tel: +32 (0)2 710 54 00
(Belgique/Belgien)

Magyarország
sanofi-aventis zrt., Magyarország
Tel.: +36 1 505 0050

Malta
sanofi-aventis Malta Ltd.
Tel: +356 21493022

Nederland
sanofi-aventis Netherlands B.V.
Tel: +31 (0)182 557 755

Norge
sanofi-aventis Norge AS
Tlf: +47 67 10 71 00

Österreich
sanofi-aventis GmbH
Tel: +43 1 80 185 – 0

Polska
sanofi-aventis Sp. z o.o.
Tel.: +48 22 280 00 00

Portugal
sanofi-aventis -
Produtos Farmacêuticos, S.A.
Tel: +351 21 35 89 400

România
sanofi-aventis România S.R.L.
Tel: +40 (0) 21 317 31 36

Slovenija
sanofi-aventis d.o.o.
Tel: +386 1 560 48 00

Slovenská republika
sanofi-aventis Pharma Slovakia s.r.o.
Tel: +421 2 57 103 777

Suomi/Finland
sanofi-aventis Oy
Puh/Tel: +358 (0) 201 200 300

Sverige
sanofi-aventis AB
Tel: +46 (0)8 634 50 00

United Kingdom
sanofi-aventis
Tel: +44 (0) 1483 505 515

AD EUR-V6_05-09

This leaflet was last approved in 12/2009

Detailed information on this medicine is available on the European Medicines Agency (EMEA) web site: http://www.emea.europa.eu

(Multaq)

Marketing Authorisation Holder
SANOFI PHARMA BRISTOL-MYERS SQUIBB SNC
174 avenue de France
F-75013 Paris - France

Manufacturer
SANOFI WINTHROP INDUSTRIE
30-36 Avenue Gustave Eiffel
37100 Tours - France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
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България
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Deutschland
Sanofi-Aventis Deutschland GmbH
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Eesti
sanofi-aventis Estonia OÜ
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Ísland
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Italia
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Τηλ: +357 22 871600

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Tel: +371 67 33 24 51

Lietuva
UAB sanofi-aventis Lietuva
Tel. +370 5 2755224

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Tel: +31 (0)182 557 755

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Tlf: +47 67 10 71 00

Österreich
sanofi-aventis GmbH
Tel: +43 1 80 185 - 0

Polska
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Slovenija
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Tel: + 386 1 560 48 00

Slovenská republika
sanofi-aventis Pharma Slovakia
Tel: + 421 2 33 100 100

Suomi/Finland
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Puh/Tel: +358 (0) 201 200 300

Sverige
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Tel: +46 (0)8 634 50 00

United Kingdom
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Tel: +44 (0) 1483 505 515

This leaflet was last approved in September 2011

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/

(CoAprovel)

In sum, the results of this part of the analysis regarding the organization of the texts and the functions, showed that apart from one, (Voltarol), all the PILs presented the moves in quite a standard and linear way. The rhetorical functions (explain/define, describe, inform, instruct, offer, monitor) were identified according to the generic structure moves (introduction to the medicine, background, dosage, constraints on patient behaviour, side effects, storage, further information about the medicine)

which all, more or less, followed the same order appropriately. In most PILs, patients were being offered a service (‘*seek the advice of your doctor or pharmacist...*’), whereas in others they were being instructed to initiate a meeting (‘*tell your doctor’*). The instructions regarding responsibility were quite clear as well, such as ‘*The usual dose is 30mg oro-dispersible tablets every day to start with, then depending on how you respond to Zoton FasTab the dose that your doctor sees best for you’,* (see PIL in appendix). Thus, the ‘doctor’ is specified for being responsible for making that decision. Language denoting uncertainty followed the same order in 32 PILs because they noted, with verbal descriptors, that the frequency of a complication was from ‘very common to very rare’ and clarified this to mean that it occurred in 1 or more of 10 patients treated, or, in less than 1 of 10000 patients treated. It has been noted, therefore, that there seems to be a clear guidance in helping the patient to understand what to do with the information presented in most of the PILs examined.

Relating the above results to the notion of generic potential as elaborated by Paltridge (1997), drawing on Hasan (1989), the PILs carried the following generic structure: [IM] ^ [BM] ^ [WP] ^ [CB] ^ [AS] ^ [SI] ^ [FI]. The letters in the square brackets are the moves: introduction to the medicine, background of the medicine, warnings and precautions, constraints on patient behaviour, account of side effects, storage instructions and further information. The identified moves followed a fixed sequence illustrated by ^ in the above representation.

4.2 Metadiscourse (The language of PILs)

It is long known in communication studies that any form of communication occurs at two levels: the content level and the relationship level, in other words, “the relationship that always takes a bold hand in

determining the content" (Brown & Keller, 1973: 166). This concept of the relationship between the interactions is essential to the definition of interaction, "the network of relations between the participants (writers and readers) in the communicative event through the text" (Harvey, 1995: 189). The definition reflects the above two levels of communication but it also emphasizes how the 'bold hand' of the relationship with the reader is used to shape the writer's message.

The PILs analysed in this study seem to be highly interactional, and exhibit an 'over-signalling' of the reader's responses and reactions (Thompson & Thetela, 1995 cited in Sultan Al- Sharief, 1996: 13). These, written for a non-specialist audience are characterized by a relatively simple language in rhetorical, lexical, and syntactical terms (Myers, 1994: 179). Such language does not, however, entail unsophisticated objectives or facts of less credibility. On the contrary they contain a lot of medical facts following some of the conventions of scientific writing which mingled to the patient's informational needs, reflect the complex role of meeting their objectives. The comprehensibility of PILs as a function relies a lot on the interaction of the reader with the text, hence, including readers' constructions of a text. The communicative success of a PIL is not always guaranteed even when the readability and comprehensibility are high because the reader may construct a meaning from the text that is coherent, but is divergent from that intended by the writer, and this gives rise to an inappropriate response. This is however different from the situation in which the reader comprehends the intended meaning but makes a considered judgment not to comply with the message. As already mentioned, it is very frequent to find readers who will not systematically read through the text from beginning to end. When reading a PIL a patient might begin by scanning the leaflet, seeking those parts that appear most

relevant or interesting, and may consciously or unconsciously skip over portions of the text. This behavior with PILs, which is not a linear reading process, makes communication less effective. Hence, the message in most of the updated PILs, and those studied in this research, seems to be appropriate and quite clear, however, it is necessary to say, as argued by Garner *et al* (2011) the PILs':

> "[…] communicative effectiveness depends on the reader's 'cognitions' (e.g. expectations, understanding), 'affect' (e.g. relief, concern, worry) and often 'intention' and 'behaviour' (e.g. taking a pill before eating)".
>
> (Garner *et al.* 2011: 8)

Research into communicative effectiveness explores the nature of the readers' actual or intended responses. Any form of communication gives rise to variant interpretations, as a result of the expectations, motivations, prior knowledge and personal circumstances of the addressee, together with other factors. As with other types of effectiveness in relation to healthcare (e.g. clinical effectiveness, cost effectiveness', a PIL should be, and rightly is, assessed on the basis of specified outcomes. This is the reason why user-testing is carried out (see Chapter One), because the notion of 'usability' is explored and identified within a concrete context, also through human-computer interaction when systematical examining of the actions are evaluated and not only reported comprehension.

Some general communicative aims frequently found in medical leaflets (however, not comprehensive) are:

- Providing a scientific background of the health problem and the medicine in question.
- Preparing the patient for the treatment by providing information about how to start the treatment.

- Persuade patients to stop unhealthy habits or at least take steps that will make them less harmful.
- Giving practical advice that will help to avoid complications of the illness or will complement the treatment.
- Arguing against some misconceptions about the disease and/or its treatment.

All the above have the function to specify the intended objectives to help the reader identify the medicine, determine whether it is safe, act correctly in the case of complications and how to use the medicine, hence: "understand, respond and comply with the PIL" (Garner *et al.* 2011: 9).

After reading the leaflet the patients should be able to:

1) Know whether the medicine fits their complaints.
2) Whether or not they can safely take the medicine.
3) How to use the medicine.
4) What side effects may occur and what to do in case they occur.
5) Whether using the medicine may affect certain activities in everyday life.
6) How to store medication.

All of the PILs studied carried the above information (as explained in 4.1). Some had more detailed information, especially the POM leaflets, but both POM and OTC PILs were rather clear and straightforward as far as their contents was concerned. The leaflets all opened with the following statement:

*Read all of this leaflet carefully before you start taking this medicine***.**

The following are further examples of the PILs analysed, responding to the general purposes of the leaflets. They may be viewed in the index section.

- Does the medicine fit?

  Dulcolax Tablets are used for relief of constipation.

  Piriton Allergy Tablets are used for the allergic symptoms of hay fever and other allergies.

  The name of your medicine is *Flecainide Acetate* 50mg or 100mg Tablets (called flecainide throughout this leaflet). This belongs to a group of medicines called anti-arrhythmic.

- Can you take this medicine?

  Before you use *Phorpain gel Maximum* Strength: DO NOT use Phorpain Gel Maximum Strength if: you are allergic to ibuprofen, aspirin or similar medicines or any of the ingredients in this gel.

  Anti-epileptic medicines are used to treat several conditions, including epilepsy and bipolar disorder. People with bipolar disorder can sometimes have thoughts of harming themselves or committing suicide. If you have bipolar disorder, you may be more likely to think this:

  - When you first start treatment
  - If you have previously had thoughts about harming yourself or about suicide
  - If you are under 25 years old

  Lamictal should not be given to people aged under 18 years o treat bipolar disorder.

- How do I use this medicine?

  How to use *Nurofen for children* 3 months to 9 years strawberry.

  Using the heat patch (*Voltarol*).

  Take *Ezetrol* at any time of the day. You can take it with or without food.

- What side effects may occur?

  Possible side-effects

  Like all medicines, *Detrusitol XL* can cause side effects, although not everybody gets them.

  Uncommon side-effects (more than 1 in 1,000 patients but less than 1 in 100 patients) are: weight gain, increased appetite, change in blood sugar levels (diabetes) of which a symptom may be excessive thirst, increased blood fat levels.

  If any of the side effects gets severe, or if you notice any not listed in this leaflet, please tell your doctor, family planning nurse or pharmacist. (*Adenuric*).

- Can this medicine affect everyday life activities?

  Driving and using machines

  Ezetrol is not expected to interfere with your ability to drive or to use machinery.

  Pregnancy and breast-feeding

  If you are pregnant, breast-feeding or if there is a chance you might be pregnant ask your doctor for advice before taking this medicine *(Zoton Fas Tab).*

- How do I store this medicine?

  Store in a dry place. Protect from light. Do not store above 25°C (*Propranolol*).

  Store in the original packaging to protect from light and moisture (*Paracetomol*).

Patients are also warned not to take medication after the expiry date. *EXP* stands for expiry and it is clearly market on the carton, and blister of the medicine. The expiry date does not indicate the day, only the month and year, but expiry refers to the last day of the month stated.

The readers will surely understand the information presented more efficiently if at the basis of their understanding there lies the schema mentioned before. It is the reader's response that determines the endpoint

of communication. Therefore, the meaning of the PIL is not constituted by what is encoded by the writer, but by the patient's behavioural, cognitive, and/or affective response: the reader knows that *X* and *Y* are symptoms of side effect *Z*. S/he knows that this side effect must not be neglected, and s/he is willing to contact the doctor to inform him/her about the side effect to discuss the consequences (Lentz & Pander Maat, 2001, cited in Bongaart, 2009: 9). If there is a lack of comprehension, due to various reasons, (some mentioned before), there is no-affective response.

4.3 Relationship between writer and reader (medical expert to lay person)

Most current PILs which have undergone user-testing are defined as being more patient-centred than the former ones. This means that patients are at the centre of the medicine-taking process (Raynor *et al*, 2007). The point of departure of the utterances is the patient and his or her immediate situational context and presumed state of knowledge rather than the medical situational context and medical knowledge. Thus, whenever new information (e.g. about the medicine and how to take it) is presented to the patient, this information is coupled with assumptions about the patient's presupposed knowledge and immediate context (as mentioned before). Jensen, a Danish expert gives advice on knowledge communication, and suggests that:

> "The equation for successful communication is actually very simple: new knowledge on top of old knowledge makes me wiser, new knowledge on top of new knowledge makes me feel more stupid".
>
> (Jensen 2001, translated from Danish by Zethsen and Askehave 2009: 101)

In PILs 'patient-centeredness' is manifested linguistically through various linguistic features. A typical way of constructing experience in our

part of the world is through processes, participants and attendant circumstances (Halliday 1994). In most of the PILs here analysed there was a frequent use of a question-answer format, complying with legal requirements. This sort of construction in Halliday's words (1994: 140), is 'congruent' because there is a close relation between the actual event (someone is doing something, somewhere) and the lexico-grammatical structure with 'participants', 'processes' and 'circumstance', thus resembling or imitating the patient's real life experience. This shows that the author had considered the relationship between writer and reader. Furthermore, the patient is assigned the semantic role of the main participant who performs an action which is common and recognizable to the average patient as in *going to the doctor*.

For example **:**'**You** (participant) **may have gone** (process) **to the doctor** (circumstance'/location) because (conjunction) **you** (participant) **had** (process) **a stomach ache** (participant)'. Thus, throughout the leaflets, the reader was almost referred to as '**you**'.

Differently from other technical texts, which tend to prefer a nominalized, objective and passive style with dense, complex noun groups, in PILs, preference goes to what Flower *et al*. (1983) cited in Killingsworth (1987: 105) refer to as 'functional prose' that is to say 'structured around a human agent performing actions in a particularized situation', trying to replicate the 'real world'- a world of action, connections and relations (*ibid*.).

Another important feature for considering the role relationship in current PILs (and those analysed in this study) is that the patient is always addressed to through the second person pronoun. According to a study on the changes in subjectivity and stance, Sanders and Spooren (2010), discuss that researchers have observed 'informalization': a shift of stylistic

preferences in written discourse towards a more conversational, or oral style. Citing Pearce (2005), Sanders and Spooren (2010: 2) say that the increase in 'informalization', is reflected in linguistic characteristics such as the number of nominalizations, and the increase of the use of first and second person pronouns.

Thus, whenever possible, the second person pronoun '***you***' is used in the PILs to address the patient rather than the impersonal choices of '*one*', '*the patient'*, or even a passive construction, which is common in medical texts, where 'the effect or result of an action is almost always more important and therefore of greater interest to the reader than knowing who or what performed the action' (Sagar *et al*. 1980). The grammatical choice accentuates the fact that the PIL is a functional text written for ***your*** sake and dedicated to ***your*** compliance rather than for the sake of the legislators, the medical community, etc. As mentioned the use of the pronoun '**you**' gives the text a less formal orientation to address the patient and this makes him/her even more responsible for taking a decision to take the medicine (see examples):

Examples 1

2. BEFORE YOU TAKE ONE-ALPHA®

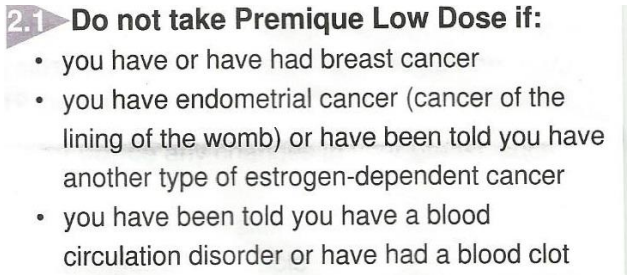
Do not take One-Alpha®
- If you are allergic (hypersensitive) to alfacalcidol or any of the other ingredients. You can find a list of these ingredients in section 6 of this leaflet.
- If you know you have a condition called hypercalcaemia. This means you have high levels of calcium in your blood.
- If you know that you have a condition called calcification. This means you have high levels of calcium in your body tissues.

If you are unsure if any of the above apply to you, talk to your doctor before taking One-Alpha®.

(One-Alpha)

If you have moderate or severe liver problems, EZETROL is not recommended.

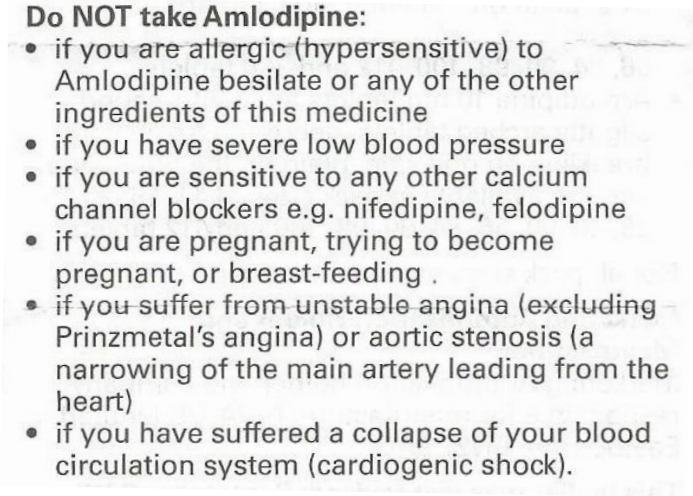
(Ezetrol)



2.1 Do not take Premique Low Dose if:

- you have or have had breast cancer
- you have endometrial cancer (cancer of the lining of the womb) or have been told you have another type of estrogen-dependent cancer
- you have been told you have a blood circulation disorder or have had a blood clot

(Premique)



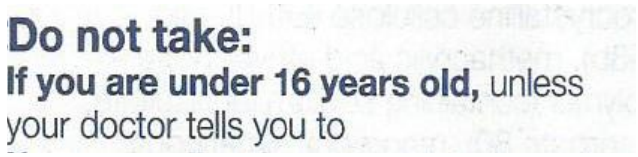
Do NOT take Amlodipine:

- if you are allergic (hypersensitive) to Amlodipine besilate or any of the other ingredients of this medicine
- if you have severe low blood pressure
- if you are sensitive to any other calcium channel blockers e.g. nifedipine, felodipine
- if you are pregnant, trying to become pregnant, or breast-feeding .
- if you suffer from unstable angina (excluding Prinzmetal's angina) or aortic stenosis (a narrowing of the main artery leading from the heart)
- if you have suffered a collapse of your blood circulation system (cardiogenic shock).

(Amlodipine)

As with the second person pronoun, the unmarked way of issuing a command is through the use of the imperative mood. Being an instructive text, where action is required within the PILs on behalf of the patient, the command is realized in the most direct way, namely through the imperative mood. The idea is to get the patient to do something, carry out an action.

Examples 2



Do not take:
If you are under 16 years old, unless your doctor tells you to

(Aspirin Enteric Tablets)

Remember:
This medicine is only for you. Only a doctor can prescribe it for you. Never give this medicine to someone else. It could harm them, even if their symptoms seem the same as yours.

(Macrodantin)

If you stop taking Lercanidipine HCl your blood pressure may increase again. Please consult your doctor before stopping the treatment.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

(Leicanidipine)

- Remove the plunger of the syringe (at least 5 ml syringe for the 15 mg tablet and 10 ml syringe for the 30 mg tablet)
- Put the tablet into the barrel
- Put the plunger back onto the syringe

(Zoton Fast Tabs)

If you wear soft contact lenses you must remove them before using LIQUIFILM TEARS eye drops. After using LIQUIFILM TEARS, you have to wait at least 15 minutes before putting your lenses back in.

(Liquifilm Tears)

If you take more flecainide than you should
If you take more flecainide than you should, tell a doctor or go to a hospital casualty department straight away. Take the carton and any flecainide tablets left with you so the doctor knows what you have taken.

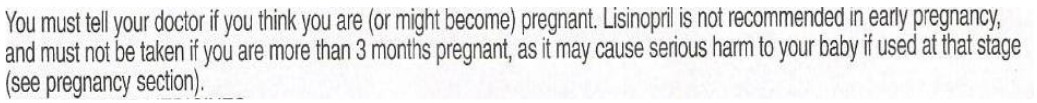
(Flecainide)

- Your doctor will adjust the amount you take until your blood pressure is controlled.
- The maximum dose is 10 mg once daily.

(Tritace)

Do not stop taking your medicine unless the doctor tells you because stopping your medicine can make your condition worse.

(Azathioprine)

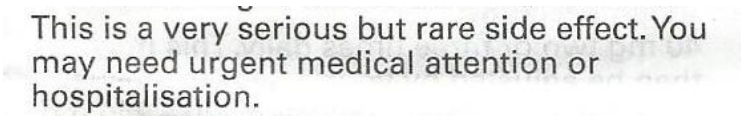

You must tell your doctor if you think you are (or might become) pregnant. Lisinopril is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

(Lisinopril)

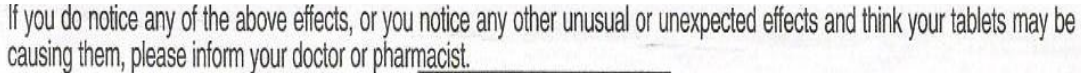
This grammatical choice accentuates the fact and makes it explicit that the PIL is a functional text that requires *action* on the part of the patient.

The PIL, therefore, is a very action-oriented and 'direct' text in the sense that it requires compliance and action on behalf of the patient. Zethsen and Askehave (2009: 102) argue that the realizations of mood and experience mentioned before, may however have a downside, namely that the text becomes too direct and 'pushy', setting up a very authoritarian relationship between the 'knowledgeable' writer, talking down to the 'less knowledgeable' patient. (e.g. *You must tell your doctor if....*; *Take the capsules exactly as directed by your doctor; Your doctor will decide whether...Do not stop taking X unless...*). But it is also true that writers of PILs try to make up for this unequal relationship by employing different types of modality which serve to tone down the force of the proposals, commands or propositions in the text.

Examples 3


This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

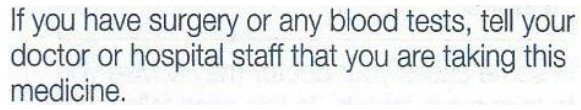
(Prednisolone)


If you do notice any of the above effects, or you notice any other unusual or unexpected effects and think your tablets may be causing them, please inform your doctor or pharmacist.

(Lisinopril)

The above interpersonal features: '*please inform your doctor...', 'you may need to inform your doctor...*', convey a less demanding tone, and were present in most of the PILs analysed. However, 7 PILs did not use '*please*' but *'tell your doctor'* or '*talk to your doctor'*: Lamictal, Aspirin Enteric Tablets, Aspirin Gastro-Resistant, Voltarol Thermal Patches, Ezetrol, Finasteride and Propranolol. These, in fact, carry a more authoritative tone than the others and may give the impression of 'pushing' the patient a bit too much to take action.

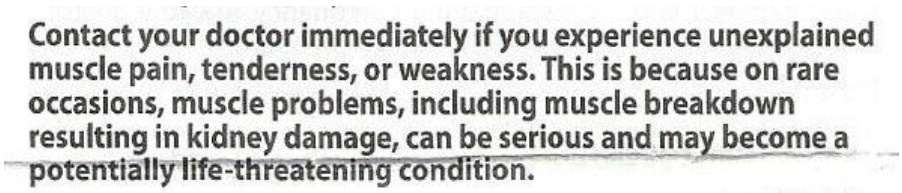
Examples 4



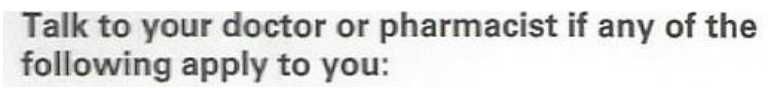
(Aspirin Enteric Tablets)

(Lamictal)

We can also notice the use of **bold** which emphasises the message and conveys a more commanding/authoritative tone:



(Ezetrol)



(Aspirin Gastro-Resistant)

4.4 The use of headings and headlines

Many of the leaflets (46/60) used left-ranging headings with the remainder having centred ones and were phrased as questions or statements. 12 headings appeared on a shaded background box, e.g.: Benadryl, Bu Transdermal Patches, Co-Codamol, Flecainide Acetate, Istin, Lipitor, and Zoton Fas Tab; 10 headings in an non-shaded box, e.g.: Flucloxacillin, Lisinopril, Losartan Potassium, Ramipril, Viscotears, and Warfarin. The other headings were not surrounded by a box, e.g.; Aspirin Enteric Tablets, Atarax, One-Alpha, Cefalexin, Clopidogrel Hydrocortisone Ointment, Multaq, Metoprolol, Phenergan, Premique, Tartrate, Temazepam. Ventolin Evohaler, Half Sinet CR Tablets. Some PILs used a combination of bold and *italic* print with variations of colours (black, brown, dark blue, light blue, red, white). Capitals were used in about 50% of the leaflets for the main heading and sub-headings (see PILs in the appendix section).

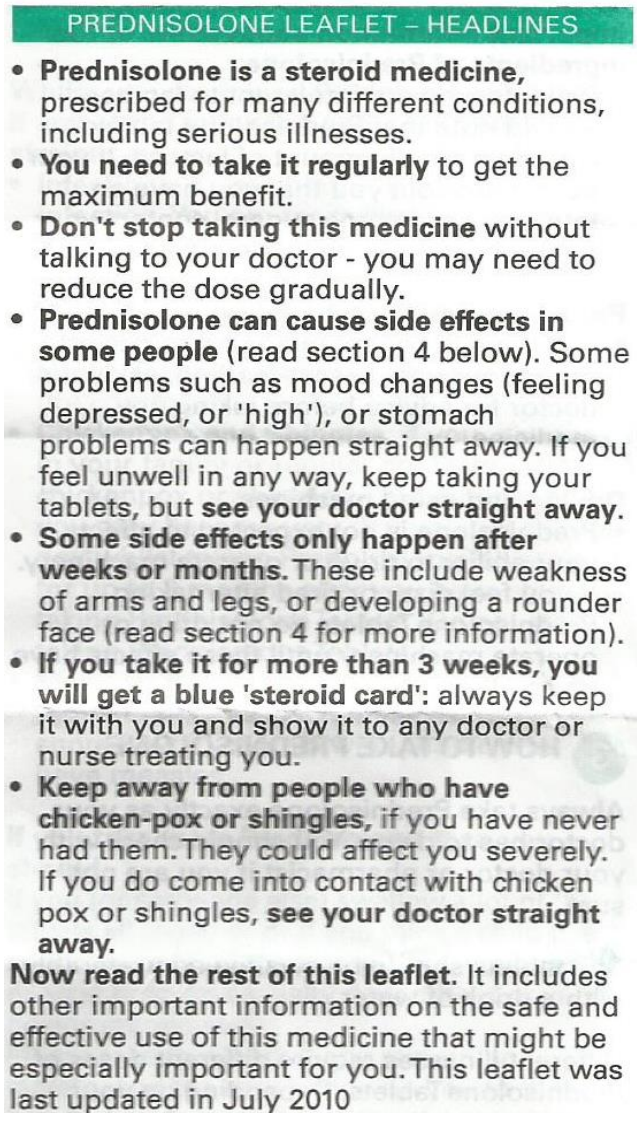
Research suggests that lower case letters are easier to read (Hartley, 1994), so manufacturers tend to avoid unnecessary capitals for important information and long headings. The use of lower-case letters had also been recommended by the European Commission in 1998.

Some of the headings are in bold to emphasize the information, however, there is not an exaggeration of the use of bold throughout the leaflets.

As for headlines, (mentioned in 1.8) which appear at the beginning of the PIL, straight after the bulleted introduction preamble that engages the consumer with the leaflet, only 1 PIL, Prednisolone, included this section. Headlines are still not very common (Prof. Raynor, 2012, in an email sent to me). They were recommended by the MHRA in 2005 to anticipate what was to be mentioned in the body of the leaflet. Research (Dolk, 2009: 15)

has shown that, on one hand, the readers' attention is drawn to the headline section due to the shaded box and its title 'Important things you need to know'. On the other hand, the risk of the inclusion of a headline may be inefficient for the patients who will just read the headline section and forget about the rest of the PIL. This means that they are still not fully aware of the risks and benefits of taking that particular medication.

The Prednisolone PIL, in this corpus, presented the headlines in a green shaded box followed by bullet points that summarise what is explained in detail in the body of the leaflet (*Fig. 4.3)*:



PREDNISOLONE LEAFLET – HEADLINES

- **Prednisolone is a steroid medicine,** prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor - you may need to reduce the dose gradually.
- **Prednisolone can cause side effects in some people** (read section 4 below). Some problems such as mood changes (feeling depressed, or 'high'), or stomach problems can happen straight away. If you feel unwell in any way, keep taking your tablets, but **see your doctor straight away.**
- **Some side effects only happen after weeks or months.** These include weakness of arms and legs, or developing a rounder face (read section 4 for more information).
- **If you take it for more than 3 weeks, you will get a blue 'steroid card':** always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chicken-pox or shingles,** if you have never had them. They could affect you severely. If you do come into contact with chicken pox or shingles, **see your doctor straight away.**

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you. This leaflet was last updated in July 2010

Fig. 4.3 Prednisolone PIL including headlines

4.5 Specialization of lexis

The draft "readability guideline" recommends using simple words with few syllables in order to make the leaflet understandable for people with poor reading skills and/or poor health literacy. In addition, the sentences should not contain more than 20 words and numerous subordinate clauses should be avoided. It may be assumed that these recommendations go back to the MHRA's publication of "Always read the leaflet" (2005) which details an evaluation for England and Wales stating that nearly half of all adults aged 16-65 were classified to have a skill level expected of 11 year olds. In a project work entitled Master of Drug Regulatory Affairs Dr Ursula Schickel, (2007) points out that:

> "A separate British survey came to the conclusion that highly educated patients do not mind if instructional materials are oversimplified for them. Actually, it is hard to believe that such a simple style and wording will be of benefit for the average of the potential patients and, even more important, will be accepted at all as patients might miss an adequate seriousness of the wording".
>
> (Schickel 2007: 82).

Dr Schickel also quotes Kenny *et al*.(1998), who found out that:

> "[…] a style which is too simple could sound patronizing and may lack interest and 'authority".… (2007: 89).

Although technical texts often do employ a wide range of specialized lexis, most of the 60 PILs analysed respond to the quotations mentioned above. Words and phrases were not very specialized and tried to suit the lay person's needs.

General terms were used for medical conditions, like 'high blood pressure', 'kidney and heart problems', 'swelling of the throat', etc. This is an interesting trend as it works against the precision sought after in medical

texts but makes sense from a patient's perspective as it provides the patient with the level of precision and information he/she needs for taking action. Furthermore, if there is a need for introducing an exact medical term, the medical term is put in brackets after the lay explanation, or vice-versa, the lay term is explained in brackets. See examples:

Examples 1

- Swelling of the face, lips or throat which make it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction to Ramipril Capsules
- Severe skin reactions including rash, ulcers in your mouth, worsening of a pre-existing skin disease, reddening, blistering or detachment of skin (such as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiform).

Or

...if you suffer from indigestion (dyspepsia) (*Aspirin Gastro-Resistant*)

Do not take *Propranolol* if you: are allergic (hypersensitive).

A chemical called uric acid (urate) (*Adenuric*)

....diuretics ('water tablets')

....euphoria ('feeling high') (*Prednisolone*)

....Palpitations (feeling your heart beat), fast or irregular heart beat, or low blood pressure (you may feel faint) (*Piriton Allergy Tablets*)

If you have a blocked bowel (intestinal obstruction) (*Dulcolax*)

(View the above PILs in the index section)

In the following extract taken from the Metoprolol Tartrate PIL, there is a significant example of specialised words and their lay explanation inside or outside brackets (see example on next page):

Example 2

Taking other medicines

Do not take Metoprolol Tartrate tablets if you are already taking:

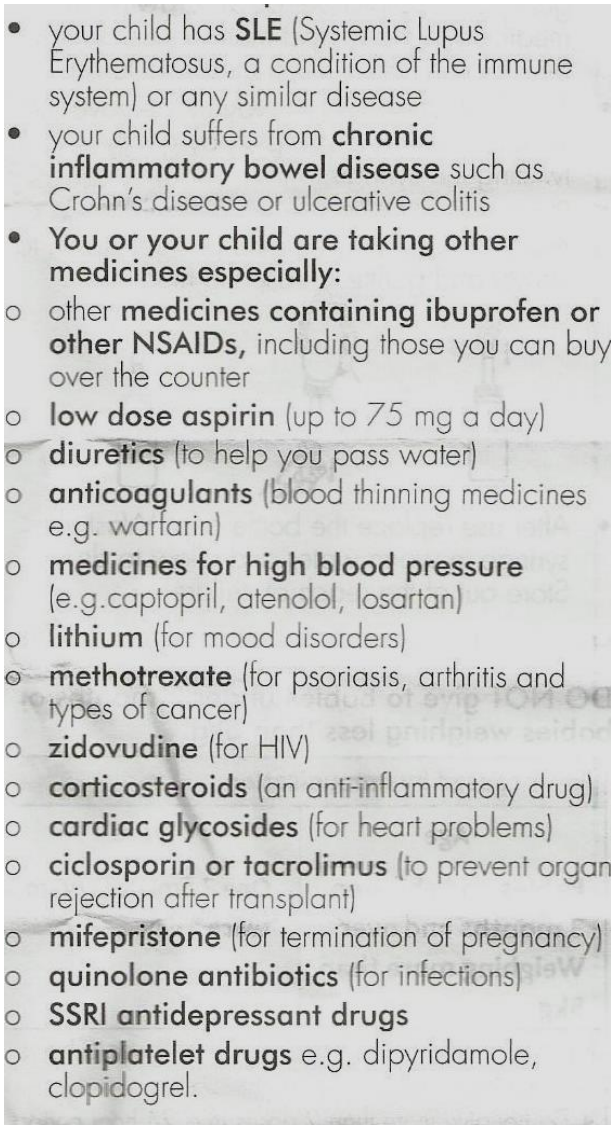
- **monoamine oxidase inhibitors** (MAOIs) for depression
- other **blood pressure lowering** medicines such as verapamil, nifedipine and diltiazem
- **disopyramide** or **quinidine** (to treat irregular heartbeat (arrhythmia)

Before taking Metoprolol Tartrate tablets, **tell your doctor if you are taking or have taken recently any of the following medicines** or are taking any non prescribed medicines:

- **cimetidine** (to treat stomach ulcers)
- **hydralazine, clonidine** or **prazosin** (to treat high blood pressure)
- **amiodarone** and **propafenone** (for irregular heart rhythm)
- **tricyclic antidepressants** (to treat depression)
- **barbiturates** (to treat epilepsy)
- **phenothiazines** (for mental illness)
- **anaesthetics** such as cyclopropane or trichloroethylene
- **aldesleukin** (to treat some cancers, particularly cancer of the kidney)
- **alprostadil** (to treat erectile dysfunction)
- **anxiolytics** or **hypnotics** (e.g. temazepam, nitrazepam, diazepam)
- **indometacin** (Non-Steroidal Anti-Inflammatory Drug (NSAID))
- **rifampicin** (antibiotics)
- **cocaine**
- **oestrogens** such as a contraceptive pill or hormone replacement therapy
- **corticosteroids** (e.g. hydrocortisone, prednisolone)
- other **beta-blockers** e.g. eye drops.
- **adrenaline** (epinephrine, used in anaphylactic shock) or other **sympathomimetics**
- medicines used to treat **diabetes**
- **lidocaine** (a local anaesthetic)
- **moxisylyte** (used in Raynaud's syndrome)
- **mefloquine** (to treat malaria)
- **tropisetron** (to prevent nausea and vomiting)
- **xanthines** such as aminophylline or theophylline (to treat asthma)
- medicines to treat **migranes** such as ergotamine
- **cardiac glycosides** e.g. digoxin (to treat heart conditions).

Another PIL that contained many specialized terms and their explanations was the Nurofen for Children, especially in the section concerning : *What Nurofen for Children 3 months to 9 years Strawberry is* and *what it is used for*, e.g.: diuretics, lithium, anticoagulants:

Example 3



- your child has **SLE** (Systemic Lupus Erythematosus, a condition of the immune system) or any similar disease
- your child suffers from **chronic inflammatory bowel disease** such as Crohn's disease or ulcerative colitis
- **You or your child are taking other medicines especially:**
  - other **medicines containing ibuprofen or other NSAIDs,** including those you can buy over the counter
  - **low dose aspirin** (up to 75 mg a day)
  - **diuretics** (to help you pass water)
  - **anticoagulants** (blood thinning medicines e.g. warfarin)
  - **medicines for high blood pressure** (e.g.captopril, atenolol, losartan)
  - **lithium** (for mood disorders)
  - **methotrexate** (for psoriasis, arthritis and types of cancer)
  - **zidovudine** (for HIV)
  - **corticosteroids** (an anti-inflammatory drug)
  - **cardiac glycosides** (for heart problems)
  - **ciclosporin or tacrolimus** (to prevent organ rejection after transplant)
  - **mifepristone** (for termination of pregnancy)
  - **quinolone antibiotics** (for infections)
  - **SSRI antidepressant drugs**
  - **antiplatelet drugs** e.g. dipyridamole, clopidogrel.

(Nurofen for children)

From the examples given, it is clear that, the lexically difficult words are not isolated but embedded in an understandable context.

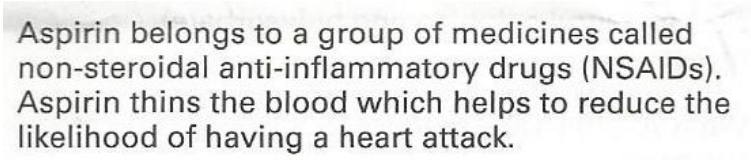
4.6 Lexical density

The lexical density (average number of content words per clause) was carried out to determine how much conceptual load was identifiable. This was of interest given the particular combination of the relatively informal nature of the channel (a medical leaflet), the potential seriousness of the information for the patient, and the intricacies of the expert-lay relationship. Results showed that the majority of the PILs fell in the upper end of the scale, that is, away from the 'spoken-like' end of the continuum and toward the academic end (Halliday, 1985) (see examples). However there also seems to be a relationship between the move at the genre level and lexical density, because the analyses was carried out on the section that describes the background of the medicine, *What X is and what it is used for,* which is lexically dense. In the following examples of the corpus, the clauses have been copied and the lexical items are given in italics.

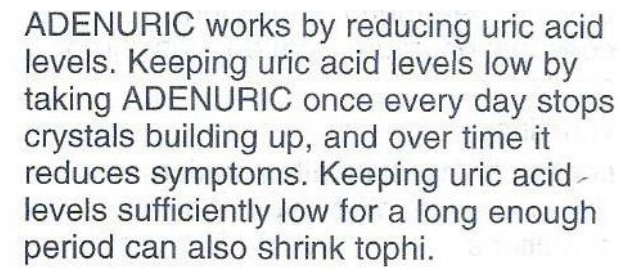
Examples

> Alendronic acid belongs to a group of non-hormonal medicines called bisphosphonates. Alendronic acid prevents the loss of bone that occurs in women after they have been through the menopause, and helps to rebuild bone. Alendronic acid reduces the risk of spine and hip fractures.

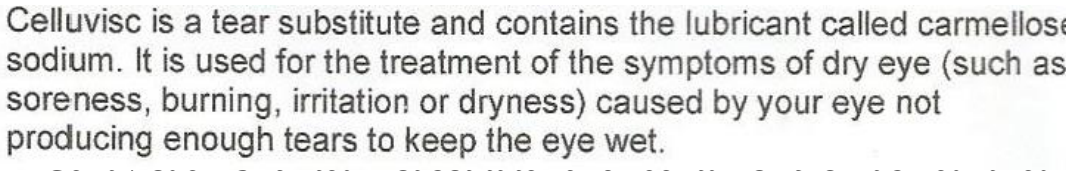
Alendronic acid belongs to a *group* of *non-hormonal medicines called bisphosphonates. Alendronic acid prevents* the *loss* of *bone* that *occurs* in *women* after they have been through the *menopause,* and *helps* to *rebuild bone. Alendronic acid reduces* the *risk* of *spine* and *hip fractures.*


Aspirin belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Aspirin thins the blood which helps to reduce the likelihood of having a heart attack.

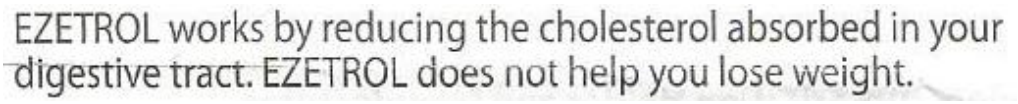
Aspirin Tablets are *used* to *reduce* the *likelihood* of *further heart attacks* or *strokes* in *patients* with a *previous history* of these *conditions,* when *taken regularly*.


ADENURIC works by reducing uric acid levels. Keeping uric acid levels low by taking ADENURIC once every day stops crystals building up, and over time it reduces symptoms. Keeping uric acid levels sufficiently low for a long enough period can also shrink tophi.

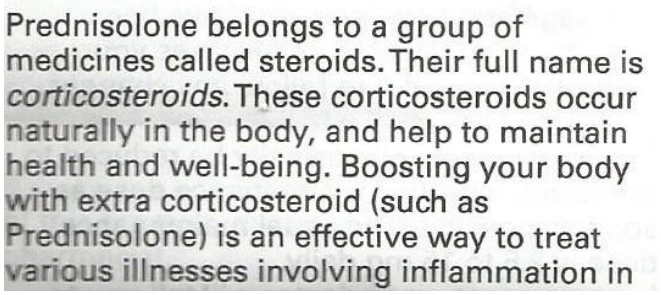
Adenuric works by *reducing uric acid levels. Keeping uric levels low* by *taking ADENURIC* once every *day stops crystals building* up, and *over time* it *reduces symptoms. Keeping uric acid levels sufficiently low* for a *long* enough *period can* also *shrink tophi.*


Celluvisc is a tear substitute and contains the lubricant called carmellose sodium. It is used for the treatment of the symptoms of dry eye (such as soreness, burning, irritation or dryness) caused by your eye not producing enough tears to keep the eye wet.

ed carmellose sodium. It is *used* for the *treatment* of the *symptoms* of *dry eye (*such as *soreness, burning, irritation* or *dryness) caused* by *your eye* not *producing* enough *tears t*o *keep* the *eye wet.*


EZETROL works by reducing the cholesterol absorbed in your digestive tract. EZETROL does not help you lose weight.

EZETROL works by *reducing* the *cholesterol absorbed* in your *digestive tract*. *Ezetro*l does not *help* you *lose weight*.



Prednisolone belongs to a group of medicines called steroids. Their full name is *corticosteroids*. These corticosteroids occur naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroid (such as Prednisolone) is an effective way to treat various illnesses involving inflammation in

Prednisolone belongs to a *group* of *medicines called steroids*. Their *full name* is *corticosteroids.* These *corticosteroids occur naturally* in the *body*, and *help* to *maintain health* and *well-being. Boosting* your *body* with *extra corticosteroid (*such as *Prednisolone)* is an *effective way* to *treat various illnesses involving inflammation in….*

We notice an occurrence of 5/6 lexical items per clause. The findings showed that about half of the PILs carried from 5 to 7 and half from about 7 to 9. If we consider the average number of content words per clause estimated by Halliday, (1996), between 3 and 5, 50% of these PILs are quite near, whereas the others are slightly away. The longer sentences do, in fact, contain more content words, on average from 7 to 9, as in the examples above. However although they may seem to carry a more academic-like language, the message conveyed is not very difficult compared to previous style and language of PILs.

4.7 Format

Document design issues such as layout, font size and style, and use of visual material are considered to have an important impact upon patients' capacity to comprehend patient information leaflets (Schriver, 1997; Hartley, 1994, 1999).

In written texts, emphasis is not only the counterpart of stress in speech; it also serves as a navigational aid. For instance, if important

warnings are presented in bold face, they can be found at a glance, even if they appear in an inaccessible location such as the middle of a paragraph. As in the case of indented lists, this benefit depends on using the device sparingly: if each page has dozens of emphasized phrases, the warning becomes a needle in a haystack. At an absurd extreme one might imagine an author emphasizing the whole text on the grounds that every word is of vital importance. Emphasizing an entire leaflet by formatting it in capital letters, for example would create a drawback because the reader would not be able to distinguish degrees of importance, and there would also be an unpleasant tone, just like a feeling of being shouted at.

Therefore the design and layout of the information is crucial in helping patients to find and understand the important messages for safe use within the PIL. As stated in Chapter One, leaflets undergo user-testing trials, hence, before submitting a leaflet, manufacturers are asked to review the way in which the information is set out within the document and to take account of 'best practice' to comply with the new article 59 of Council Directive 2001/83/EC, and with the revised guidelines of the MHRA.

As required by the recent PIL guidance (2012) manufacturers need to follow a common design and layout which include the following important aspects:

- Font style and font size:

> "Typography can be defined as designing with type in order to communicate a message. The typeface used and other elements of graphic design such as colour of text need to be chosen with the audience in mind. When used well these aspects organise and communicate the information in a way which meets the needs of the reader. No matter how well written the text is in the PIL if it is set out in a typography which is difficult to read it is unlikely that patients will take the time or be encouraged to read it".
>
> (PIL Guidance 07/12 final p. 6).

- Headings and sub-headings including consistency of placement
- PIL dimensions including whether the document is laid out in portrait or landscape format and number of columns
- Use of colour and choice of colour
- Style of writing and language used
- Layout of critical safety sections of the PIL
- Use of pictograms

And, some of the key points that manufacturers must note which help patients to navigate the information are:

- headings must be placed consistently and stand out by using either a larger font or by emboldening the text;
- judicious use of colour can help but it must not make a contrast;
- patients like an index, so this is very important if a booklet format is being used which is known to be more difficult to navigate.
- The text size used should be as large as possible and there should be a good use of white space. Dense text means patients lose concentration and therefore cannot find the information required.
- Long lists of side effects are frightening and short bullet points have been found to be helpful. The side effects should be grouped according to seriousness and allow patients to immediately distinguish when to take urgent action.
- Related information should be located together and not split over different columns or sides of the leaflet.
- Information should not be repeated as this is known to confuse.
- Information which appears before the index or in a box is overlooked by patients so these devices should not be used.

The PILs analysed presented several designs, however the order of information was quite standard. All 60 were printed on single sheets but with different dimensions. 25 had a portrait format and the rest had a landscape model, (see *Figures 4.4; 4.5*). Most of them were folded in a Z shape, except for 3 which were A4 sheets double-folded. None of the leaflets were transparent, nor used glossy paper which is known to make readability more difficult (Guideline 2001).

The readability guideline recommends dark text to be contrasted against a light background as a general rule, in rare occasions the opposite may be adequate to highlight particular warnings. Different colours may be used for displaying headings or important information clearly and easily recognisable, whereas red colour print should be reserved for very important warnings only.

Colour is both a way of emphasising a message and of communicating in an emotional manner in a presumably universally way. Since it has been criticised that the information in package leaflets is often understandable but hard to find, associating certain sections of a package leaflet with corresponding colours might be of benefit to improve their readability (Schickel, 2007).

The colour in the 60 PILs studied was mainly black on white paper, however 8 used light blue on white paper: Adenuric, Aspirin Enteric Tablets, BuTrans, Istin, Losartan Potassium, Multaq, Phenergan, Tritace and Voltarol; 1, Benadryl, used dark blue and light green, and Benylin, used violet and red (see PILs in the index section).

As for the names of the medication in the headings,1, Zoton, had a dark brown shaded box with white writing; 2, Co-Codamol and Flecainide Acetate, had white writing in a dark grey shaded box; 1, Nystatin used

black on light grey; 3, BuTrans, Coaprovel and Istin; had blue writing in a light blue shaded box. Lipitor and Lecaniside were the only PILs to use red colour print for the headings and for the illustrated symbols, (important information) and white print on a red background for the numbered sections. There was no contrast between the colours, therefore the background was clearly distinguished.

White space inside the text was used quite appropriately according to the guidelines:

> **"**White space within the written text is helpful in creating a feeling of openness about the information being presented"
> (PIL Guidance 07/12 final p. 7).

As for the use of columns and spacing, the PIL Guidance states:

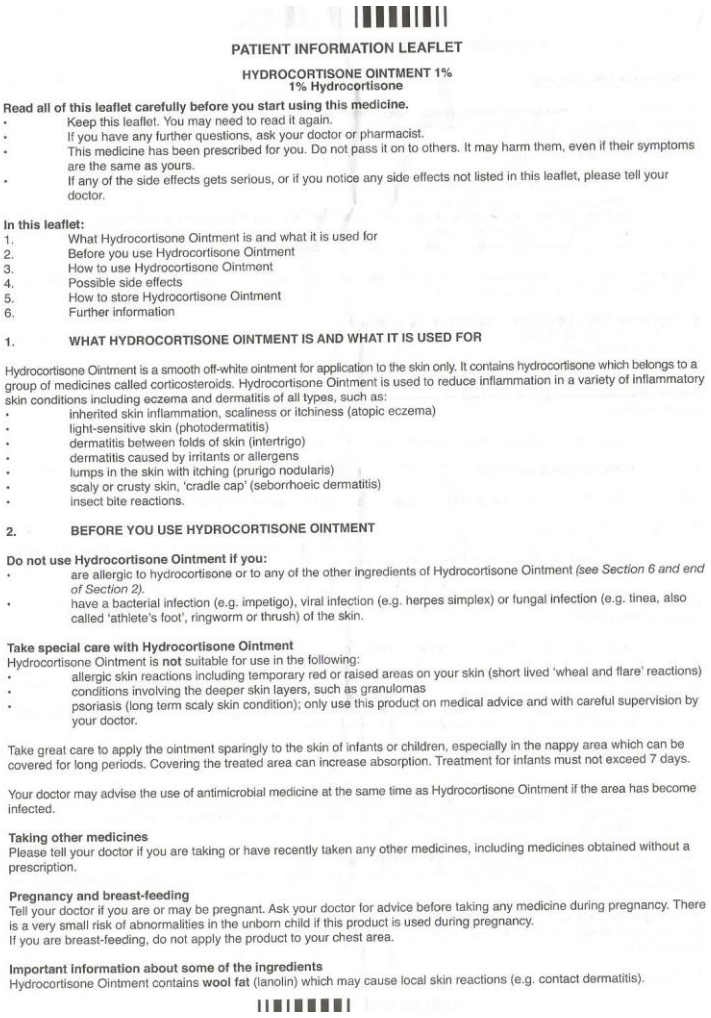
> "The use of columns which are familiar to most readers through newsprint help readers to easily assimilate information. Line length and line spacing are important aspects of design and should be taken into account when deciding on an appropriate layout".
> (PIL Guidance 07/12 final p. 7)

The PILs in this study showed to prefer a column format which is found to help the reader navigate the information. It is thought (User-testing, Raynor 2009) that patients feel more comfortable with landscape layout as opposed to portrait format, especially when printing the heading over the entire breadth as this resembles the typical appearance of newspapers. 25 PILs used a single-column diagram, that is the portrait layout (e.g. Clopidogrel, Lisinopril, Simvastin, Losartan Potassium, Zofran), the rest were in the landscape format. The division of the columns was as follows: 20 had a double-column (e.g. Adenuric, Buscopan, Dulcolax, Omeprazole, Naproxen, Temazepam); 2 had three-columns (Alendronic, Benadryl and Benylin); 6 had four-columns (Citalopram, Lipitor, Phenergan, Ramipril, Tritace and Warfarin); 2 had five-columns

(Avodart and Liquifilm Tears); 1 PIL had six columns (Coaprovel); 2 had a seven- column diagram (Lamictal and Premique); and 1 PIL presented 11 columns (BuTrans).

Separation between columns seemed adequate as it ranged from 4 to 6mm, and there were margins in all of them. The amount of white space between the lines was from 1mm to 4mm according to the font type size. This more or less complies with the readability guideline details that recommends to keep the line spaces clear and that the space between one line and the next should be at least 1.5 times the space between words on a line.

On the following pages there is an example of a portrait model (Hydrocortisone Ointment), and a landscape model (Avodart):



PATIENT INFORMATION LEAFLET

HYDROCORTISONE OINTMENT 1%
1% Hydrocortisone

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:
1. What Hydrocortisone Ointment is and what it is used for
2. Before you use Hydrocortisone Ointment
3. How to use Hydrocortisone Ointment
4. Possible side effects
5. How to store Hydrocortisone Ointment
6. Further information

1. WHAT HYDROCORTISONE OINTMENT IS AND WHAT IT IS USED FOR

Hydrocortisone Ointment is a smooth off-white ointment for application to the skin only. It contains hydrocortisone which belongs to a group of medicines called corticosteroids. Hydrocortisone Ointment is used to reduce inflammation in a variety of inflammatory skin conditions including eczema and dermatitis of all types, such as:
- inherited skin inflammation, scaliness or itchiness (atopic eczema)
- light-sensitive skin (photodermatitis)
- dermatitis between folds of skin (intertrigo)
- dermatitis caused by irritants or allergens
- lumps in the skin with itching (prurigo nodularis)
- scaly or crusty skin, 'cradle cap' (seborrhoeic dermatitis)
- insect bite reactions.

2. BEFORE YOU USE HYDROCORTISONE OINTMENT

Do not use Hydrocortisone Ointment if you:
- are allergic to hydrocortisone or to any of the other ingredients of Hydrocortisone Ointment *(see Section 6 and end of Section 2).*
- have a bacterial infection (e.g. impetigo), viral infection (e.g. herpes simplex) or fungal infection (e.g. tinea, also called 'athlete's foot', ringworm or thrush) of the skin.

Take special care with Hydrocortisone Ointment
Hydrocortisone Ointment is **not** suitable for use in the following:
- allergic skin reactions including temporary red or raised areas on your skin (short lived 'wheal and flare' reactions)
- conditions involving the deeper skin layers, such as granulomas
- psoriasis (long term scaly skin condition); only use this product on medical advice and with careful supervision by your doctor.

Take great care to apply the ointment sparingly to the skin of infants or children, especially in the nappy area which can be covered for long periods. Covering the treated area can increase absorption. Treatment for infants must not exceed 7 days.

Your doctor may advise the use of antimicrobial medicine at the same time as Hydrocortisone Ointment if the area has become infected.

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
Tell your doctor if you are or may be pregnant. Ask your doctor for advice before taking any medicine during pregnancy. There is a very small risk of abnormalities in the unborn child if this product is used during pregnancy.
If you are breast-feeding, do not apply the product to your chest area.

Important information about some of the ingredients
Hydrocortisone Ointment contains **wool fat** (lanolin) which may cause local skin reactions (e.g. contact dermatitis).

Fig. 4.4 Portrait model of PIL

Avodart®
0.5 mg soft capsules
dutasteride

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- **If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

In this leaflet:

1 What Avodart is and what it's used for

Avodart is used to treat men with an enlarged prostate *(benign prostatic hyperplasia)* - a non-cancerous growth of the prostate gland, caused by producing too much of a hormone called dihydrotestosterone.

The active ingredient is dutasteride. It belongs to a group of medicines called 5-alpha reductase inhibitors.

As the prostate grows, it can lead to urinary problems, such as difficulty in passing urine and a need to go to the toilet frequently. It can also cause the flow of the urine to be slower and less forceful. If left untreated, there is a risk that your urine flow will be completely blocked *(acute urinary retention)*. This requires immediate medical treatment. In some situations surgery is necessary to remove or reduce the size of the prostate gland. Avodart lowers the production of dihydrotestosterone, which helps to shrink the prostate and relieve the symptoms. This will reduce the risk of acute urinary retention and the need for surgery.

Avodart may also be used with another medicine called tamsulosin (used to treat the symptoms of an enlarged prostate).

2 Before you take Avodart

Do not take Avodart
- **if you're allergic** *(hypersensitive)* **to dutasteride** or to any of the other ingredients of Avodart
- **if you're allergic to other 5-alpha reductase inhibitors**
- **if you have a severe liver disease.**

→ **Tell your doctor** if you think any of these apply to you.

This medicine is for men only. It must not be taken by women, children or adolescents.

Take special care with Avodart
- **Make sure your doctor knows about liver problems.** If you have had any illness affecting your liver, you may need some additional check-ups while you are taking Avodart.
- **Women, children and adolescents** must not handle leaking Avodart capsules, because the active ingredient can be absorbed through the skin. **Wash the affected area immediately** with soap and water if there is any contact with the skin.
- **Use a condom during sexual intercourse.** Dutasteride has been found in the semen of men taking Avodart. If your partner is or may be pregnant, you must avoid exposing her to your semen as dutasteride may affect the normal development of a male baby. Dutasteride has been shown to decrease sperm count, semen volume and sperm motility. This could reduce your fertility.
- **Avodart can affect a blood test for PSA** (prostate-specific antigen), which is sometimes used to detect prostate cancer. Your doctor should be aware of this effect and can still use the test to detect prostate cancer. If you are having a blood test for PSA, tell your doctor that you are taking Avodart.

→ **Contact your doctor or pharmacist** if you have any questions about taking Avodart.

Taking other medicines
Tell your doctor if you're taking, or have recently taken, any other medicines. This includes any medicines you've bought without a prescription. Some medicines can react with Avodart and may make it more likely that you'll have side-effects. These medicines include:
- **verapamil or diltiazem** (for high blood pressure)
- **ritonavir or indinavir** (for HIV)
- **itraconazole or ketaconazole** (for fungal infections)
- **nefazodone** (an antidepressant)
- **alpha-blockers** (for enlarged prostate or high blood pressure).

→ Tell your doctor if you are taking any of these medicines. Your dose of Avodart may need to be reduced.

Food and drink with Avodart
Avodart can be taken with or without food.

Pregnancy and breast-feeding
Women who are pregnant (or may must not handle leaking capsules. Dutasteride is absorbed through th skin and can affect the normal development of a male baby. This i particular risk in the first 16 weeks pregnancy.

Use a condom during sexual intercourse. Dutasteride has been found in the semen of men taking Avodart. If your partner is or may t pregnant, you must avoid exposing to your semen.

Avodart has been shown to reduce sperm count, semen volume and sp movement. Therefore male fertility may be reduced.

→ **Contact your doctor** for advice if pregnant woman has come into contact with dutasteride.

Driving and using machines
Avodart is unlikely to affect your al to drive or operate machinery.

TURN

11

Fig 4.5 Landscape model of PIL

As far as typography is concerned, the MHRA states that:

> "Typography can be defined as designing with type in order to communicate a message. The typeface used and other elements of graphic design such as colour of text need to be chosen with the audience in mind. When used well these aspects organise and communicate the information in a way which meets the needs of the reader. No matter how well written the text is in the PIL if it is set out in a typography which is difficult to read it is unlikely that patients will take the time or be encouraged to read it".
>
> (PIL Guidance 07/12 final p. 6).

The type size varied in the PILs , about 4 had point- type as large as 14 (Adenuric, Premique, Zoton, Zofran), the others ranged from 9 to 12 , but, 4 PILs (Atarax, Benadryl, Benylin and Voltarol) presented an 8 point type. A font size of 12 point is desirable, however, it is not practical with regard to the amount of information that has to be included in a package leaflet. Readability is also dependent on the amount and size of paper the patient has to handle and especially when he/she needs to unfold and refold the PIL for placing it back in the respective packet.

The readability guideline recommends to use an 8 point font size, for the main body of the text and where practical, a larger font size for headings, e.g. 12 and 14 points. For visually impaired patients the preferred font size should even be between 16 and 20. Italic fonts and underlining are not very frequent in the PILs. There is also a minimum use of capital letters and this is because the human eye recognizes words in written documents by the word shape, so large lower case text is preferred in large blocks of text.

Most of the PILs analysed comply with the guideline as they have larger font size than 8. However manufacturers are making the font size

slightly bigger bearing in mind the difficulties for certain age groups like older patients or those with eyesight problems.

The information was split up into modules, meaning that the information is transferred into relevant questions of the user, thus, formulating the information from the perspective of the user. Risk information described as procedural information was in longer or shorter lists and bullet points according to the seriousness of the disease. For example, Propranolol (a beta-blocker for the heart) had 19 bullet points for side effects, while Celluvisc eye drops only had 2. None of the PILs had repetition of side effects or other information.

The style in most of the PILs met the National Health Service (NHS) guidelines (2007) and the MHRA guidelines (2005, 2012). The sentences were not very long (from about 15 to 20 words). Lower-case letters were used more where possible. The question and answer format divided the text into blocks, quite small blocks, or modules as mentioned before. The bullet or numbered points divided up complicated information and began with the uncommon and specific case and ended with the common or general case, unless this is inappropriate for the product.

Example

Tell your doctor if you are suffering from

- pulmonary tuberculosis
- any allergies that affect your lungs
- any chronic lung condition.

As required by the Guideline a minimum number of words were used in the bullet points and never more than one sentence. There were no more

than nine items where the bullet points were simple and no more than five when they were complex. Abbreviations were avoided.
Large bold font was used when emphasizing the text excluding upper case letters, italics and underlining. Underlining was not used at all.

4.7.1 The use of pictograms

Article 62 of Directive 2001/83/EC, as amended, also permits the use of images, pictograms and other graphics to improve comprehension except for elements of promotional nature. As detailed in the readability guideline the use of pictograms, symbols and graphics tends to be misleading and confusing due to cultural differences although it is judged as a very helpful tool for improving readability of package information leaflets.

A pictogram is a stylized figurative drawing that is used to convey information of an analogical or figurative nature directly to indicate an object or to express an idea. Pictograms can fulfill many functions. They are used to replace written indications and instructions expressing regulatory, mandatory, warning and prohibitory information, when that information must be processed quickly (e.g. road traffic signs), when users speak different languages (i.e. non-natives), have limited linguistic ability (e.g. people with low levels of literacy or little education), or have visual problems (e.g. older people), and especially when there is a legal obligation to inform, and for the user to comply with, mainly for safety purposes (e.g. use of dangerous materials at work). A pictogram needs to capture users' attention (users need to *see* the pictogram), to improve users' comprehension of warnings (users need to *attend to* it), and it also needs to increase their awareness of risk, generally by serving as an "instantaneous memorandum" of a risk (Otsubo, 1988: 540).

As reported by Tijus *et al*., (2005) cited in Schickel, 2007: 90). there are a number of recognized advantages of pictograms in the literature. First of all, they have the potential to be interpreted more accurately and more quickly than words. Thus, they can serve as "instant reminders" of a hazard or an established message. They improve understanding of warnings for those with visual or literacy difficulties. They can make warnings more noticeable or "attention grabbing", and they can improve their legibility. Pictograms are more easily processed at a distance compared to textual information.

However, there are also a number of disadvantages to relying on pictograms. Firstly, the potential for significant confusion (interpreting the opposite or often inappropriate meaning), can create an additional safety hazard, (Tijus *et al*., 2005, in Schickel, 2007, 91). Not many pictograms are universally understood, hence, they may not be interpreted correctly by all groups of consumers and across all cultures. For example a slashed belly of a pregnant woman was misinterpreted as avoiding pregnancy as opposed to its intended meaning, i.e. "do not use the medicinal product during pregnancy" (*ibid*., 91). Nevertheless, it is deemed that possibilities remain to create pictograms and symbols especially with regard to the preparation and administration of different dosage forms. One example could be the correct demonstration of dissolving a dry powder of an antibiotic preparation with water, its storage and its processing immediately prior to administration including details on the time intervals for application, as it is a medicinal preparation which is widely used especially in paediatric populations.

The same would be easily applicable for displaying certain storage conditions with regard to temperature control. Next, it always takes many years for any pictogram to reach maximum effectiveness.

In order to be adopted, a pictogram must reach a certain level of effectiveness, especially when the information to be conveyed concerns safety. The method of testing the comprehension and effectiveness of pictograms used in ISO 9186 (Public Information Signs) relies on judges choosing from a number of response categories: correct understanding of the symbol is certain; correct understanding of the symbol is likely; correct understanding of the symbol is fairly likely; the meaning conveyed is the opposite to that intended; incorrect response given; 'don't know' response given; no response given (Tijus *et al*., 2005 cited in Schickel, 2007: 93). Pictograms are quite common in patient information leaflets and are intended to provide full and comprehensible information about the medicine. A study conducted by Dowse and Ehlers (2005) demonstrated that even when instructions were written in a straightforward language, there were still unacceptable degree of misunderstanding health care professionals and this is made worse when dealing with low-literacy patients. So one way of helping these patients is to incorporate visual aids such as pictograms.

They are of benefit to the comprehension and recall of prescription instructions, and participants who are given "natural language plus pictogram" labels understand information better than participants with only "natural language labels" (Dowse and Ehlers, 1998, 2003). In order to evaluate the effects of pictograms in patient information leaflets, Bernardini and his collaborators (2000) interviewed 1004 patients in pharmacies and reported that participants usually read the patient information leaflet but they neither understood it easily nor found the required information readily. However, most participants (74.3%) considered the use of symbols helpful in finding the required information. They analyzed to what extent five symbols could be used for each of five

topics, and found consistent responses for “side effects”", “pediatric use”, “use in pregnancy” and “dosage”, but not for “therapeutic indications” and “contraindications”.

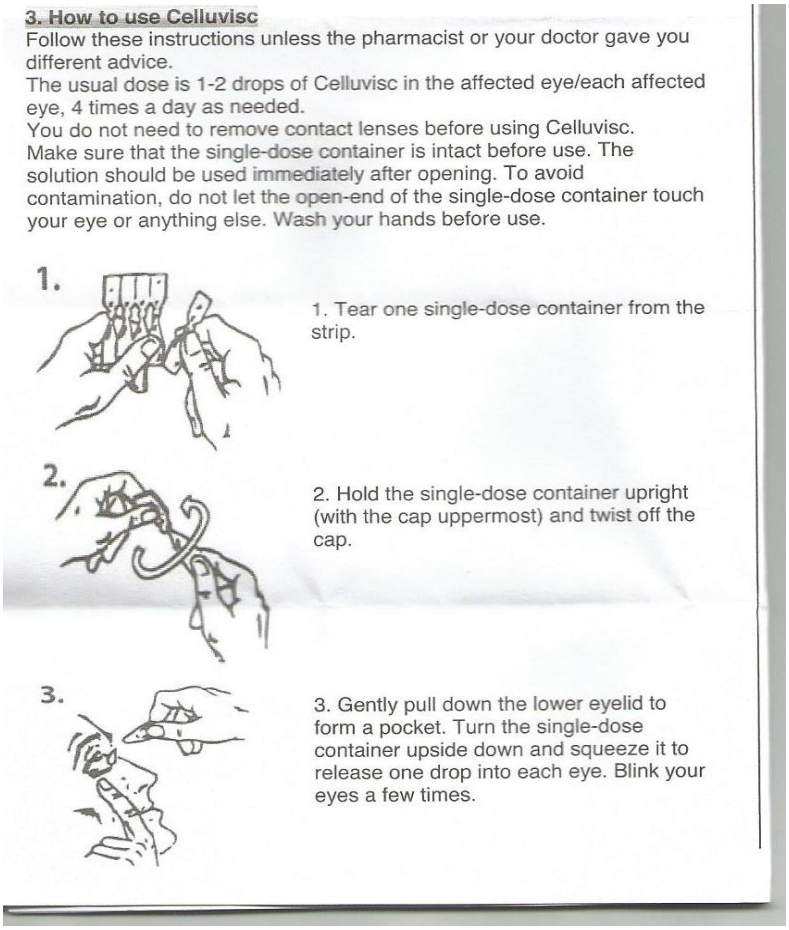
There have, however, also been negative responses to the use of pictures because some research has not supported the hypothesis that pictograms are beneficial for the acquisition and comprehension of information. Such discrepancies may be not related to education, but to familiarity and context. Dowse and Ehlers (2003) collected demographic data together with information on literacy skills for participants and asked them to interpret 46 pictograms. Results showed that there was misinterpretation across all educational groups. Another research carried out by Knapp, Raynor, Jebar and Price (2005), who examined the effects of repeat presentation of pictograms on understandability, found great variability in rate of correct interpretation (8 to 90%) and that only three of the ten different instruction and warning pictograms were understood by at least 85% of the population. After providing their interpretation, participants were informed of the correct meaning and then the experimental trials were repeated a week later. Results showed that participants performed significantly better at the second presentation of pictograms.

According to the European Commission Guideline (1998), symbols and pictograms can be used to deliver information provided that the symbol is clear and the graphic is understandable. However, pictograms must not be used as the only source of communication as seen before, because they may convey inadequate details for proper understanding of the medical leaflets (Dowse and Ehlers, 2005). The European Commission (1998) also stated that pictograms should not replace the actual text, but only be used to assist navigation, elucidate or emphasize certain aspects of the text. The health

care providers must also give guidance and verbal reinforcement to the patients when they are using the medical leaflets (Dowse and Ehlers, 2005). Pictograms are especially useful when delivering information such as dosing schedule, indication of the drug, side effects, instructions of administration and the importance of finishing the medications (Bernardini *et al.*, 2000).

About 8 of the PILs studied contained pictograms: especially the eye drop medications: Celluvisc, Xalatan the inhaler, the thermal patches, the Nurofen PIL for children, (see examples):

Examples



3. How to use Celluvisc

Follow these instructions unless the pharmacist or your doctor gave you different advice.
The usual dose is 1-2 drops of Celluvisc in the affected eye/each affected eye, 4 times a day as needed.
You do not need to remove contact lenses before using Celluvisc.
Make sure that the single-dose container is intact before use. The solution should be used immediately after opening. To avoid contamination, do not let the open-end of the single-dose container touch your eye or anything else. Wash your hands before use.

1.

1. Tear one single-dose container from the strip.

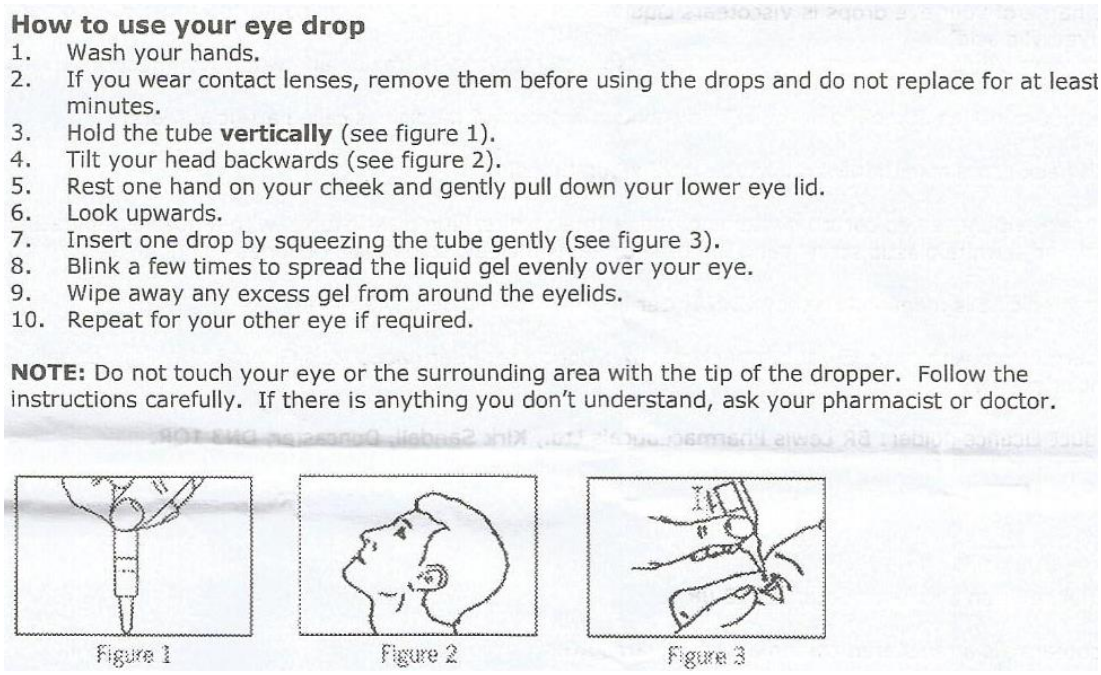
2.

2. Hold the single-dose container upright (with the cap uppermost) and twist off the cap.

3.

3. Gently pull down the lower eyelid to form a pocket. Turn the single-dose container upside down and squeeze it to release one drop into each eye. Blink your eyes a few times.

(Celluvisc eye drops)



How to use your eye drop

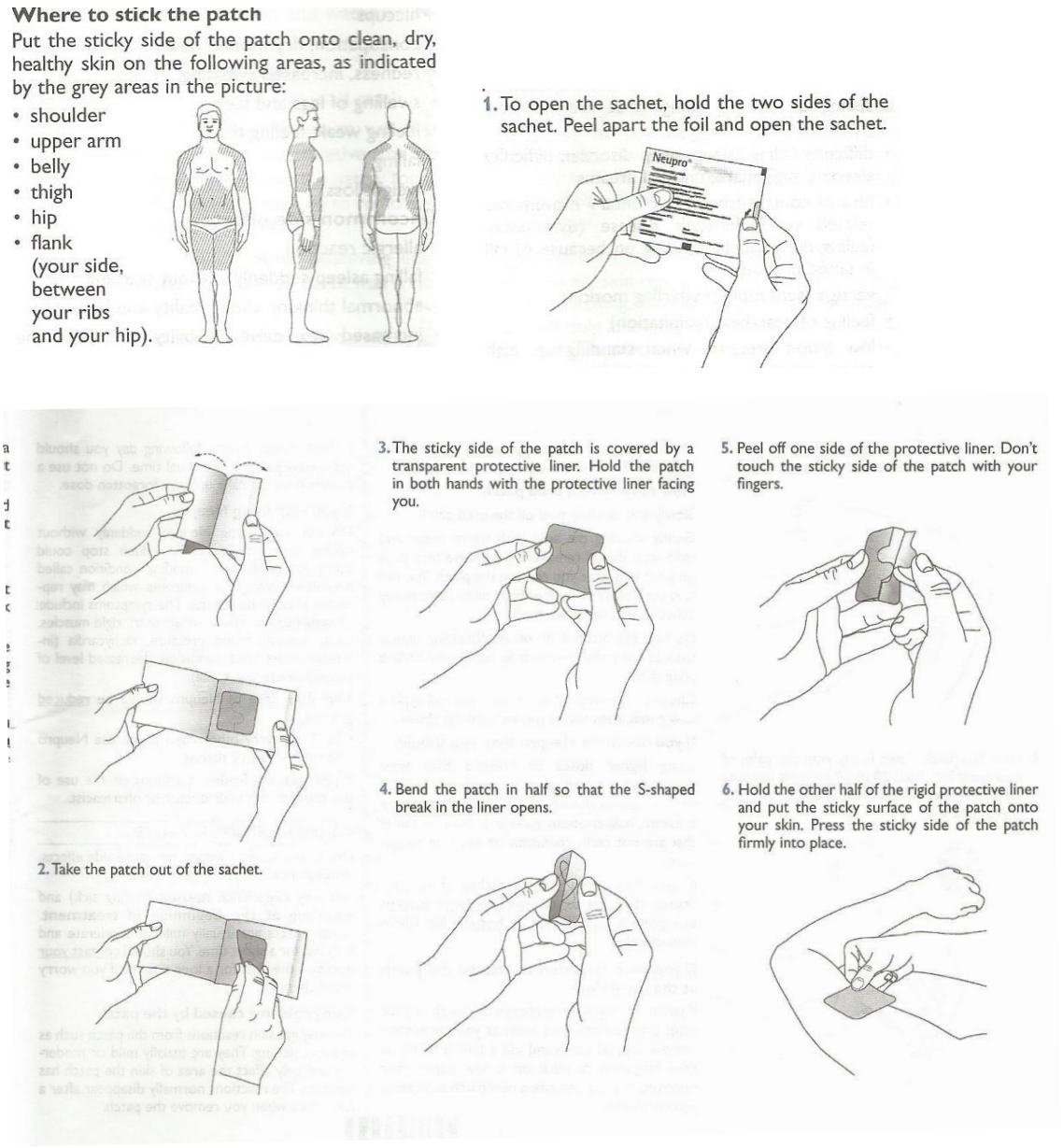
1. Wash your hands.
2. If you wear contact lenses, remove them before using the drops and do not replace for at least minutes.
3. Hold the tube **vertically** (see figure 1).
4. Tilt your head backwards (see figure 2).
5. Rest one hand on your cheek and gently pull down your lower eye lid.
6. Look upwards.
7. Insert one drop by squeezing the tube gently (see figure 3).
8. Blink a few times to spread the liquid gel evenly over your eye.
9. Wipe away any excess gel from around the eyelids.
10. Repeat for your other eye if required.

NOTE: Do not touch your eye or the surrounding area with the tip of the dropper. Follow the instructions carefully. If there is anything you don't understand, ask your pharmacist or doctor.

(Viscotears)

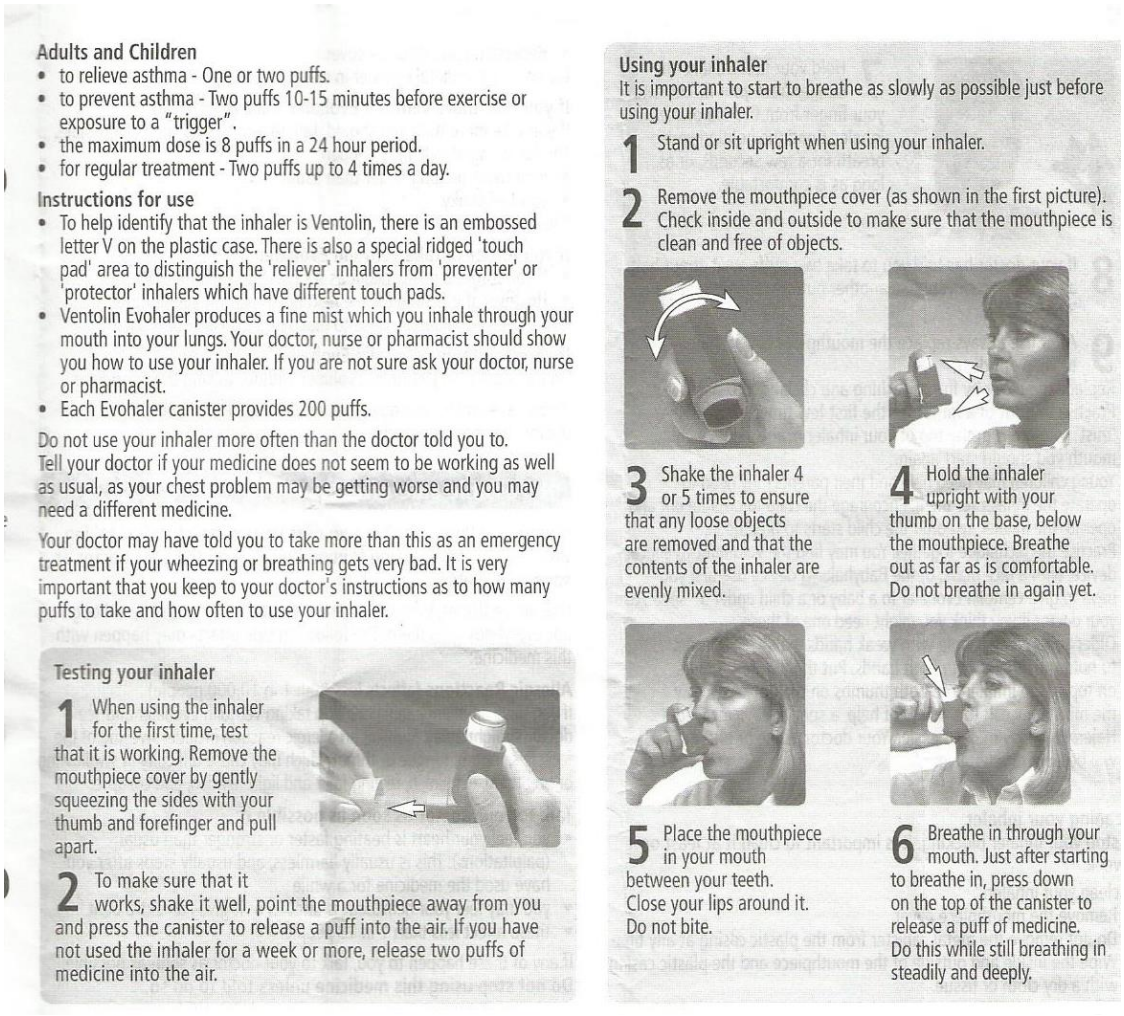
The illustrations show the steps to follow in order to use the eye drops correctly. We can notice that the text flow is not interrupted by the pictures, neither do these surround the images to create confusion. The pictures are separated from the verbal text, but at the same time they integrate the words as if they were functioning as expert guides, to help the user during the process of performing the act of administrating the medicine.

The next example illustrates medication patches which may be applied on various human anatomy parts. The verbal instructions accompany the actions depicted, that is, the steps that need to be taken to extract the transdermal patch from the sachet and apply it correctly on the skin:



(Neupro transdermal patch)

In the example that follows there are two types of instructions: a) how to test an inhaler before use, and b) how to use the inhaler correctly. The pictures are not replacing the actual text, but emphasizing certain aspects of its verbal parts (see next page).



Adults and Children

- to relieve asthma - One or two puffs.
- to prevent asthma - Two puffs 10-15 minutes before exercise or exposure to a "trigger".
- the maximum dose is 8 puffs in a 24 hour period.
- for regular treatment - Two puffs up to 4 times a day.

Instructions for use

- To help identify that the inhaler is Ventolin, there is an embossed letter V on the plastic case. There is also a special ridged 'touch pad' area to distinguish the 'reliever' inhalers from 'preventer' or 'protector' inhalers which have different touch pads.
- Ventolin Evohaler produces a fine mist which you inhale through your mouth into your lungs. Your doctor, nurse or pharmacist should show you how to use your inhaler. If you are not sure ask your doctor, nurse or pharmacist.
- Each Evohaler canister provides 200 puffs.

Do not use your inhaler more often than the doctor told you to. Tell your doctor if your medicine does not seem to be working as well as usual, as your chest problem may be getting worse and you may need a different medicine.

Your doctor may have told you to take more than this as an emergency treatment if your wheezing or breathing gets very bad. It is very important that you keep to your doctor's instructions as to how many puffs to take and how often to use your inhaler.

Testing your inhaler

1 When using the inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.

2 To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release a puff into the air. If you have not used the inhaler for a week or more, release two puffs of medicine into the air.

Using your inhaler

It is important to start to breathe as slowly as possible just before using your inhaler.

1 Stand or sit upright when using your inhaler.

2 Remove the mouthpiece cover (as shown in the first picture). Check inside and outside to make sure that the mouthpiece is clean and free of objects.

3 Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.

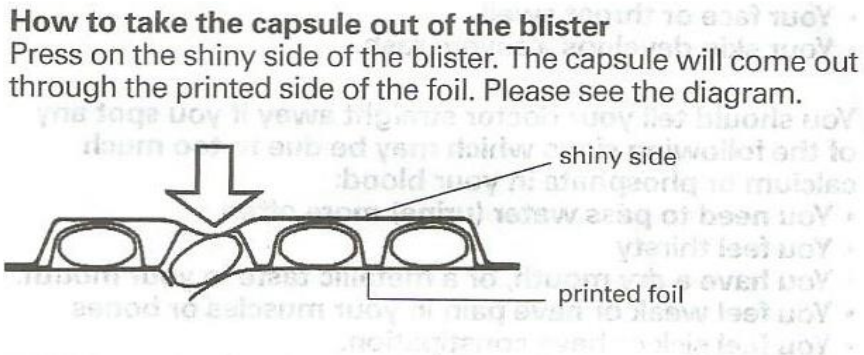
4 Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable. Do not breathe in again yet.

5 Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.

6 Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply.

(Ventolin Evohaler)

The sketch below is elucidating the user on how to take the capsule out of the blister. Perhaps many would give this procedure for granted, but it might not be so easy for all users, especially those who encounter visual or literacy difficulties.

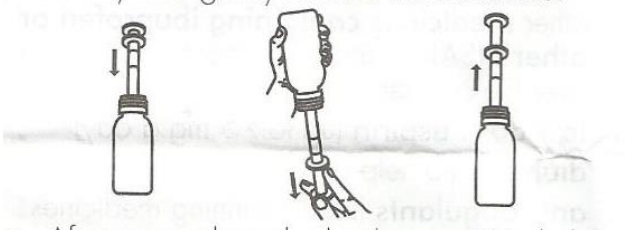


(One-Alpha Capsules)

The example that follows illustrates the steps necessary for dosing the right quantity of medicine with an appropriate syringe, included inside the packet:

Using the 5ml easy dosing syringe

- Push the syringe firmly into the plug (hole) in the neck of the bottle.
- To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark on the syringe. See section "How much medicine to use".
- Turn the bottle the right way up, remove the syringe from the bottle plug by gently twisting the syringe.
- Place the end of the syringe into the child's mouth and gently press the plunger down to slowly and gently release the medicine.



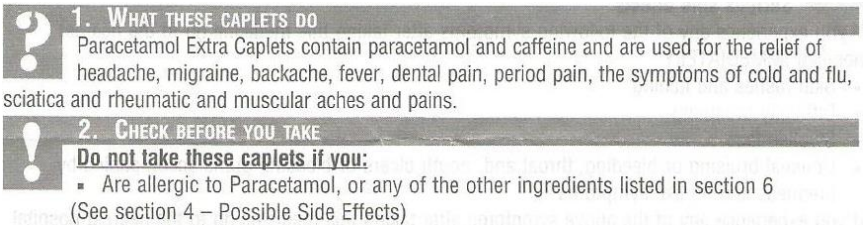
- After use replace the bottle cap. Wash the syringe in warm water and allow to dry. Store out of the reach of children.

(Nurofen for Children)

Very interestingly, several PILs: Benadryl Plus, Benylin, Istin, Lipitor, Paracetamol, Phenergan, Piriton, Tritace and Zovirax included symbols such as question marks, exclamation marks, ticks and crosses as visual aids beside the sub-headings. These symbols help the reader to grasp the message before reading the text or perhaps support the reader who encounters reading difficulties. They are very eye catching and give the PILs a multimodal nature. Kress and van Leeuwan (2001: 152), describe the non-verbal elements "as the visual grammar of multimodal texts", suggesting that "multimodal reading is not of verbal text, but rather

composite reading in which attention jumps back and forth between illustrations and text". All the visual elements are used to make meaning more potent. The following are some examples:

Examples



1. WHAT THESE CAPLETS DO

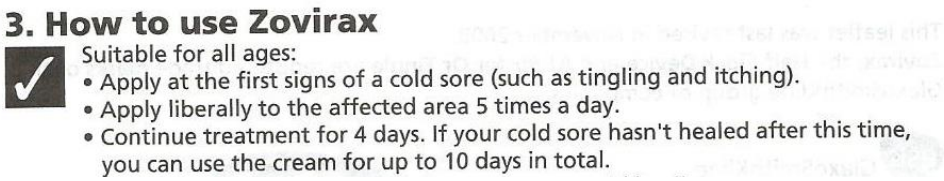
Paracetamol Extra Caplets contain paracetamol and caffeine and are used for the relief of headache, migraine, backache, fever, dental pain, period pain, the symptoms of cold and flu, sciatica and rheumatic and muscular aches and pains.

2. CHECK BEFORE YOU TAKE

Do not take these caplets if you:

- Are allergic to Paracetamol, or any of the other ingredients listed in section 6 (See section 4 – Possible Side Effects)

(Paracetomol)

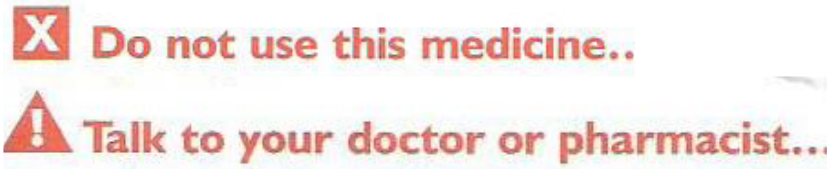


3. How to use Zovirax

Suitable for all ages:

- Apply at the first signs of a cold sore (such as tingling and itching).
- Apply liberally to the affected area 5 times a day.
- Continue treatment for 4 days. If your cold sore hasn't healed after this time, you can use the cream for up to 10 days in total.

(Zovirax)



Do not use this medicine..

Talk to your doctor or pharmacist...

(Benylin)

2. Check before you take Piriton Allergy Tablets

Do not take Piriton Allergy Tablets:

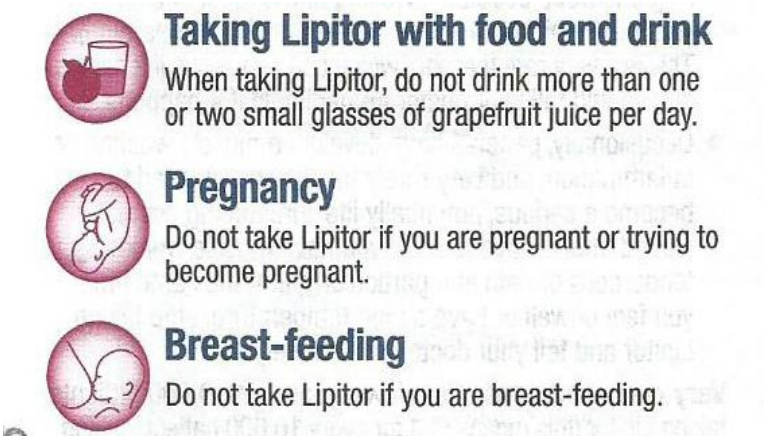
(Piriton)

2. BEFORE YOU TAKE ISTIN

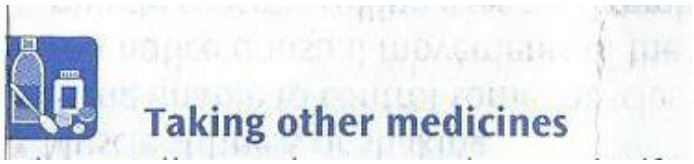
(Istin)

In the Lipitor and Tritace PILs colourful pictures for warnings are used in the contra-indication section '*Before you take X'*. In the following symbols, we may notice a glass with a drink and a fruit, that serves to warn which drinks and food must be avoided when taking Lipitor. The next picture symbolizes a warning for pregnant women, or in case a women is trying to become pregnant; the third pictogram is warning breast-feeding mothers not to take the medicine.

Examples

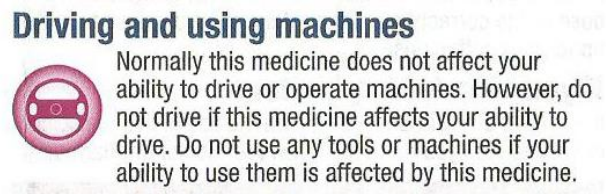


The Phenergan symbol (below) is a warning for interaction with other medicines:



(Phenergan)

The pictures on the next page integrate the warnings about driving abilities and using other machines, because these abilities can be affected whilst taking that medicine:



(Lipitor)

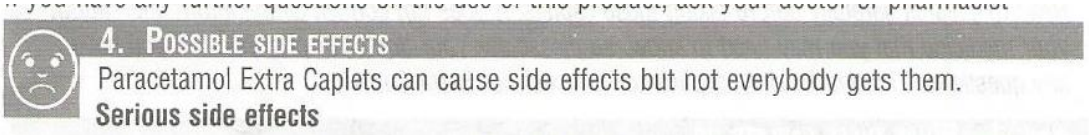
(Tritace)

In the Paracetomol PIL there is also an example of an emoticon beside the sub-heading: *possible side effects*. Taking in consideration the use of emoticons, Rezabek and Cochenour (1998) give the following explanation:

> "Emoticons can provide support to written communication, in much the same way that visuals or body language can enhance verbal communication. Facial expressions are especially important in conveying emotions and nuances of meaning during face-to-face interactions, and emoticons are a means for better defining emotions and intent regarding a particular phrase or statement sent via electronic mail".
>
> (Rezabek and Cochenour, 1998: 202)

Although emoticons were initially used to clarify the exact meaning of an electronic message, they are now also used in everyday written language. In the Paracetomol leaflet the connotation is very clear: '*be very careful and be informed before taking this medicine or you will have a bad time after*!'. Not at all *smiley*, the icon in the example emphasizes a sad statement and worrying consequences.

Example



4.8 Summary of findings

In this research Chapter, 60 PILs (dating from February 2008 to February 2012) have been examined from both a discourse and lexico-grammatical level. The relevant elements of the linguistic theory for the assessment of patient information leaflets were identified as generic structure and rhetorical functions, specialization of lexis, lexical density, status relations. There was concordance between the texts to the extent that the PIL was identified as a genre with up to seven structural moves (e.g. introduction to the medicine, account of side effects, dosage, storage). This indicates that there seems to be agreement between manufacturers on the organization of information within the leaflet, and that they, more or less, keep to the recommendations promoted by regulatory organizations. In most of the identified moves, more than one rhetorical element is involved, thus, suggesting that the reader may be receiving different signals (e.g., instruct and inform).

In a functional text, the objectives of the communication govern what takes place at all the other levels in the document, including headings and how technical the lexis needs to be. Headings (macro-themes, Martin, 1992) in a functional text are important because they are signposts by which the patient attempts to make sense of the document in response to the questions they have (Wright, 1999). When they are inconsistent or inappropriate, this hampers the effectiveness of the text, but in the corpus they were used appropriately. As for technicality, it needs to be acknowledged that patients need to deal with some level of specialised language in order to comprehend essential elements of their condition and how it might be treated. Most of the PILs did not carry a level of technicality that could impede understanding the text. Specialised

terminology was, in fact, presented in a way that could be comprehended by the user, for example, the explanation given of the technical word in brackets. Only few instances in the corpus appeared rather technical from the patient's perspective.

Readers, whether they believe they know the author of a patient leaflet or not, will form an impression of the identity of the writer and his/her understanding of the relationship with the writer, from the way the leaflet is written. Users may be confused about the authorship, they may be asking whether the sender of the message knows the individual situation or not. Patients may comprehend what they read, but they can also decide that the information received, does not apply to them (Wright, 1999). This is where relations established between doctor/expert and patient/lay user, by way of the text are crucial. This role relationship was quite consistent in the PILs investigated, for example, the use of the second person pronoun to address the patient directly and make him/her an active "participant" in the "process" (Halliday, 1994) of 'taking the medicine'.

There was variability in text length because some were longer than others, especially the PILs that dealt with more serious illnesses. Bullets and numbering were used in most of the leaflets. Bullets served for the listing of items where the order and relations between them were not important, and numbering for the listing of items where the order was important, or when a taxonomy actually existed (e.g. giving instructions for using a medication).

The information contained in the leaflets was not found to be densely packed. The lexis used in the majority of the PILs can be identified as being far from the 'spoken-like' end as estimated by Halliday, (1985). Analyses of lexical density, carried out on one section of the leaflet, demonstrated that the average number of density items was from 5 to 7 in

shorter texts, and from 7 to 9 in longer texts. This might sound as being more academic in theory, but in practice, the PILs are nearer to user-friendliness in style, in order to meet patients' needs.

Design issues (Hartley, 1994; 1999) such as layout, font size and style, and use of visual material may also have an impact upon patients' capacity to comprehend information leaflets. The results showed that a few PILs had a font type as large as 14, a few, a font size as small as 8, and the rest ranged from 10 to 12 (12 font type is recommended by the regulating authorities). Considering the MHRA's guidelines as regard to layout, also columns, spacing, and the use of colour were taken account of for the analyses. As for visual material, about 20% of the corpus included photographs, pictograms, symbols and other illustrations, thus, conveying a multimodal nature (Kress and van Leeuwan, 2001) to the leaflets.

4.9 Conclusion

In conclusion, the patient information leaflets in this corpus were characterised by low variability in generic structure, and by quite a standard set of rhetorical elements within and between the generic moves. As a sub-genre instance of medical texts, they have shown to carry a number of conventional indicators. The overall communicative purpose is to *inform* the reader about a therapeutic medication.

In answer to the research questions: what are the features in PILs to contribute to the fulfilment of writer and reader objectives? Is there a standard/conventional text structure in PILs? And, is patient centeredness manifested linguistically? Findings show that almost all the PILs analysed followed a standard text structure of seven moves. They displayed numerous examples of plain language features which accentuate a patient-centred, user-friendly approach, therefore, contributing to the role

relationship between health professionals and lay patients. However, as noticed throughout the analysis, there were also some examples of the use of traditional expert language, and some aspects of layout print, which act to the detriment of user-friendliness in patient communication. In sum, about 70% of the PILs could be said to constitute a best-practice example; 20%, a mixture of positive and negative features. 10% was still quite far from constituting communicative best practice both from a linguistic and layout point of view. It is also true, however, that several leaflets included examples of very colloquial language to a degree that had never been seen in patient information leaflets before.

Since its authoritative introduction, the statutory PIL has been a subject of study and improvement. However, there is still ample room for further improvement. The reason being is that the patient information leaflet is a very challenging genre with its many legal requirements, and with a target group which potentially consists of the entire population of a country. It plays a significant role in the patient empowerment process and the improvements to the genre witnessed over the past years deserve to be highlighted, while it is still important to point out any shortcomings to ensure continuous development.

CHAPTER FIVE

LABELS

5.1 New Labels on medicine packets and bottles

PILs are the leaflets (folded in a sort of Z shape) produced by the manufacturers and placed inside medicine packets, both prescribed (P) and OTC medications. Labels, on the other hand, are the printed texts added, actually stuck, on medicine packets and bottles by the pharmacist (as already mentioned). The label on the medicine repeats the instructions on the prescription the doctor wrote out for the patient. When the pharmacist dispenses the medicine, he/she will stick the label on the medicine container or its packaging, and every label is tailored to each patient's case.

The information on the medicine's dispensing label usually includes:

- the name of the patient;
- the name and address of the pharmacy that dispensed the medicine;

- the date the medicine is dispensed;
- the name of the medicine;
- the dose the patient should take, how to take it and how often;
- the total quantity of medicine in the container and the medicine strength;
- if necessary, any cautions or warning messages that apply to the medicine are added.

a) The medicine's name

The medicine may have two names:

- the brand name (manufacturer's name);
- the generic name for the active ingredient in the medicine scientific name). For example Pantoprazole is the active ingredient found in tablets to protect the stomach from producing too much acid.

If the prescription shows the medicine's brand name, the label should show both the brand name and the generic name.

b) The dose

The label on the prescribed medicine will repeat the dosage instructions from the prescription. This says how to take or use the medicine, for example:

- take one tablet four times a day;
- take one 5ml spoonful four times a day.

c) Extra instructions

The pharmacist may also include other instructions on the medicine label. Some examples are:

- shake the bottle
- store in a cool place
- discard, for example, 28 days after opening
- do not use after a certain date

d) Cautions and warning messages

It's a legal requirement that the dispensing label for all dispensed medicines should say 'Keep out of the reach of children'. All liquid medicines for external use, for example a cream to go on the skin, should also say 'For external use only'.

Depending on the type of medicine, cautions or warning messages may be added on a separate label. There are recommended wordings for these cautions, some of which were changed in 2011 (see next paragraph).

The labels should also have the following features:

- **Words typed in easy-to-read 12-point type, with the patient's name, drug name, and drug instructions in the largest letters.** But not all pharmacies follow this suggestion.
- **Warnings typed directly onto patient labels in a large typeface.** Research has found that fewer than 10 percent of people examine their drug containers for the colorful warning stickers that sometimes appear on the bottle. And warnings that appear on the labels that are typed in very small type can be hard to read or hard to find.
- **The generic and brand name of a drug.** This might prevent someone from mistakenly taking a double dose of the same

medication prescribed by two doctors and filled at two different pharmacies, one as the generic version and one as the brand-name drug. In fact patients should be advised to fill all of their prescriptions at the same pharmacy to help them avoid accidental mix-ups like the above stated.

- **Images or physical descriptions of the pills in the container.** Someone who reads that he or she should be taking round blue tablets will probably call the pharmacy if there are oval-shaped white pills in the container.
- **No extra zeroes (like 5.0 mg),** so patients who take 5 mg of a medication don't incorrectly remember it as "50 mg" when talking to a doctor.
- **The pharmacy's information—name, address, and phone number—at the bottom of the label,** so the patient's medicine information is prominently displayed at the top for easy reading, (see appendix for examples).

5.2 New wordings on medicine labels

Wordings on the labels had not been changed since 1985. The words of the original cautionary advisory labels was recommended by a working party of the Royal Pharmaceutical Society of Great Britain and since 1985 had been included in the British National Formulary (BNF), the authoritative textbook that pharmacists, doctors and nurses, and other health professionals use for looking up information about prescription and non-prescription medicine. The BNF is published by the Royal Pharmaceutical Society and the British Medical Association, under the authority of a Joint Formulary Committee made up of representatives from these bodies and the Department of Health.

But last March 2011, the BNF brought some important changes following the work by a group of researchers at the University of Leeds, in collaboration with Leeds-based company Luto Research. The researches revealed that many commonly-used phrases on medicine labels were easily misunderstood by many people.

On Thursday 3 March 2011 an interview on BBC Radio 4[5] was released called: ***Clear English coming to your medicine cabinet.***

The expert interviewed was Professor of Pharmacy Theo Raynor of Luto and University of Leeds (see transcript, 5.4).

Professor Raynor argued that there were confusing instructions on medicine bottles and packets of pills dispensed from the UK pharmacies and that it was necessary to replace those with simpler words and phrases in order to help people understand them better.

Around two million prescriptions are issued every day in the UK, and every medicine must have a printed label that gives details on how to take the medicine. However, the Leeds research results showed that some of the standard phrases that were printed on the labels were confusing and caused some patients to behave in ways that would compromise the safety and effectiveness of their treatment. Researchers gathered that the switch to clearer language would help make sure that patients would take their medicines as they should do.

"It is vital that wordings on labels are simple and straightforward", said Professor Raynor. "Most medicines do contain leaflets providing detailed information for patients, but these leaflets can get lost or overlooked. Patients' behaviour tends to be guided by the instructions on the outside of medicine bottles and packets of pills, so these must be as clear and unambiguous as possible." (Raynor, BBC Radio 4, 2011).

[5] **BBC Radio 4** Today Programme: Interview with John Humphries, 3 March 2011

The research carried out by Professor Raynor and Dr Peter Knapp (from the University of Leeds, School of Healthcare) and David Bryant (General Manager, Luto Research), consisted in testing a selection of instructions on a large number of volunteers from the general public. Participants were all literate in English and covered a range of ages 20-80, and had educational abilities. They were asked to read and answer questions about medicines with several label wordings and medicines with single-label wordings. A group of paediatric medicines was also created and used for participants who were parents or carers of children. The questions were agreed by an expert panel consisting of pharmacists from Luto Research and the BNF. Almost 200 lay participants were involved over three rounds of testing. The results from each round of testing were combined with good practice and research evidence to produce revised wordings that reflect current best practice[3] in written medicine information for patients. In other words, if any of the phrases were found confusing by the volunteers, the researchers rewrote them by using best practice in clear English, and then tested them again with another group of volunteers. Of the 32 labels, three existing wordings -labels 12, 17, and 29- (see paragraph 4.3) worked well and are retained in the proposed revised wordings for the new labels. Although the wording of individual labels may have changed, the intended instruction of each of the numbered labels remains the same.

The proposed changes include a terminology that is better understood by patients and not misleading. For example, user testing showed that, in label 1, the word "drowsiness" is not always readily understood and has been improved by using the wording "This medicine may make you sleepy". The recommended changes (see section 5.3), following user testing, also produce more precise instructions, which present little

opportunity for different interpretations. Thus, in label 4, the wording "Avoid alcoholic drink", is replaced with "Do not drink alcohol while taking this medicine". Dr Raynor said, in fact, that the word "Avoid" to some people meant that they should only limit their alcohol intake. Hence "Do not " conveys a simpler command. (Raynor, BBC Radio 4, 2011).

Luto's testing showed that label wordings that can be incorporated in an appropriate position in the directions for dosage or administration (labels 21 to 28) did not generally work well. Separating these wordings into a discrete instruction worked better and this format was adopted in the proposed wordings.

The revised phrases were included in the last version of the BNF (BNF 61, March 2011), and Duncan Enright, Publishing Director at BNF Publications said: "It has never been easier to change labels on medicines given current computerised systems and therefore we hope that the large pharmacy chains and independent pharmacies will adopt these recommendations", (March 2011).

The new software version has been downloaded by the pharmacies and currently the new instruction labels are printed.

5.3 BNF cautionary and advisory labels: Before and after recommended changes

On the label

Before: wording of original cautionary and advisory labels

1 Warning: May cause drowsiness

2 Warning: May cause drowsiness. If affected do not drive or operate machinery.

4 Warning. Avoid alcoholic drink

5 Do not take indigestion remedies at the same time of day as this medicine

7 Do not take milk, indigestion remedies, or medicines containing iron or zinc at the same time of day as this medicine

8 Do not stop taking this medicine except on your doctor's advice

9 Take at regular intervals. Complete the prescribed course unless otherwise directed

10 Warning. Follow the printed instructions you have been given with this medicine

11 Avoid exposure of skin to direct sunlight or sun lamps

14 This medicine may colour the urine

15 Caution flammable: keep away from fire or flames

16 Allow to dissolve under the tongue. Do not transfer from this container. Keep tightly closed. Discard eight weeks after opening

19 Warning. Causes drowsiness which may continue the next day. If affected do not drive or operate machinery. Avoid alcoholic drink

21 . . . with or after food

22 . . . half to one hour before food

23 . . . an hour before food or on an empty stomach

25 . . . swallowed whole, not chewed

27 . . . with plenty of water

28 To be spread thinly …

30 Do not take with any other Paracetamol products

32 Contains aspirin

<u>After:</u> wording of revised cautionary and advisory labels (BNF 61)

1 Warning: This medicine may make you sleepy

2 Warning: This medicine may make you sleepy . If this happens, do not drive or use tools or machines. Do not drink alcohol

4 Warning: Do not drink alcohol while taking this medicine

5 Do not take indigestion remedies 2 hours before or after you take this medicine

7 Do not take milk, indigestion remedies, or medicines containing iron or zinc, 2 hours before or after you take this medicine

8 Warning: Do not stop taking this medicine unless your doctor tells you to stop

9 Space the doses evenly throughout the day. Keep taking this medicine until the course is finished, unless you are told to stop

10 Warning: Read the additional information given with this medicine

11 Protect your skin from sunlight — even on a bright but cloudy day. Do not use sunbeds

12 This medicine may colour your urine. This is harmless

15 Caution: flammable. Keep your body away from fire or flames after you have put on the medicine

16 Dissolve the tablet under your tongue—do not swallow. Store the tablets in this bottle with the cap tightly closed. Get a new supply 8 weeks after opening

19 Warning: This medicine makes you sleepy. If you still feel sleepy the next day, do not drive or use tools or machines. Do not drink alcohol

21 Take with or just after food, or a meal

22 Take 30 to 60 minutes before food

23 Take this medicine when your stomach is empty. This means an hour before food or 2 hours after food

25 Swallow this medicine whole. Do not chew or break

27 Take with a full glass of water

28 Spread thinly on the affected skin only

30 Contains Paracetamol. Do not take anything else containing Paracetamol while taking this medicine

32 Contains aspirin. Do not take anything else containing aspirin while taking this medicine

5.4 Transcript

Clear English coming to your medicine cabinet by Theo Raynor

Location: BBC Radio 4 Today Programme: Interview with John Humphries

University of Leeds press release
Thursday 3 March 2011

The interview may be downloaded at:
http://leeds.academia.edu/TheoRaynor/Talks/37030/Clear_English_coming_to_your_cabinet...

Interviewer: Pharmacists are getting worried about the instructions stuck on the medicines prescribed by GPs. Apparently an awful lot of us don't understand them and that can be dangerous. Theo Raynor is professor of Pharmacy Practice at Leed's University who led a research into this.

Interviewer: Good morning Theo!

Prof. Theo: Good morning!

Int: How misleading, in what sense?

Prof. Theo: Well, there are about 30 labels that pharmacies routinely use on medicines, things like 'Avoid alcohol whether before or after food', 'Take at regular intervals', and we found in our research that many of these things even if they look simple, people didn't understand them very well. We worked with

nearly 200 people of the public to test the labels and that's where we found that they can be misunderstood. So we used the clinical expertise of the British National Formulary and our research expertise of the University of Leeds, and we used a testing user research at Luto Research, and came up with what we have found to be much more straightforward and clearer labels.

Int: Right, so this has nothing to do with the GP, then?
Prof. Theo: No, the pharmacists are required to put additional labels when they dispense medicines, so we now come up with a new set of labels which they will now routinely use for all the prescriptions that are written by GPs.

Int: So, effectively, it's a different kind of language, obviously, you're not changing the way we take things, like particular drugs, it's just the use of language?
Prof. Theo: Absolutely! Let me give you an example: we've previously used the wording 'Avoid alcoholic drink', and we found that people interpreted that in a number of different ways, but what we mean is 'Do not drink alcohol while taking this medicine'. So it's just simply setting things in ways that people can understand.

Int: I wonder why people couldn't understand 'avoid alcohol'. What did they think about it then?

Prof. Theo: Well, some people thought it meant 'you should try.., well, if you drink alcohol, try and see if it affects you before you drive, for instance, and so on. It does give the opportunity to give various interpretations, so 'avoid' isn't very specific.

Int: Oh, right! Anything else like that sort of thing?
Prof. Theo: Oh, well, yes. Many medicines either won't work or you'll have more side effects if you don't have food in your stomach when you take them. And we used to put on the labels 'with or without food', and again, even that is a little bit vague, so we are now going to say: 'Take with or just after food, or a meal'. So, we're just thinking about things from the medicine's taker perspective and write in a way that they can relate it to their daily lives.

Int: And it really matters, does it? Because I suppose an awful lot of us think when they actually say 'Take with a meal', they don't actually really mean before, after or during.

Prof. Theo: It matters very much. If you think of medicines like *Ibuprofen* if you don't take them on a full stomach, then they can cause quite serious upsets and stomach ulcers. So, yes, it matters very much in many cases.

Int: Well, thanks very much Professor Theo.

The picture below shows Professor Theo Raynor with examples of medicine packets and bottles including the new wordings on the labels.

Fig. 5.1 Picture of Professor Raynor

LIST OF ANAGRAMS

ABPI	**Association of the British Pharmaceutical Industry**
AIFA	**Agenzia Italian del Farmaco**
APBI	**Association of the British Pharmaceutical Industry**
BNF	**British National Formulary**
BROMI	**Better Regulation of Over-the Counter Medicines Initiative**
BSOC	**Body System Order Class**
CDH	**Chronic daily headache**
CRO	**Contract Research Organisation**
DH	**Department of Health**
EMEA	**European Medicine Agency**
EU	**European Union**
FDA	**Food and Drug Administration**
FKRGL	**Flesch-Kincaid Reading Grade Level**
FOG	**Gunning Fog Index formula**
GP	**General Practitioner**
GSL	**General sales list medicines**
ISO	**International Organisation for Standardisation**
MA	**Marketing Holder**
MHA	**Marketing Holder Authorization**
MHLW	**Ministry of Health, Labor, and Welfare**
MHRA	**Medicines and Healthcare Regulatory Agency**
NHS	**National Health Service**
OTC	**Over-the-counter**
P	**Pharmacy medicines**

PIL	**Patient information leaflet**
PIQU	**Patient Information Quality Unit**
POM	**Prescription only Medicine**
QRD	**Quality Review of Documents**
RMS	**Reference Member State**
RNIB	**Royal National Institute of the Blind**
SFL	**Systemic Functional Linguistics**
SMOG	**Simple Measure of Gobbledegook**
SPC	**Summary of Product Characteristics**
TGA	**Therapeutic Goods Administration**

LIST OF FIGURES

LIST OF TABLES

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http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=164

MHRA, Labels, patient information leaflets, and packaging for medicines, available at: http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=164

MHRA, Further guidance on designing patient information leaflets and how to achieve success in user testing, March 2007, available at: http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=164

Raynor , D.K. (2005) User Testing and How It Will Revolutionise How We Think About Patient Information Leaflets 2005; 86: 4-5, available at: http://www.luto.co.uk/news/1_04_05.pdf

Raynor, D.K. (2011) on BBC Radio 4: Today Programme: Interview with John Humphries. University of Leeds press release. Thursday 3 March 2011: http://leeds.academia.edu/TheoRaynor/Talks/37030/Clear_English_coming_to_your_cabinet...

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, available at:

http://ec.europa.eu/enterprise/pharmaceuticals/review/doc/final_publ/reg_2004_726_20040430_en.pdf

QRD "Human" Product information template with explanatory notes (version 7.2 EMEA 10/2006), available at: http://www.emea.europa.eu/htms/human/qrd/qrdplt/AnnotatedTemplate-H.pdf

QRD Human Product Information Templates, adopted by the QRD Working Group, available at: http://www.emea.europa.eu/index/indexh1.htm

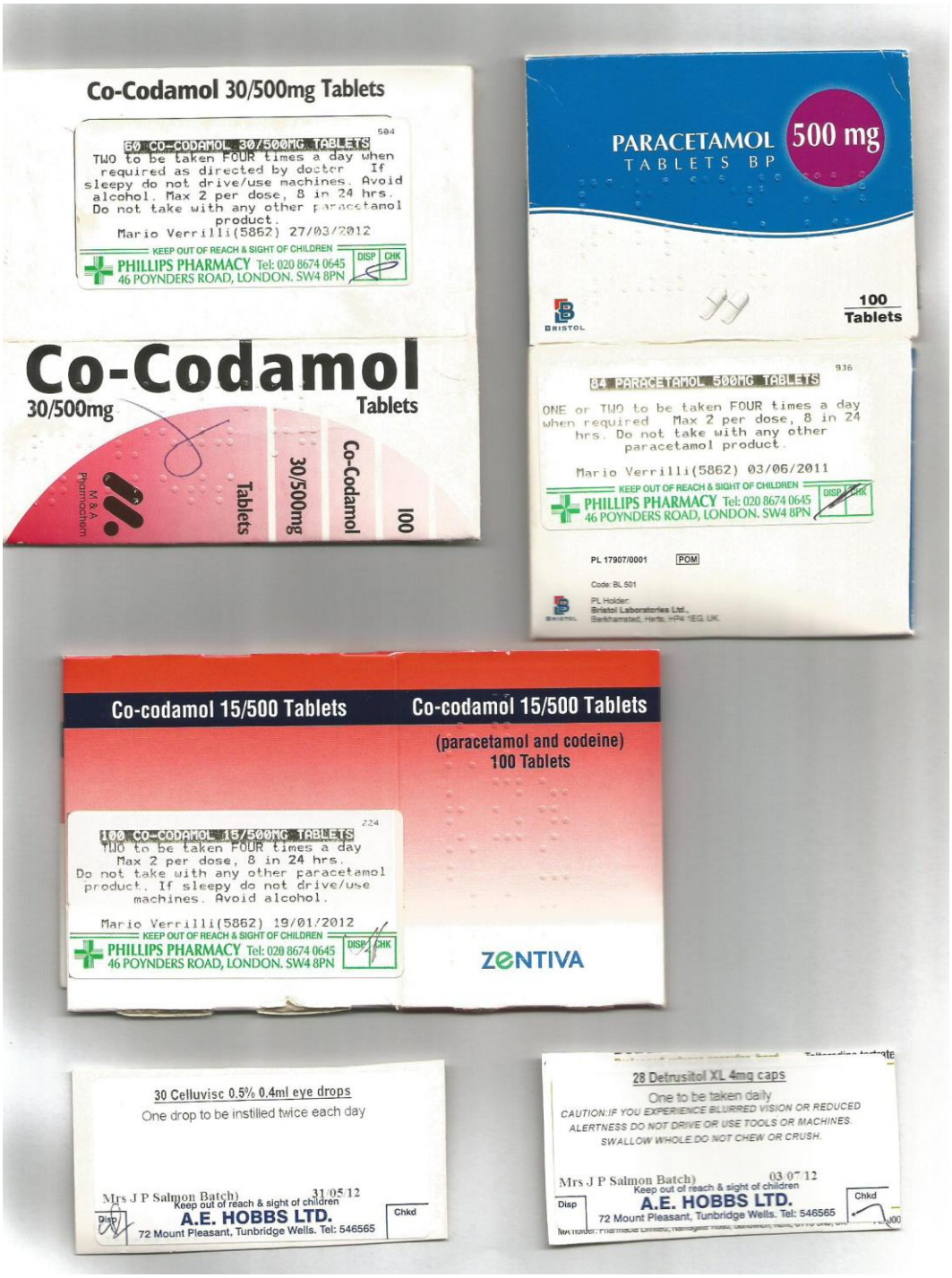
U.S. Department of Health and Human Services. *Healthy People 2010: Understanding and Improving Health.* 2nd ed. Washington. Dc: U.S. Government Printing Office; 2000. Available at: http://www.healthypeople.gov/Document/tableofcontents.htm.

X-PIL, Patient Information Leaflets Online, available at:

http://xpil.medicines.org.uk/WhatsNew.aspx

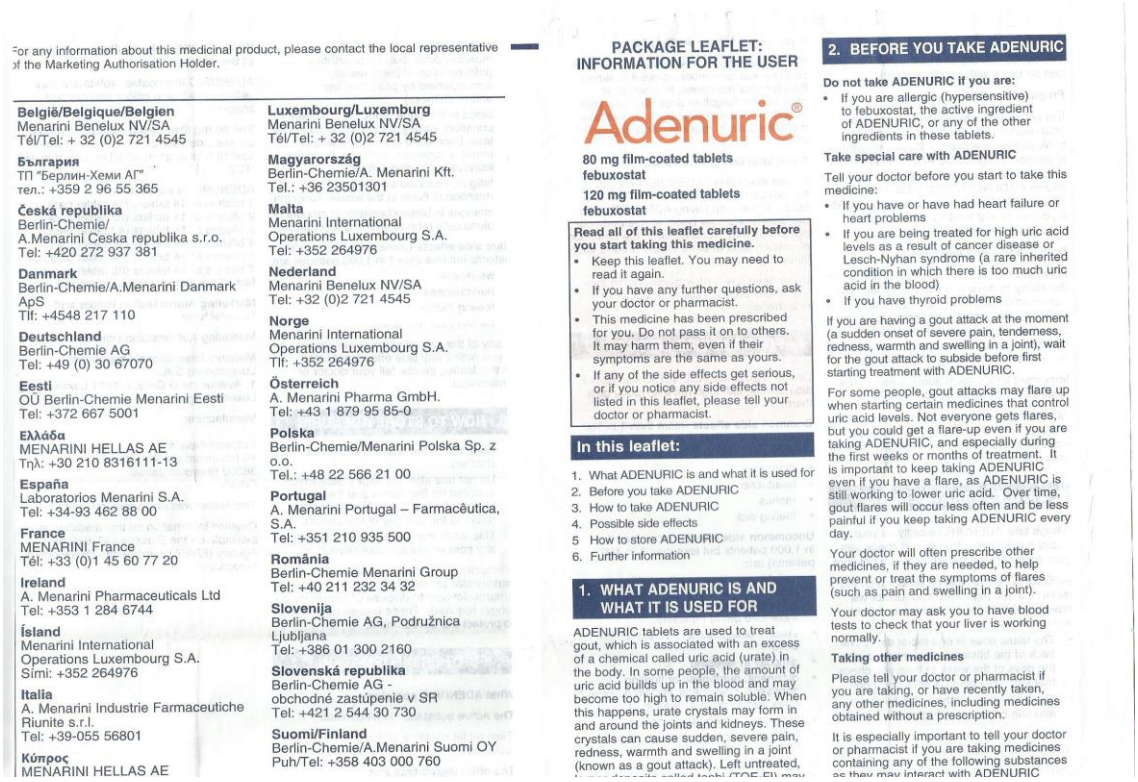
APPENDIX 1

Medicine labels



APPENDIX 2

Copies of PILs in alphabetical order



For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

België/Belgique/Belgien
Menarini Benelux NV/SA
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Slovenija
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Slovenská republika
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Puh/Tel: +358 403 000 760

PACKAGE LEAFLET: INFORMATION FOR THE USER

Adenuric®

80 mg film-coated tablets
febuxostat

120 mg film-coated tablets
febuxostat

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT ADENURIC IS AND WHAT IT IS USED FOR

ADENURIC tablets are used to treat gout, which is associated with an excess of a chemical called uric acid (urate) in the body. In some people, the amount of uric acid builds up in the blood and may become too high to remain soluble. When this happens, urate crystals may form in and around the joints and kidneys. These crystals can cause sudden, severe pain, redness, warmth and swelling in a joint (known as a gout attack). Left untreated,

2. BEFORE YOU TAKE ADENURIC

Do not take ADENURIC if you are:
- If you are allergic (hypersensitive) to febuxostat, the active ingredient of ADENURIC, or any of the other ingredients in these tablets.

Take special care with ADENURIC

Tell your doctor before you start to take this medicine:
- If you have or have had heart failure or heart problems
- If you are being treated for high uric acid levels as a result of cancer disease or Lesch-Nyhan syndrome (a rare inherited condition in which there is too much uric acid in the blood)
- If you have thyroid problems

If you are having a gout attack at the moment (a sudden onset of severe pain, tenderness, redness, warmth and swelling in a joint), wait for the gout attack to subside before first starting treatment with ADENURIC.

For some people, gout attacks may flare up when starting certain medicines that control uric acid levels. Not everyone gets flares, but you could get a flare-up even if you are taking ADENURIC, and especially during the first weeks or months of treatment. It is important to keep taking ADENURIC even if you have a flare, as ADENURIC is still working to lower uric acid. Over time, gout flares will occur less often and be less painful if you keep taking ADENURIC every day.

Your doctor will often prescribe other medicines, if they are needed, to help prevent or treat the symptoms of flares (such as pain and swelling in a joint).

Your doctor may ask you to have blood tests to check that your liver is working normally.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

It is especially important to tell your doctor or pharmacist if you are taking medicines containing any of the following substances as they may interact with ADENURIC

Taking ADENURIC with food and drink

The tablets should be taken by mouth and can be taken with or without food.

Pregnancy and breast-feeding

It is not known if ADENURIC may harm your unborn child. Tell your doctor if you think you are pregnant or if you are planning to become pregnant as ADENURIC should not be used during pregnancy. It is not known if ADENURIC may pass into human breast milk. You should not use ADENURIC if you are breast feeding, or if you are planning to breastfeed.

Driving and using machines

No studies on the effects of ADENURIC on the ability to drive and use machines have been performed. However, you should be aware that you may experience dizziness, sleepiness and numbness or tingling sensation during treatment and should not drive or operate machines if affected.

Important information about some of the ingredients of ADENURIC

ADENURIC tablets contain lactose (a type of sugar). If you have been told that you have an intolerance to some sugars contact your doctor before taking this medicine.

3. HOW TO TAKE ADENURIC

Always take ADENURIC exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

ADENURIC is available as either an 80 mg tablet or a 120 mg tablet. Your doctor will have prescribed the strength most suitable for you.
- The usual dose is one tablet daily. The back of the blister pack is marked with the days of the week to help you check that you have taken a dose each day.
- The tablets should be taken by mouth and can be taken with or without food.

It is important that you do not stop taking ADENURIC unless your doctor tells you to.

Continue to take ADENURIC every day even when you are not experiencing gout flare or attack.

If you forget to take ADENURIC

If you miss a dose of ADENURIC take it as soon as you remember unless it is almost time for your next dose, in which case miss out the forgotten dose and take your next dose at the normal time. Do not take a double dose to make up for a forgotten dose.

If you stop taking ADENURIC

Do not stop taking ADENURIC without the advice of your doctor even if you feel better. If you stop taking ADENURIC your uric acid levels may begin to rise and your symptoms may worsen due to the formation of new crystals of urate in and around your joints and kidneys.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ADENURIC can cause side effects, although not everybody gets them.

Common side effects (more than 1 in 100 patients but less than 1 in 10 patients) are:
- abnormal liver test results
- diarrhoea
- headache
- rashes
- feeling sick

Uncommon side effects (more than 1 in 1,000 patients but less than 1 in 100 patients) are:
- weight gain, increased appetite, change in blood sugar levels (diabetes) of which a symptom may be excessive thirst, increased blood fat levels
- erectile difficulties and/or loss of sex drive
- difficulty in sleeping
- dizziness, numbness or tingling sensation, sleepiness, impaired sense of taste, reduction in sensation of touch
- abnormal ECG heart tracing
- hot flushes or blushing (e.g. redness of the face or neck), increased blood pressure
- cough, shortness of breath, flu-like symptoms
- dry mouth, abdominal pain/discomfort
- muscle cramp, pain/ache in muscles/joints, bursitis or arthritis (inflammation of joints usually accompanied by pain, swelling and/or stiffness)
- blood in the urine, abnormal frequent urination, kidney stones, abnormal urine tests (increased level of proteins in urine), a reduction in the ability of the kidneys to function properly
- fatigue, localised swelling due to the retention of fluids in the tissues (oedema)
- changes in blood chemistry or amount of blood cells (abnormal blood test results)

Rare side effects (more than 1 in 10,000 patients but less than 1 in 1,000 patients) are:
- weakness
- nervousness
- feeling thirsty
- feeling your heartbeat

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ADENURIC

- Keep out of the reach and sight of children.
- Do not use after the expiry date which is stated on the carton and the tablet blister foil after 'EXP.' The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What ADENURIC contains

The active substance is febuxostat.

Each tablet contains 80 mg or 120 mg of febuxostat.

The other ingredients are:

Tablet core: lactose monohydrate, microcrystalline cellulose, magnesium

What ADENURIC looks like and conten of the pack

ADENURIC film-coated tablets are pale yellow to yellow in colour and capsule shaped.

The 80 mg film-coated tablets are mark on one side with '80'. The 120 mg film-coated tablets are marked on one side '120'.

ADENURIC is supplied in
1 blisters of 14 tablets (14 tablet pack),
2 blisters of 14 tablets (28 tablet pack),
3 blisters of 14 tablets (42 tablet pack),
4 blisters of 14 tablets (56 tablet pack),
6 blisters of 14 tablets (84 tablet pack)
7 blisters of 14 tablets (98 tablet pack).
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Menarini International Operations Luxembourg S.A.
1, Avenue de la Gare, L-1611 Luxembo Luxembourg

Manufacturer

Patheon France
40 boulevard de Champaret
38300 Bourgoin Jallieu
France

This leaflet was last approved in 08/201

Detailed information on this medicine is available on the European Medicines Agency (EMEA) website http://www.em europa.eu/

Avodart®

0.5 mg soft capsules
dutasteride

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- **If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

In this leaflet:

1 What Avodart is and what it's used for

Avodart is used to treat men with an enlarged prostate *(benign prostatic hyperplasia)* - a non-cancerous growth of the prostate gland, caused by producing too much of a hormone called dihydrotestosterone.

The active ingredient is dutasteride. It belongs to a group of medicines called 5-alpha reductase inhibitors.

As the prostate grows, it can lead to urinary problems, such as difficulty in passing urine and a need to go to the toilet frequently. It can also cause the flow of the urine to be slower and less forceful. If left untreated, there is a risk that your urine flow will be completely blocked *(acute urinary retention)*. This requires immediate medical treatment. In some situations surgery is necessary to remove or reduce the size of the prostate gland. Avodart lowers the production of dihydrotestosterone, which helps to shrink the prostate and relieve the symptoms. This will reduce the risk of acute urinary retention and the need for surgery.

Avodart may also be used with another medicine called tamsulosin (used to treat the symptoms of an enlarged prostate).

2 Before you take Avodart

Do not take Avodart
- **if you're allergic** ***(hypersensitive)*** **to dutasteride** or to any of the other ingredients of Avodart
- **if you're allergic to other 5-alpha reductase inhibitors**
- **if you have a severe liver disease.**

→ **Tell your doctor** if you think any of these apply to you.

This medicine is for men only. It must not be taken by women, children or adolescents.

Take special care with Avodart
- **Make sure your doctor knows about liver problems.** If you have had any illness affecting your liver, you may need some additional check-ups while you are taking Avodart.
- **Women, children and adolescents** must not handle leaking Avodart capsules, because the active ingredient can be absorbed through the skin. **Wash the affected area immediately** with soap and water if there is any contact with the skin.
- **Use a condom during sexual intercourse.** Dutasteride has been found in the semen of men taking Avodart. If your partner is or may be pregnant, you must avoid exposing her to your semen as dutasteride may affect the normal development of a male baby. Dutasteride has been shown to decrease sperm count, semen volume and sperm motility. This could reduce your fertility.
- **Avodart can affect a blood test for PSA** (prostate-specific antigen), which is sometimes used to detect prostate cancer. Your doctor should be aware of this effect and can still use the test to detect prostate cancer. If you are having a blood test for PSA, tell your doctor that you are taking Avodart.

→ **Contact your doctor or pharmacist** if you have any questions about taking Avodart.

Taking other medicines

Tell your doctor if you're taking, or have recently taken, any other medicines. This includes any medicines you've bought without a prescription.

Some medicines can react with Avodart and may make it more likely that you'll have side-effects. These medicines include:
- **verapamil or diltiazem** (for high blood pressure)
- **ritonavir or indinavir** (for HIV)
- **itraconazole or ketaconazole** (for fungal infections)
- **nefazodone** (an antidepressant)
- **alpha-blockers** (for enlarged prostate or high blood pressure).

→ Tell your doctor if you are taking any of these medicines. Your dose of Avodart may need to be reduced.

Food and drink with Avodart

Avodart can be taken with or without food.

Pregnancy and breast-feeding

Women who are pregnant (or may must not handle leaking capsules. Dutasteride is absorbed through th skin and can affect the normal development of a male baby. This particular risk in the first 16 weeks pregnancy.

Use a condom during sexual intercourse. Dutasteride has been found in the semen of men taking Avodart. If your partner is or may b pregnant, you must avoid exposing to your semen.

Avodart has been shown to reduce sperm count, semen volume and sp movement. Therefore male fertility may be reduced.

→ **Contact your doctor** for advice if pregnant woman has come into contact with dutasteride.

Driving and using machines

Avodart is unlikely to affect your al to drive or operate machinery.

TURN

3 How to take Avodart

Always take Avodart exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

How much to take
- **The usual dose is one capsule (0.5 mg) taken once a day.** Swallow the capsules whole with water. Do not chew or break open the capsule. Contact with the contents of the capsules may make your mouth or throat sore.
- Avodart is a long term treatment. Some men notice an early improvement in their symptoms. However, others may need to take Avodart for 6 months or more before it begins to have an effect. Keep taking Avodart for as long as your doctor tells you.

If you take too much Avodart

Contact your doctor or pharmacist for advice if you take too many Avodart capsules.

If you forget to take Avodart

Don't take extra capsules to make up for a missed dose. Just take your next dose at the usual time.

Don't stop Avodart without advice

Don't stop taking Avodart without talking to your doctor first. It may take up to 6 months or more for you to notice an effect.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Avodart can cause side effects, although not everybody gets them.

Very rare allergic reaction

The signs of allergic reactions can include:
- **skin rash** (which can be itchy)
- **hives** (like a nettle rash)
- **swelling of the eyelids, face, lips, arms or legs.**

→ **Contact your doctor immediately** if you get any of these symptoms, and **stop using Avodart.**

Common side effects

These may affect up to 1 in 10 men taking Avodart:
- impotence *(not able to achieve or maintain an erection)*
- decreased sex drive *(libido)*
- difficulty with ejaculation
- breast enlargement or tenderness *(gynecomastia)*
- dizziness when taken with tamsulosin.

→ If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 How to store Avodart

Keep out of the reach and sight of children.

Don't store Avodart above 30°C.

Don't use Avodart after the expiry date which is stated on the carton or the foil blister strip. The expiry date refers to the last day of that month.

If you have any unwanted Avodart capsules, don't dispose of them in waste water or household rubbish. Take them back to your pharmacist, who will dispose of them in a way that won't harm the environment.

accord

PACKAGE LEAFLET : INFORMATION FOR THE USER

Alendronic Acid Once weekly 70 mg Tablets

(Alendronic Acid)

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Alendronic Acid Tablets is and what it is used for

Alendronic acid belongs to a group of non-hormonal medicines called bisphosphonates. Alendronic acid prevents the loss of bone that occurs in women after they have been through the menopause, and helps to rebuild bone. Alendronic acid reduces the risk of spine and hip fractures.

What is Alendronic Acid Tablets used for?
Your doctor has prescribed alendronic acid tablets because you have a disease called osteoporosis.
Osteoporosis is a thinning and weakening of the bones. It is common in women after the menopause. At the menopause, the ovaries stop producing the female

How can osteoporosis be treated/prevented?
Osteoporosis can be treated and it is never too late to begin treatment. Alendronic acid Tablet not only prevents the loss of bone but actually helps to rebuild bone you may have lost and reduces the risk of bones breaking in the spine and hip.

As well as your treatment with Alendronic acid Tablet, your doctor may suggest you make changes to your lifestyle to help your condition, such as:

Stopping smoking:	Smoking appears to increase the rate at which you lose bone and, therefore, may increase your risk of fracture.
Exercise:	Like muscles, bones need exercise to stay strong and healthy. Consult your doctor before you begin any exercise programme.
Eating a balanced diet:	Your doctor can advise you about your diet or whether you should take any dietary supplements.

2. Before you take Alendronic Acid Tablets

Do not take Alendronic Acid Tablets
- If you have certain disorders of the oesophagus (sometimes called the gullet and is the tube that connects your mouth with your stomach)
- If you are unable to stand or sit upright for at least 30 minutes
- If you are allergic (hypersensitive) to alendronic acid or any of the other ingredients of alendronic acid
- If your doctor has told you that you have low blood calcium

If you think any of these apply to you, do not take the tablets. Talk to your doctor first and follow his advice.

Take special care with Alendronic Acid Tablets
It is important to tell your doctor before taking Alendronic Acid Tablets
- If you suffer from kidney problems
- If you have any allergies
- If you have any swallowing or digestive problems
- If you have low blood calcium
- If you have gum disease
- If you have a planned dental extraction

A dental examination should be considered before you start treatment with Alendronic Acid Tablets if you have any of the conditions below.
- You have cancer

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is likely that calcium supplements, antacids, and some oral medicines will interfere with the absorption of Alendronic acid Tablets if taken at the same time. Therefore, it is important that you follow the advice given under the heading HOW TO TAKE ALENDRONIC ACID TABLETS.

Taking Alendronic Acid Tablets with food and drink
It is likely that food and beverages (including mineral water) will make Alendronic acid Tablets less effective if taken at the same time. Therefore, it is important that you follow the advice given in heading HOW TO TAKE ALENDRONIC ACID TABLETS.

Children and adolescents
Alendronic acid Tablets should not be given to children and adolescents.

Pregnancy and breast-feeding:
You should not take alendronic acid tablets if you are or think you may be pregnant, or if you are breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Alendronic acid tablets should not affect your ability to drive or use machines.

Important information about some of the ingredients of Alendronic Acid Tablets
Alendronic Acid Tablets contains 0.272 g of lactose. When taken according to the dosage recommendations each dose supplies up to 0.272 g of lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

3. How to take Alendronic Acid Tablets

Take one Alendronic Acid Tablet once a week.
Follow these instructions carefully to make sure you will benefit from alendronic acid.

Do not chew the tablet or allow it to dissolve in your mouth.

3) Do not lie down stay fully upright (sitting, standing or walking) for at least 30 minutes after swallowing the tablet. Do not lie down until after your first food of the day.
4) Do not take alendronic acid bedtime or before getting up for the day.
5) If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking alendronic acid and contact your doctor.
6) After swallowing your alendronic acid tablet, wait at least 30 minutes before taking your first food, drink, or other medicine of the day, including antacids, calcium supplements and vitamins. Alendronic Acid is effective only if taken when your stomach is empty.

If you take more Alendronic Acid Tablets than you should
If you take too many tablets by mistake, drink a full glass of milk and contact your doctor immediately. Do not make yourself vomit, and do not lie down.

If you forget to take Alendronic Acid Tablets
If you miss a dose, just take one Alendronic Acid Tablets 70 mg on the morning after you remember. Do not take two tablets on the same day. Return taking one tablet once a week, as originally scheduled on your chosen day.

If you stop taking Alendronic Acid Tablets
It is important that you continue taking Alendronic Acid Tablets for as long as your doctor prescribes the medicine. Alendronic Acid Tablets can treat your osteoporosis only if you continue to take the tablets.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, alendronic acid tablets can cause side effects, although not everybody gets them.

Most patients do not have side effects from taking these tablets; however, as with any medicine, they may have unintended or undesirable effects.

The following terms are used to describe how often side effects have been reported.

connects your mouth with your stomach) which can cause chest pain,
- bone, muscle and/or joint pain
- abdominal pain;
- uncomfortable feeling in the stomach or belching after eating;
- constipation;
- full or bloated feeling in the stomach;
- diarrhoea;
- flatulence;
- headache

Uncommon side effects (less than 1 out of 100 but equal or more than 1 out of 1,000 patients):
- nausea;
- vomiting
- irritation or inflammation of the gullet (oesophagus the tube that connects your mouth with your stomach) or stomach
- black or tar-like stools
- rash;
- itching;
- redness of the skin

Rare side effects (less than 1 out of 1000 but equal or more than 1 out of 10,000 patients):
- allergic reactions such as hives; swelling of the face, lips, tongue and/or throat, possibly causing difficulty breathing or swallowing
- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth
- stomach or peptic ulcers (sometimes severe or with bleeding)
- narrowing of the gullet (oesophagus the tube that connects your mouth with your stomach)
- jaw problems associated with delayed healing and infection, often following tooth extraction
- blurred vision, pain or redness in the eye
- rash made worse by sunlight
- severe bone, muscle and/or joint pain
- mouth ulcers when the tablets have been chewed or sucked
- transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment

Very rare side effects (less than 1 out of 10,000 patients):
- severe skin reactions

During post-marketing experience the following side effects

5. How to store Alendronic Acid Tablets

- Keep out of reach and sight of children.
- This medicinal product does not require any specia storage conditions
- Do not take the tablets after the 'EXP', which is clearly marked on the carton, and blister. The expiry date refers to the last day of that month.
- Medicine should not be disposed of via wastewate or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Alendronic Acid Tablets contains
The active substance is alendronic acid (as sodium alendronate).

Each tablet contains 70mg alendronic acid (as alendronate sodium)

The other ingredients are lactose anhydrous, cellulose microcrystalline (E460), croscarmellose sodium and magnesium stearate.

What Alendronic Acid Tablets looks like and content of the pack:
Alendronic Acid 70 mg Tablets are available as white to off-white, oval, biconvex tablet debossed with 'AHI' or one side and plain on other side.

Alendronic Acid 70 mg Tablets are available in OPA-Al-PVC/Al blister packs containing 4 or 12 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Accord Healthcare Limited
Sage House, 319 Pinner Road,
North Harrow, Middlesex
HA1 4HF,
UK

The leaflet was last approved in 11/2009

AMLODIPINE 5 mg AND 10 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

1 WHAT AMLODIPINE IS AND WHAT IT IS USED FOR

- Amlodipine belongs to a group of drugs called calcium-channel blockers. It relieves heart problems by widening blood vessels to allow more blood to flow through. This helps to reduce blood pressure and relieve the strain on the heart muscle.
- Amlodipine is used in the treatment of high blood pressure and angina, including the rare form, Prinzmetal's angina. Amlodipine does not provide immediate relief of chest pain from angina.

2 BEFORE YOU TAKE AMLODIPINE

Do NOT take Amlodipine:
- if you are allergic (hypersensitive) to Amlodipine besilate or any of the other ingredients of this medicine
- if you have severe low blood pressure
- if you are sensitive to any other calcium channel blockers e.g. nifedipine, felodipine
- if you are pregnant, trying to become pregnant, or breast-feeding
- if you suffer from unstable angina (excluding Prinzmetal's angina) or aortic stenosis (a narrowing of the main artery leading from the heart)
- if you have suffered a collapse of your blood circulation system (cardiogenic shock).

Take special care with Amlodipine
Tell your doctor before you start to take this medicine if you:
- have problems with your liver
- have had a heart attack within the last month
- suffer from heart failures
- have a hypertensive crisis (very high blood pressure)
- have kidney failure.

Children
Safety and effectiveness have been studied in 6-17 year old boys and in girls. Amlodipine has not been studied in children under the age of 6 years. For more information, talk to your doctor.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Amlodipine with food and drink
Amlodipine Tablets are for oral use and should be swallowed with a drink of water.

Pregnancy and breast-feeding
Do not take Amlodipine if you are pregnant, trying to become pregnant, or breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Amlodipine may cause dizziness, headache, fatigue and feeling sick. If you are affected, DO NOT drive or operate machinery.

3 HOW TO TAKE AMLODIPINE

Always take Amlodipine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dosage instructions are given below:

Adults (including the elderly)
The starting dose is one 5 mg tablet, once a day. This may be increased to a maximum of 10 mg (two 5 mg tablets or one 10 mg tablet) once a day.

Children
For children (6-17 years old), the recommended usual starting dose is 2.5 mg a day. The maximum recommended dose is 5 mg a day. Amlodipine 2.5 mg is not currently available and the 2.5 mg dose cannot be obtained with amlodopine 5 mg as these tablets are not manufactured to break into two equal halves.

If you take more Amlodipine than you should
If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause redness of the skin and low blood pressure (dizziness and fainting). Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Amlodipine
If you forget to take a tablet, take one as soon as your remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten tablet. Take your next dose at the usual time.

4 POSSIBLE SIDE EFFECTS

Like all medicines, Amlodipine can cause side effects, although not everybody gets them.

If you experience the following, stop taking Amlodipine and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Difficulty breathing and swelling of the lips, face and neck.

This is a very serious but very rare side effect, which affects fewer than one person in 10,000. You may need urgent medical attention or hospitalisation.

The following side effects have been reported at the approximate frequencies shown:

Common (affecting fewer than one person in 10 but more than one person in 100):
- Headache
- Water retention causing swelling
- Sleepiness, tiredness
- Abdominal pain, nausea
- Flushing
- Dizziness
- Palpitations.

Uncommon (affecting fewer than one person in 100 but more than one person in 1,000):
- Shortness of breath, fainting
- Indigestion, vomiting, dry mouth, altered bowel habit
- Difficulty sleeping, mood changes
- Impotence, breast enlargement in men
- Problems with urination including an increased need to urinate
- Changes to taste perception
- Low blood pressure
- Blocked or runny nose, sneezing
- Back, muscle or joint pain
- Rash, skin discoloration, increased sweating, itching
- Visual disturbances
- Ringing in the ears
- Loss of sensation, muscle cramps
- Shaking, generally feeling unwell, feeling of weakness
- Hair loss
- Weight increase or decrease
- Chest pain.

Very rare (affecting fewer than one person in 10,000):
- Unusual bleeding or unexplained bruising
- High level of blood sugar
- Inflammation of the blood vessels
- Coughing
- Enlarged gums
- Numbness or tingling in the hands and feet
- Abnormal liver function test results
- Hepatitis
- Jaundice (yellowing of the skin and whites of the eyes)
- Gastritis (inflammation of the stomach lining) causing abdominal pain.
- Low levels of white blood cells (increased risk of infection)
- Severe skin reaction.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 HOW TO STORE AMLODIPINE

Keep out of the reach and sight of children. Do not store above 25°C. Store in the original packaging. Keep the blister in the outer carton. Do not use Amlodipine after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month. Do not take these tablets if there are any signs of discolouration or deterioration of the tablets.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION

What Amlodipine contains:
- The active ingredient is amlodipine (as besilate).
- The other ingredients are microcrystalline cellulose, calcium hydrogen phosphate, sodium starch glycolate and magnesium stearate.

What Amlodipine looks like and contents of the pack:
- Amlodipine 5 mg Tablets are white, round, slightly arched tablets debossed AB 5 on one side, plain on the other side and are available in pack sizes of 15, 20, 28, 30, 50, 56, 84, 90, 98, 100, 112 and 300 tablets.
- Amlodipine 10 mg Tablets are white, round, slightly arched tablets, debossed AB 10 and breakline on one side, plain on the other side and are available in pack sizes of 14, 15, 20, 28, 30, 50, 56, 84, 90, 98, 100 and 112 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN22 9AG.

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PIL173

Information for the user

Aspirin 75 mg Enteric Coated Tablets

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to treat minor conditions. However, you still need to take it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice

What this medicine is for

This medicine belongs to a group of medicines called antiplatelet agents that help prevent blood cells sticking together.

It can be used to help prevent further heart attacks and strokes in patients who have had a history of these conditions. It can also be used after by-pass surgery.

It should not be used for pain relief.

Before you take this medicine

This medicine can be taken by adults aged 16 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.
If you are taking this medicine for the first time, talk to your doctor to make sure it is suitable for you.

Do not take:

- **If you are under 16 years old,** unless your doctor tells you to
- **If you are allergic** to any of the ingredients
- **If you have ever had a bad reaction** to aspirin or any other non-steroidal anti-inflammatory medicines (you have ever had asthma, swelling of the lips or face, itchy skin or runny nose after taking them)
- **If you have a stomach ulcer,** or have had one
- **If you have a blood clotting disorder** (e.g. haemophilia) or are taking medicines to thin your blood
- **If you have gout**
- **If you are pregnant or breastfeeding**

! Talk to your pharmacist or doctor:

- If you have asthma or other allergic disease
- If you have kidney or liver problems
- If you have high blood pressure (your doctor may want to monitor you more closely)
- If you are dehydrated
- If you have diabetes
- If you have a condition called glucose-6-phosphate dehydrogenase deficiency
- If you are elderly (your doctor may want to monitor you more closely)

Other important information

If you have surgery or any blood tests, tell your doctor or hospital staff that you are taking this medicine.

There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children under the age of 16 years unless on the advice of a doctor.

If you drink alcohol (wine, beer, spirits) when you are taking these tablets, it may make your stomach more sensitive to aspirin.

If you take other medicines

Before you take these tablets, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:

- Warfarin or other blood thinners
- Medicines for depression
- Methotrexate (for cancer, skin problems, rheumatic problems, Crohn's disease)
- Mifepristone (for termination of pregnancy) - do not take this medicine for 8 to 12 days after taking mifepristone
- Other non-steroidal anti-inflammatory medicines, including aspirin and ibuprofen (to relieve pain, reduce swollen joints, muscles and ligaments)
- Corticosteroids (used for many conditions such as pain, swelling, allergy, asthma, rheumatism and skin problems)
- Phenytoin and sodium valproate (for epilepsy)
- Tablets for diabetes (e.g. glibenclamide) or insulin
- ACE inhibitors (for high blood pressure)
- Water tablets (diuretics e.g. spironolactone and acetazolamide)
- Metoclopramide (for feeling sick or being sick)
- Probenecid and sulfinpyrazone (for gout)
- Sulphonamide antibiotics (e.g. co-trimoxazole)
- Zafirlukast (for asthma)
- Antacids (for indigestion) or adsorbents (e.g. kaolin for diarrhoea)

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

How to take this medicine

Check the foil is not broken before use.
If it is, do not take that tablet.

Age	How many to take	How often to take
Adults of 16 years and over	One or two	Once a day

In some cases your doctor may advise you to take more tablets. In this case follow your doctor's instructions.

Swallow the tablet whole with water. Do not cut, chew or crush the tablet.

Do not give to children under 16 years, unless your doctor tells you to.

Do not take more than the amount recommended above.

! If you take too many tablets: Talk to a doctor straight away.

Possible side effects

Most people will not have problems, but some may get some.

! If you get any of these serious side effects, stop taking the tablets. See a doctor at once:

- You are sick and it contains blood or dark particles that look like coffee grounds
- Pass blood in your stools or pass black tarry stools
- Difficulty in breathing, asthma, swelling of the face, neck, tongue or throat, runny nose (severe allergic reactions)
- Unusual bleeding which may cause blood in the urine, coughing up blood or a stroke due to bleeding in the brain

These other effects are less serious. If they bother you talk to a pharmacist:

- Other allergic reactions such as itchy skin or skin rash
- Feeling sick, being sick, heartburn, stomach irritation or pain
- Ringing in the ears
- Pain in your lower abdomen or back, difficulty in passing urine - this maybe a sign of kidney stones
- Nose bleeds (if a nose bleed is severe or lasts for a long time, talk to a doctor straight away)
- Feeling very tired or severely exhausted
- Unusual bruising or infections such as sore throats – this may be a sign of very rare changes in the blood

If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.

How to store this medicine

Do not store above 25°C.

Store in the original package.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the end flap of the carton.

What is in this medicine

Each gastro-resistant tablet contains Aspirin 75 mg, which is the active ingredient.

As well as the active ingredient, the tablets also contain potato starch, calcium hydrogen phosphate dihydrate (E341), microcrystalline cellulose (E460), talc (E553b), methacrylic acid-ethylacrylate – copolymer (containing sodium laurilsulfate, polysorbate 80), macrogol, simeticone.

The pack contains 56 white, circular tablets, plain on both sides.

Who makes this medicine

Manufactured for The Boots Company PLC Nottingham NG2 3AA by the Marketing Authorisation holder Bristol Laboratories Ltd Unit 3 Canalside Northbridge Road Berkhamsted HP4 1EG.

Leaflet prepared May 2009

If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA

PIL173

ASPIRIN 75 mg GASTRO-RESISTANT TABLETS

PATIENT INFORMATION LEAFLET

1 WHAT ASPIRIN 75 mg GASTRO-RESISTANT TABLETS ARE AND WHAT THEY ARE USED FOR

Your medicine is called Aspirin 75 mg Gastro-resistant Tablets (called Aspirin Tablets throughout the rest of this leaflet).

What this medicine does

Aspirin Tablets are used to reduce the likelihood of further heart attacks or strokes in patients with a previous history of these conditions, when taken regularly. They can also be taken following bypass surgery. Due to the slow release of Aspirin, this product is not useful for relieving acute pain.

Aspirin belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Aspirin thins the blood which helps to reduce the likelihood of having a heart attack.

These tablets have been specially coated (enteric coating) to help minimise stomach upset and feeling sick (sometimes experienced as side effects of these tablets – see Section 4 Possible side effects).

2 BEFORE YOU TAKE ASPIRIN TABLETS

There is a possible association between aspirin and Reye's Syndrome when given to children. Reye's syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor.

Do not take Aspirin Tablets if you:

- are allergic (hypersensitive) to aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen, or any of the other ingredients of Aspirin Tablets (see Section 6 What Aspirin Tablets contain). Symptoms may include rhinitis (runny nose), swollen face, mouth or tongue, itchy rash or asthma attack;
- have or have had a stomach ulcer;
- have a condition where your blood does not clot properly (e.g. haemophilia);
- are taking medicines to thin your blood such as warfarin;
- have or have had gout;
- are in the last 3 months of pregnancy or are breast-feeding.

Talk to your doctor or pharmacist if any of the following apply to you:

- if you have asthma, or suffer from allergies;
- if you have nasal polyps (inflamed swellings inside the nose)
- if you suffer from indigestion (dyspepsia)
- if you have an infection
- if you have problems with your heart, kidneys or liver;
- if you are dehydrated;
- if you have high blood pressure;
- if you have a lack of glucose 6-phosphate dehydrogenase (G6PD);
- if you are elderly
- if you are diabetic.

The product belongs to a group of medicines which may impair the fertility in women. This effect is reversible on stopping the medicine.

You should let your doctor know you are taking aspirin tablets, particularly if you are going to have an operation, as you may need to stop taking your tablets several days before the operation. Your blood, kidney and liver should be monitored during prolonged use of aspirin as blood, kidney and liver disorders may develop.

Using other medicines

Before using aspirin you should inform a healthcare professional about the medicines you

Make sure your doctor knows if you are taking a medicine listed here:

- **Alcohol:** some of the effects of aspirin are enhanced.
- **Mifepristone** (used to terminate pregnancy). You should not take aspirin until eight to twelve days after mifepristone. If taken with aspirin this medicine may not be as effective.
- **Non-steroidal anti-inflammatory (NSAIDs)** e.g. ibuprofen or diclofenac sodium (used for pain relief and to treat inflammation) or **Corticosteroids** e.g. prednisolone and betamethasone (used to treat allergy or inflammation): if taken with aspirin you may have more severe side effects e.g. increased risk of bleeding or ulcers in the stomach. If you suddenly stop taking corticosteroids you may develop aspirin poisoning.
- **Metoclopramide** (used to treat nausea and vomiting): it may increase the effect of aspirin.
- **Adsorbents** e.g. kaolin (for diarrhoea) and **Antacids** e.g. aluminium hydroxide and magnesium carbonate (used to treat indigestion): these medicines may reduce the effect of aspirin.
- **Medicines known to affect the clotting of your blood:** if you take one of these medicines below with aspirin you may increase the likelihood of bleeding.
  - Coumarins e.g. warfarin, phenindone, streptokinase or heparins (blood thinning medicines).
  - Clopidogrel and ticlopidine (used to prevent strokes and heart attacks).
- **Calcium channel blockers** such as verapamil, used to treat high blood pressure.
- **ACE Inhibitors or Angiotensin-II Receptor Antagonists** e.g. captopril, enalapril maleate, valsartan, losartan (used to lower high blood pressure): taken with aspirin these medicines may not be as effective and you may suffer from kidney problems.
- **Antidepressants (used to treat depression)** e.g. Selective Serotonin Re-uptake Inhibitors (SSRIs) (such as venlafaxine): if taken with aspirin you may increase the likelihood of bleeding.
- **Medicines to control epilepsy** e.g. phenytoin and valproate: aspirin may increase the effect of these medicines. If you take sodium valproate with aspirin you may increase the likelihood of bleeding.
- **Zafirlukast** (used to prevent or treat asthma).
- **Spironolactone** (diuretic) water tablets, **Probenicid** or **Sulfinpyrazone** (used to treat gout) and diuretics used to treat high blood pressure: if taken with aspirin these medicines may not be as effective. Phenylbutazone may reduce the effect of aspirin.
- **Methotrexate** (used in the treatment of rheumatoid arthritis, Crohn's disease and cancer) or **Carbonic anhydrase inhibitors** e.g. acetazolamide (used in the treatment of glaucoma, epilepsy and excess water retention): if taken with aspirin the side effects of these medicines may become more severe.
- **Thiopental** (used as an anaesthetic).
- **Gold compounds** (used to treat rheumatoid arthritis).
- **Insulin** and other drugs used to treat diabetes.
- **Sulphonamides**, such as sulphamethoxazole, used to treat infections.
- **Vitamin C.**
- **Cilostazol** (for leg pain that occurs when walking due to poor circulation): the dose of aspirin should not be greater than 80 mg a day.

Aspirin may affect the results of thyroid function tests.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant, thinking of becoming pregnant, or breast-feeding, ask your doctor or pharmacist for advice before taking Aspirin Tablets.

3 HOW TO TAKE ASPIRIN TABLETS

For oral use.

Consult a doctor before commencing therapy for the first time.

Follow the instructions on the label about how to take your medicine.
Check with your doctor or pharmacist if you are not sure.

Adults (including the elderly and children over 16 years)
The usual dose for long-term use is one or two tablets once daily.
The tablets should be swallowed whole with water. Do not chew, crush or break the tablets. In some circumstances your doctor may advise a higher dose of up to four tablets daily.
Take the tablets with or immediately after food to reduce the risk of getting stomach and bowel irritation.

Do not exceed the stated dose.

If symptoms persist for more than three days, consult your doctor.

Children and Adolescents
Aspirin should not be given to children aged under 16 years of age unless on the advice of a doctor.

If you take more Aspirin Tablets than you should
If you take more Aspirin Tablets than your doctor has prescribed contact your nearest hospital casualty department or doctor immediately. Take the medicine or this leaflet with you to show the doctor. Symptoms of an overdose include vomiting, dehydration, tinnitus, vertigo, headache, nausea, dizziness, restlessness, heart failure, breathing failure, deafness, sweating, warm extremities with racing pulse, increased breathing rate and hyperventilation.

If you forget to take Aspirin Tablets

- If you forget to take a dose, do not worry. Take the next dose when it is due.
- Do not take double the amount to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 POSSIBLE SIDE EFFECTS

Like all medicines, Aspirin Tablets can cause side effects, although not everybody gets them.
If you experience the following side effects while taking your medicine, you should stop taking your tablets and tell your doctor straight away:

- allergic reaction (hypersensitivity) which may include lumpy skin or hives, skin rash, swelling of eyelids, face, lips, mouth or tongue, or sudden wheeziness, or induce or worsen asthma attacks;
- you suffer from severe or persistent indigestion, stomach upset or pain, you may develop ulcers or bleeding from the stomach which can cause severe stomach pain, bloody or black tarry stools or vomiting blood.

Other possible side effects:

- stomach upset and feeling sick;
- an increased tendency to bleed;
- anaemia and other blood disorders;
- slight blood loss which may result in iron-deficiency anaemia during long term use;
- diarrhoea;
- blood in the urine;
- Stevens-Johnson syndrome (fever, rash sore mouth and eyes, joint and muscle aches);
- severe skin problem with shedding of the upper layer;
- mouth ulcers;
- you may succumb to infections more easily;
- you may bruise more easily.

Some patients have developed liver problems (particularly with high doses).
If any of the side effects get serious, or if you

5 HOW TO STORE ASPIRIN TABLETS

Keep out of the reach and sight of children.
Do not use after the expiry date stated on the label. Do not store above 25°C. Store in the original container in order to protect from moisture.
Do not use if you notice that the pack is damaged. Return it to your pharmacist.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION

What Aspirin Tablets contain
The active substance is aspirin. Each gastro-resistant tablet contains 75 mg of aspirin.
The other ingredients are potato starch, calcium hydrogen phosphate, microcrystalline cellulose, talc, methacrylic acid copolymer (also contains sodium lauryl sulphate and polysorbate), macrogol and simethicone.

What Aspirin Tablets look like and contents of the pack
Aspirin Gastro-resistant Tablets are white, circular tablets, which are plain on both sides. Each pack of Aspirin Gastro-resistant Tablets contains 28, 32, 56 or 84 tablets.
Packs of 32, 56 or 84 tablets are only available from your pharmacist. Not all pack sizes are marketed.

Marketing Authorisation Holder
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Manufacturer
CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Other formats
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product Name	Reference Number
Asprin 75mg Gastro-Resistant Tablets	29831/0014

This leaflet was last revised in November 2010

ALLIANCE

PATIENT INFORMATION LEAFLET

Atarax® Tablets

hydroxyzine hydrochloride

Read all of this leaflet carefully before you start taking this medicine
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

The information in this leaflet has been divided into the following sections:

1. What Atarax is and what it is taken for

Atarax belongs to a group of medicines called antihistamines (used to treat allergic reactions). It is used in adults and children to reduc itching caused by urticaria (nettle rash) and dermatitis (eczema).

Atarax is also used to treat anxiety in adults.

2. Check before you take Atarax

Do not take Atarax
- if you are allergic (hypersensitive) to hydroxyzine hydrochloride or any of the ingredients of Atarax (see Section 6 Further informatio
- if you are trying to become pregnant or are in the early stages of pregnancy.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Atarax.

Take special care with Atarax

Before you take Atarax tell your doctor if:
- you have kidney disease or are on dialysis
- you have difficulty passing water e.g. due to an enlarged prostate.

Your doctor will reduce your dose by about half if you have kidney disease.

If the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Atarax.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines as they may interfere with Atarax Atarax may increase the effects of these medicines:
- barbiturates such as sodium amytal or phenobarbitol, used to treat sleeping disorders and epilepsy
- other CNS depressants, these include: sedatives, tranquillisers, anti-anxiety medicines (such as diazepam and temazepam) and medicines that help you sleep (such as zolpidem, chlormethiazone and buspirone).

Please tell your doctor or pharmacist if you are taking or have recently taken/used any other medicines, including medicines obtained without a prescription.

Taking with food and drink

You should not take alcohol with Atarax because the sedative effects of the alcohol may be increased.

Pregnancy and breast-feeding

Do not take Atarax if you are pregnant, trying to become pregnant or breast-feeding. If you become pregnant whilst taking Atarax tell y doctor immediately.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Atarax may make you drowsy and make you feel less alert than usual for the first few days after you start taking it. If you are affected d not drive or operate machinery until this effect has worn off.

Important information about some of the ingredients of Atarax

Atarax contains lactose, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Atarax

Always take Atarax exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

The usual dose for each condition is given below:

For treating itching in adults and elderly

The starting dose is 25mg at night, your doctor may increase the dose up to 25mg three or four times daily.

For treating itching in children

The dose of Atarax depends on the age of the child:

Children aged 6 months to 6 years:

5mg to 15mg daily which your doctor may increase up to 50mg daily, taken throughout the day.

Children over 6 years:

15mg to 25mg daily which your doctor may increase up to 50mg -100mg daily, taken throughout the day.

For treating anxiety in adults

The dose is 50mg to 100mg four times a day.

For treating anxiety in children

Atarax is not suitable for treating anxiety in children.

For patients with kidney disease

Your doctor will reduce your dose by about half if you have kidney disease.

What to do if you take more Atarax than you should

You probably need not worry if you have taken an extra dose of Atarax by mistake, but if you, or someone else have taken a large overdo you should tell your doctor or contact the nearest accident and emergency department immediately. Show any leftover medicines or the empty packet to the doctor.

Atarax can cause considerable sedation that requires treatment. If any other medicines or substances have been taken at the same time a Atarax tell the medical staff carrying out the treatment of the overdose.

If you forget to take Atarax

If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Do not take a double dose. Then g on as before.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Do not worry. Like all medicines, Atarax can cause side effects, although not everyone gets them. Atarax can cause the following side effects in some people:
- drowsiness during the first few days of treatment, this usually disappears as treatment continues
- feeling giddy
- weakness
- headache
- confusion
- dryness of the mouth.

Rarely, you may suffer more serious side effects, tell your doctor immediately if you get any of the following:
- tremor (shakiness)
- convulsions (fits)
- you have difficulty passing water.

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Atarax

Keep out of the reach and sight of children.

Do not take Atarax after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longe required. These measures will help protect the environment.

6. Further information

What is in Atarax?

The active ingredient in this medicine is hydroxyzine hydrochloride.

The other ingredients are:

Calcium phosphate, lactose, magnesium stearate, maize starch, silicon dioxide and sodium lauryl sulphate.

The 10mg tablet coating contains Opadry® II Orange 85G23730. This is a mixture of Poly(vinyl alcohol), Talc, Macrogol 3350, Sunset yellow (E110), Titanium dioxide (E171), Iron oxide yellow (E172), Quinoline yellow (E102), Lecithin (E322).

The 25mg tablet coating contains Opadry® II Green 85G21674. This is a mixture of Poly(vinyl alcohol), Talc, Macrogol 3350, Quinoline yellow (E104), Titanium dioxide (E171), Brilliant blue (E133), Indigo carmine (E132), Lecithin (E322).

What Atarax looks like and contents of the pack

Atarax 10mg film-coated tablets are coloured orange imprinted with 'AX' on one side.

Atarax 25mg film-coated tablets are coloured green imprinted with 'AX' on one side.

Atarax tablets are supplied in blister packs contained in a carton. The 10mg tablet contains either 84 or 280 tablets and the 25mg tablet contains 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The product licence holder is: Alliance Pharmaceuticals Ltd, Avonbridge House, Chippenham, Wiltshire, SN15 2BB, UK.

Atarax is manufactured by: Recipharm Limited, Vale of Bardsley, Ashton-under-Lyne, Lancashire, OL7 9RR, UK.

The information in this leaflet applies only to Atarax. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

This leaflet was last approved: 29th September 2008.

P121

PACKAGE LEAFLET: INFORMATION FOR THE USER

Azathioprine 50mg Tablets

Azathioprine

Read this entire leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT AZATHIOPRINE 50MG TABLETS ARE AND WHAT THEY ARE USED FOR

Your medicine contains the active substance azathioprine which belongs to a group of medicines called immunosuppressants. This means that they reduce the strength of your immune system.

Immunosuppressant medicines are sometimes necessary to help your body accept an organ transplant, or to treat some diseases where your immune system is reacting against your own body (autoimmune diseases).

Azathioprine Tablets are used to:
- help your body accept a kidney, liver, heart, lung or pancreas transplant. (Azathioprine Tablets are usually used together with other medicines in order to enhance their effect).
- treat severe rheumatoid arthritis
- treat severe inflammation of the gut (Crohn's disease or ulcerative colitis)
- treat some diseases where your immune system is reacting against your own body (autoimmune diseases) including severe inflammatory diseases of the skin, liver, arteries and some blood disorders.

2. BEFORE YOU TAKE AZATHIOPRINE 50MG TABLETS

Do not take Azathioprine 50mg Tablets:
- If you are allergic (hypersensitive) to azathioprine or mercaptopurine
- If you are allergic to any of the other ingredients in the tablets (see section 6 'Further Information')
- If you have a severe infection
- If you have severe liver disease or severe bone marrow disease
- If you have an inflamed pancreas
- If you need or are going to have a vaccination such as BCG, smallpox or yellow fever vaccine
- If you are breast-feeding (see "Pregnancy and breast-feeding").

Take special care with Azathioprine 50mg Tablets
You should tell your doctor if any of the following apply to you:
- If you have or have ever had any liver or kidney problems
- If you have a condition where your body produces too little of a natural chemical called thiopurine methyltransferase (TPMT)
- If you have an infection for which you have not yet received treatment
- If you are pregnant or trying to become pregnant (see "Pregnancy and breast-feeding")
- If you are going to have an operation (this is because medicines including tubocurarine, pancuronium or succinylcholine used as muscle relaxants during operations may interact with your Azathioprine Tablets).
- If you have a rare genetic disorder called "Lesch-Nyhan syndrome".

You should take care to avoid too much sun (including sunbeds) whilst taking Azathioprine Tablets.

You must use contraceptive methods whilst taking these tablets and for up to 3 months after you have finished taking them. Suitable methods of contraception should be discussed with your doctor. Women using intra uterine devices (IUDs) should use additional contraceptive methods while taking Azathioprine Tablets.

Taking other medicines
Tell your doctor if you are taking or have taken any of the following medicines as they may interact with your Azathioprine Tablets:
- Allopurinol, oxipurinol or thiopurinol (used mainly to treat gout)
- Ciclosporin or tacrolimus (also used as immunosuppressant medicines)
- Infliximab (used to treat inflammation of the bowels [Crohn's disease])
- Olsalazine, mesalazine or sulfasalazine (used mainly to treat ulcers or chronic inflammation of the colon and anal passage)
- Warfarin or phenprocoumon (used to prevent blood clots)
- ACE-inhibitors (used to treat high blood pressure and heart failure)
- Furosemide (used mainly to treat high blood pressure)
- Trimethoprim/sulfamethoxazole (used to treat bacterial infections)
- Cimetidine (used to treat stomach ulcers and indigestion)
- Indometacin (used as a painkiller and to treat inflammation)
- Cytotoxic medicines - also called "chemotherapy" (used to treat cancer)
- Vaccines (such as hepatitis B vaccine)
- Tubocurarine, pancuronium or succinylcholine (used as muscle relaxants during operations)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal medicines.

Pregnancy and breast-feeding
Azathioprine Tablets should only be taken if your doctor thinks it is absolutely necessary. Tell your doctor if you are pregnant or think you may be pregnant.

Do not take the tablets if you are breast-feeding.

Driving and using machines
Studies on the effects of azathioprine on the ability to drive and use machines have not been performed. This product may cause dizziness, which could affect a patient's ability to drive.

3. HOW TO TAKE AZATHIOPRINE 50MG TABLETS

Always take Azathioprine Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The label on the carton will tell you how many tablets to take and when. The tablets should be swallowed whole with one full glass of water (about 200ml). Take your tablets during meals.

Your doctor will monitor how you respond to your medicine and may change your dose if required.

<u>After organ transplant</u>
A dose of 5mg per kilogram of your bodyweight per day may be given on the 1st day of your treatment. However, the usual maintenance dose is between 1 and 4mg per kilogram of your bodyweight per day. Your doctor may adjust this dose according to your body's response to your medicine.

<u>Patients with chronic active hepatitis</u>
The usual dose is between 1 and 1.5mg per kilogram of your bodyweight per day.

(front page)

Other conditions
The usual starting dose is between 1 and 3mg per kilogram of your bodyweight per day. Your doctor will adjust the dose until it is right for you.

Children and Adolescents
Where treatment is recommended, the dosage for children and adolescents is the same as the adult dose.

Elderly patients or patients with kidney or liver disease
A smaller adult dose may be required.

Whilst you are taking Azathioprine 50mg Tablets, your doctor will want you to have a complete blood test performed, at least once a week, during the first 8 weeks of treatment. After 8 weeks the frequency of the testing may be reduced and your doctor may ask you to repeat the complete blood test every month or at least at intervals of not longer than 3 months.

If you have taken more Azathioprine 50mg Tablets than you should
In the event of overdose the most likely effect is bone marrow suppression reaching its maximum 9-19 days after dosing. You may get a sore throat, fever or infection. You may also feel tired or experience bruising and bleeding. If you have taken too many tablets, contact your doctor or go the nearest hospital casualty department immediately. Remember to take the pack and any remaining tablets with you to show the doctor.

If you forget to take your Azathioprine 50mg Tablets
Do not take a double dose to make up for a forgotten tablet but wait and take your next dose at the usual time. If you have missed more than one dose, contact your doctor for advice.

If you stop taking Azathioprine 50mg Tablets
Do not stop taking your medicine unless the doctor tells you because stopping your medicine can make your condition worse.

If your doctor does not see an improvement in your condition within three to six months, your doctor may wish to gradually reduce your dose and finally stop giving you this medicine.

It is important that you stop your treatment gradually. You should stop taking the tablets slowly, over a period of time.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Azathioprine Tablets can cause side effects, although not everybody gets them.

You should tell your doctor immediately if you:
- **get any ulcers in the throat, fever, bruises or bleeding, or you think you have an infection.**
- **experience any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting the whole body).**

The following side effects have been reported. Tell your doctor if any of these side effects become troublesome:

Very common side effects (probably affecting more than 1 in 10 patients):
- infections (in kidney transplant patients)
- feeling and being sick (nausea and vomiting)
- reduction in number of white blood cells which makes infections more likely
- loss of appetite (anorexia).

Common side effects (probably affecting less than 1 in 10 patients):
- liver disease
- increased infections in patients with bowel inflammation
- reduction in blood platelets which increases risk of bleeding or bruising
- decrease in red blood cells in the blood (anaemia)
- inflammation of the pancreas, which causes severe pain in the abdomen and back.

Certain types of cancer (lymphomas, cancer of the cervix, vulva and skin (especially on areas of the skin exposed to the sun)) are common in patients after kidney transplant.

Uncommon side effects (probably affecting less than 1 in 100 patients):
- allergic reactions including dizziness or feeling unwell, low blood pressure, fever, feeling cold , feeling severely sick and vomiting, diarrhoea, rash, rigors, kidney problems, muscle pain (myalgia), pain in the joint (arthralgia), inflammation of blood vessels (vasculitis), high number of liver enzymes
- increased infections in patients suffering from rheumatoid arthritis
- blood disorder after transplant surgery
- foul smelling stools which are bulky, loose and greasy
- hair loss (alopecia).

Rare side effects (probably affecting less than 1 in 1000 patients):
- paleness or fatigue or feeling short of breath caused when the body's bone marrow is not producing enough blood cells (aplastic anaemia)
- cough and fever caused by pneumonia or inflammation of the lung
- stomach ulcer and disease which may cause heartburn, vomiting, general discomfort in the stomach.

Very rare side effects (probably affecting less than 1 in 10,000 patients):
- blood disorders (including acute myeloid leukaemia and myelo-dysplastic syndromes)
- very serious allergic reaction.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE AZATHIOPRINE 50MG TABLETS

Keep out of the sight and reach of children.

Do not use Azathioprine Tablets after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Azathioprine 50mg Tablets contain

The active substance is azathioprine. Each tablet contains 50mg of azathioprine.

The other ingredients are:
Tablet core: Microcrystalline cellulose, Mannitol, Maize starch, Povidone K25, Croscarmellose sodium, Sodium stearyl fumarate.
Tablet coat: Hypromellose, Macrogol 400.

What Azathioprine 50mg Tablets look like and contents of the pack

Azathioprine 50mg Tablets are light yellow, round, biconvex tablets, engraved with "AZA", a break line and "50" on one side and plain on the other.

Azathioprine 50mg Tablets are available in blister packs containing 50, 56 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:
Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom

Manufacturer:
Arrow Pharm (Malta) Limited, HF 62, Hal Far Industrial Estate, Birzebbugia BBG 06, Malta

This leaflet was last approved in 07/2008.

301782

(back page)

Benadryl PLUS CAPSULES

pseudoephedrine, acrivastine

- This medicine is used to relieve the symptoms of hay fever and similar allergic conditions.
- This medicine is for use by adults and children aged 12 - 65 years.
- **Do not take this medicine:**
  - There are some people who should not use this medicine. *See Section 2 to find out if you are one of them* ▸
  - If you have ever had a bad reaction to any of the ingredients. *See Section 6 for the list of ingredients* ▸
- **Speak to your doctor:**
  - If you suffer from any of the conditions mentioned in section 2. *See Section 2* ▸
  - If you are taking any other medicines. *See Section 2* ▸
- **Follow the dosage instructions carefully.** *See Section 3* ▸

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

1 What the medicine is for

Benadryl Plus Capsules is a medicine which is used to relieve the symptoms of hay fever and similar allergic conditions. The capsules contain pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion and acrivastine which is an antihistamine that helps relieve allergy symptoms such as sneezing, runny nose and watery eyes.

2 Before taking this medicine

This medicine is suitable for most adults under 65 years old and children aged 12 years and over. If you are in any doubt, talk to your doctor or pharmacist.

Do not take this medicine...

- If you have **very high blood pressure** or **severe heart disease**.
- If you have ever had a **bad reaction** to any of the ingredients, or to the antihistamine *triprolidine*.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- If you are taking the **antibacterial agent**, *furazolidone*.
- If you have **kidney problems**.

If any of these apply to you, **get advice from a doctor or pharmacist without taking Benadryl Plus Capsules**.

Talk to your doctor or pharmacist...

- If you have **high blood pressure** or **heart disease**.
- If you have **diabetes**.
- If you have an over active **thyroid gland**.
- If you have **glaucoma** (increased pressure in the eye).
- If you have **prostate problems** (difficulty with passing water or needing to pass water often).
- If you are taking **alcohol**.
- If you are taking any **other medicines**, including:
  - *Antihypertensives* (drugs to treat **high blood pressure**, such as *guanethidine, methyldopa, alpha* and *beta blockers, debrisoquine, bretylium* and *betanidine*).
  - *Sympathomimetic drugs* (*stimulants* or *appetite suppressants* and drugs used to treat **congestion** and **asthma**).
  - *Tricyclic antidepressants* (used to treat **mood disorders**).
  - *Sedatives* or *tranquillisers* (used to treat **anxiety** or **sleep disorders**).

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist**.

If you are pregnant or breast-feeding

- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

Special warnings about this medicine

- In most people this product does not cause drowsiness. However, there are rare exceptions and you should take care when you use this product for the first time. If this product makes you feel drowsy, do not drive or operate machinery.
- As with all antihistamines, it is advisable to avoid excessive alcohol consumption when taking this medicine.

Some of the ingredients can cause problems

- This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

turn over ▸

3 How to take this medicine

Check the table below to see how much medicine to take.

- For oral use only.

Children under 12 years old

This medicine is not recommended for children aged under 12 years old.

Adults and Children 12 - 65 years old

Age	Dose
Adults and children 12 - 65 years	**1 capsule** up to 3 times a day

- Do not take more than 3 doses in 24 hours.
- If symptoms persist talk to your doctor.

Adults over 65 years

This medicine is not recommended for adults aged over 65 years old.

If anyone has too much

If anyone has too much contact a doctor or your nearest Accident and Emergency Department (Casualty) taking this leaflet and pack with you.

If you forget to take the medicine

If you forget to take a dose, take the next dose when needed provided that you only take a maximum of 3 capsules in 24 hours. **Do not** take a double dose.

4 Possible side-effects

Benadryl Plus Capsules can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

If you experience the following, stop taking this medicine and talk to your doctor:

- A few people have had hallucinations, but this is rare.
- Occasionally people get skin rashes that are sometimes itchy.
- A few men, especially men with prostate problems, may have trouble passing water.

Other effects which may occur include:

- Restlessness, having trouble getting to sleep or bad dreams.

If you experience any side-effects not included in this leaflet or are not sure about anything, **talk to your doctor or pharmacist**.

5 Storing this medicine

Store below 25°C.

Keep the product dry and store in its original packaging.

Keep the product out of the reach and sight of children.

Do not use after the end of the month shown as an expiry date on the packaging.

6 Further Information

What's in this medicine?

The active ingredients in Benadryl Plus Capsules are: 60 mg Pseudoephedrine hydrochloride and 8 mg acrivastine in each capsule.

Other ingredients are: Lactose, sodium starch glycollate, magnesium stearate, gelatin, titanium dioxide and patent blue V.

What the medicine looks like

Benadryl Plus Capsules are blue and opaque-white capsules available in blister packs of 12 capsules.

Product Licence holder:

McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

Manufacturer:

Janssen Cilag S.A., Domaine de Maigremont, 27100 Val de Reuil, France.

This leaflet was revised September 2008.

Benadryl is a registered trade mark.

McNeil

Benylin®

Children's Chesty Coughs

2–12 years

guaifenesin

- This medicine is used to help relieve children's chesty coughs.
- This medicine is for use by children aged 2-12 years.
- **Do not use this medicine:**
  - There are some people who should not use this medicine. *To find out if your child is one of them see section 2* ►
  - If your child has ever had a **bad reaction** to any of the ingredients. *For the list of ingredients see section 6* ►
- **Speak to your doctor:**
  - If your child suffers from any of the conditions mentioned in section 2. *See section 2* ►
  - If you are taking any other medicines. *See section 2* ►
- **Follow the dosage instructions carefully.** Children of different ages need different amounts *See section 3* ►

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

1 What the medicine is for

Benylin Children's Chesty Coughs is a medicine which is used to help relieve chesty coughs in children. It contains guaifenesin (an expectorant) to help loosen mucus (phlegm) from the lungs and make it easier to cough up.

The medicine is for use in children aged 2-12 years.

2 Before giving this medicine to your child

This medicine is suitable for most children but a few children should not use it. If you are in any doubt, talk to your doctor or pharmacist.

Do not use this medicine...

- If your child has ever had a **bad reaction** to this product or any of the ingredients. See section 6 for full list of ingredients.
- If your child is taking **any other cough and cold medicine.**

If any of these apply, **get advice from a doctor or pharmacist without using Benylin Children's Chesty Coughs.**

Talk to your doctor or pharmacist...

- **If your child is under 6 years old.**
- If your child suffers from **liver** or **kidney problems**.
- If your child has had a **cough** for a few weeks that may be caused by **asthma**, or a cough which brings up a lot of mucus (phlegm).

If any of these apply now or in the past, **talk to a doctor or pharmacist.**

If you are pregnant or breast-feeding

The following advice is included in case an older child or adult is taking the medicine.

- If you are pregnant or breast-feeding, only use this medicine on the advice of your doctor.

Some of the ingredients can cause problems

- This medicine contains sorbitol liquid. This should be taken into account in patients with diabetes mellitus.
- This medicinal product contains 14.88 mg sodium per 5 ml. To be taken into consideration by patients on a controlled sodium diet.

3 How to use this medicine

Check the table below to see how much medicine to take.

- For oral use only.
- Do not give more than the stated dose shown below.

Children under two years old

This medicine is not recommended for children under 2 years old.

Children 2 - 12 years

Age	Dose
Children 2 – 5 years	**One 5 ml spoonful** four times a day.
Children 6 – 12 years	**Two 5 ml spoonfuls** four times a day.

- Do not give more than 4 doses in 24 hours.
- If symptoms persist, talk to your doctor or pharmacist.

If anyone has too much

If anyone has taken too much, contact a doctor or your nearest Accident and Emergency department (Casualty), taking this leaflet and pack with you.

If you forget to give the medicine

You should only give this medicine as required following the dosage instructions above carefully. If you forget to give a dose, give the next dose when needed. **Do not** give a double dose.

turn over ►

4 Possible side-effects

Benylin Children's Chesty Coughs can have side-effects, like all medicines, although these don't affec everyone and are usually mild.

If you experience any side-effects or are not sure about anything, **talk to your doctor or pharmacis**

5 Storing this medicine

Do not store this product above 25°C.
Store in the original package.

Keep the product out of the reach and sight of children

Do not use after the end of the month shown as an expiry date on the packaging.

6 Further information

What's in this medicine?

The active ingredient in 5 ml of Benylin Children's Chesty Coughs is: 50 mg Guaifenesin.

Other ingredients are: Glycerol, sorbitol liquid (E420), carmellose sodium, sodium citrate, sodium saccharin, sodium benzoate (E211), citric acid monohydrate, strawberry flavour and water.

What the medicine looks like

Benylin Children's Chesty Coughs is a clear colourles syrup, available in 125 ml, glass bottles.

Product Licence holder: McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

Manufacturer: McNeil Manufacturing, 5 avenue de Concyr, 45071 Orleans, Cedex 2, France.

This leaflet was revised April 2008.

Benylin is a registered trade mark.

Package Leaflet: Information for the User

Buscopan® Tablets

(hyoscine butylbromide)

Boehringer Ingelheim

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT BUSCOPAN TABLETS ARE AND WHAT THEY ARE USED FOR

BUSCOPAN Tablets contain a medicine called "hyoscine butylbromide". This belongs to a group of medicines called "antispasmodics".

BUSCOPAN Tablets are used to relieve cramps in the muscles of your:
- Stomach
- Gut (intestine)
- Bladder and the tubes that lead to the outside of your body (urinary system)

It can also be used to relieve the symptoms of Irritable Bowel Syndrome (IBS).

2. BEFORE YOU TAKE BUSCOPAN TABLETS

Do not take BUSCOPAN Tablets if:
- You are allergic (hypersensitive) to hyoscine butylbromide or any of the other ingredients (listed in section 6)
- You have glaucoma (an eye problem)
- You have megacolon (a very enlarged bowel)
- You have something called "myasthenia gravis" (a very rare muscle weakness problem)
- You are pregnant, likely to get pregnant, or are breast-feeding

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Take special care with BUSCOPAN Tablets
Check with your doctor or pharmacist before taking your medicine if:
- You have a very fast heart rate or other heart problems
- You have a problem with your thyroid gland such as an overactive thyroid gland
- You have difficulty or pain passing water (urine) such as men with prostate problems
- You have constipation
- You have a fever

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking BUSCOPAN Tablets.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because BUSCOPAN Tablets can affect the way some other medicines work. Also some other medicines can affect the way BUSCOPAN Tablets work.

In particular, tell your doctor or pharmacist if you are taking any of the following:
- Medicines for depression called "tricyclic antidepressants" such as doxepin
- Medicines for allergies and travel sickness called "antihistamines"
- Medicines to control your heart beat such as quinidine or disopyramide
- Medicines for severe mental illness such as haloperidol or fluphenazine
- Medicines for breathing problems such as tiotropium and ipratropium
- Amantadine - for Parkinson's disease and flu
- Metoclopramide - for feeling sick (nausea)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking BUSCOPAN Tablets.

Pregnancy and breast-feeding
Do not take BUSCOPAN Tablets if you are pregnant, likely to get pregnant or are breast-feeding.

Driving and using machines
Some people may have sight problems while taking this medicine. If this happens to you, wait until your sight returns to normal before driving or using any tools or machines.

(front page)

Important information about some of the ingredients of BUSCOPAN Tablets
BUSCOPAN Tablets contain sucrose. Talk to your doctor before taking this medicine if they have told you that you cannot tolerate or digest some sugars.

3. HOW TO TAKE BUSCOPAN TABLETS
Always take your medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine
- Take your tablets with water
- Do not break, crush or chew the tablets

How much to take
Adults and children over 12 years
- The usual dose is two tablets 4 times a day
- For Irritable Bowel Syndrome, your doctor may give you a lower starting dose of one tablet 3 times a day. This dose may be increased, if further relief is necessary

Children 6 - 12 years:
- The usual dose is one tablet 3 times a day

BUSCOPAN Tablets are not recommended for children under 6 years.

If you take more BUSCOPAN Tablets than you should
If you take more BUSCOPAN Tablets than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you even if there are no BUSCOPAN Tablets left.

If you forget to take BUSCOPAN Tablets
- If you forget a dose, take it as soon as you remember. However, if it is time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS
Like all medicines, BUSCOPAN Tablets can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Stop taking your medicine and see a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:
- Allergic reactions such as skin rash (affects fewer than 1 in 100 people) and itching
- Severe allergic reactions (anaphylactic shock) such as difficulty breathing, feeling faint or dizzy (shock)
- Painful red eye with loss of vision

Other side effects
- Dry mouth (affects fewer than 1 in 100 people)
- Making less sweat than usual (affects fewer than 1 in 100 people)
- Increased heart rate (affects fewer than 1 in 100 people)
- Being unable to pass water (urine) (affects fewer than 1 in 1,000 people)

If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

5. HOW TO STORE BUSCOPAN TABLETS
- Do not take this medicine after the expiry date which is printed on the packaging
- BUSCOPAN Tablets should be protected from light and stored in a dry place below 25°C
- Keep this medicine out of the sight and reach of children

6. FURTHER INFORMATION

What BUSCOPAN Tablets contain
Each tablet contains 10 mg of the active ingredient hyoscine butylbromide.

The other ingredients are: calcium hydrogen phosphate, maize starch, soluble starch, colloidal silica, tartaric acid, stearic acid, sucrose, talc, acacia, titanium dioxide, macrogol 6000, carnauba wax, white beeswax and povidone.

What BUSCOPAN Tablets look like and contents of the pack
BUSCOPAN Tablets are sugar-coated, round and white in colour.

BUSCOPAN Tablets are available in blister packs of 56 tablets.

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation is held by:

Boehringer Ingelheim Limited,
Ellesfield Avenue,
Bracknell, Berkshire,
RG12 8YS, United Kingdom.

and the tablets are manufactured by:

Delpharm Reims S.A.S.
10 Rue Colonel Charbonneaux
51100 Reims
France

This leaflet was revised in October 2009.

20080218

(back page)

Package leaflet: Information for the user

BuTrans® 5 micrograms/hour transdermal patches
BuTrans® 10 micrograms/hour transdermal patches
BuTrans® 20 micrograms/hour transdermal patches

Buprenorphine

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What *BuTrans* patches are and what they are used for

BuTrans patches contain the active ingredient buprenorphine which belongs to a group of medicines called strong analgesics or 'painkillers'. They have been prescribed for you by your doctor to relieve moderate, long-lasting pain that requires the use of a strong painkiller.

BuTrans patches should not be used to relieve acute pain.

BuTrans patches act through the skin. After application, buprenorphine passes through the skin into the blood. Each patch lasts for seven days.

2. Before you use *BuTrans* patches

Do not use *BuTrans* patches:
- if you are allergic (hypersensitive) to buprenorphine or any of the other ingredients of ***BuTrans*** patches;
- if you have breathing problems;
- if you are addicted to drugs;
- if you are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromide, phenelzine, isocarboxazid, moclobamide and linezolid), or you have taken this type of medicine in the last two weeks;
- if you suffer from myasthenia gravis (a condition in which the muscles become weak);
- if you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking alcohol.

BuTrans patches must not be used to treat symptoms associated with drug withdrawal.

Take special care with *BuTrans* patches

Before treatment with ***BuTrans*** patches tell your doctor or pharmacist:
- if you suffer from seizures, fits or convulsions;
- if you have a severe headache or feel sick due to a head injury or increased pressure in your skull (for instance due to brain disease). This is because the patches may make symptoms worse or hide the extent of a head injury;
- if you are feeling light-headed or faint;
- if you have severe liver problems;
- if you have ever been addicted to drugs;
- if you have a high temperature, as this may lead to larger quantities of the active ingredient being absorbed into the blood than normal.

If you have recently had an operation, please speak to your doctor before using these patches.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you use ***BuTrans*** patches with some other medicines, the effect of ***BuTrans*** patches or the other medicine may be changed.
- ***BuTrans*** patches must not be used together with a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromide, phenelzine, isocarboxazid, moclobamide and linezolid), or if you have taken this type of medicine in the last two weeks.
- If you take some medicines such as phenobarbital or phenytoin (medicines commonly used to treat seizures, fits or convulsions), carbamazepine (a medicine to treat seizures, fits or convulsions and certain pain conditions), or rifampicin (a medicine to treat tuberculosis) the effects of ***BuTrans*** patches may be reduced.
- ***BuTrans*** patches may make some people feel drowsy, sick or faint or make them breathe more slowly or weakly. These side effects may be made worse if other medicines that produce the same effects are taken at the same time. These include certain medicines to treat depression, anxiety, psychiatric or mental disorders, medicines to help you sleep, medicines to treat high blood pressure such as clonidine, other opioids (which may be found in painkillers or certain cough mixtures e.g. morphine, dextropropoxyphene, codeine, dextromethorphan, noscapine), antihistamines which make you drowsy, or anaesthetics such as halothane.
- ***BuTrans*** patches must not be used together with benzodiazepines (medicines used to treat anxiety or to help you sleep). This combination may cause serious breathing problems which may be fatal.

6. Further information

What *BuTrans* patches contain

The active ingredient is buprenorphine.

BuTrans 5 microgram/hour transdermal patch
Each transdermal patch contains 5 mg of buprenorphine in a patch size of 6.25 cm^2 and releases about 5 micrograms of buprenorphine per hour (over a period of 7 days).

BuTrans 10 microgram/hour transdermal patch
Each transdermal patch contains 10 mg of buprenorphine in a patch size of 12.5 cm^2 and releases about 10 micrograms of buprenorphine per hour (over a period of 7 days).

BuTrans 20 microgram/hour transdermal patch
Each transdermal patch contains 20 mg of buprenorphine in a patch size of 25 cm^2 and releases about 20 micrograms of buprenorphine per hour (over a period of 7 days).

The other ingredients are:
- Polyacrylate (Durotak 387-2051 & 387-2054)
- Levulinic acid
- Oleyl oleate
- Povidone
- Polyethyleneterephthalate

What *BuTrans* patches look like and contents of the pack

Transdermal patch

Three sizes are available.

5 micrograms/hour: square, beige coloured patch with rounded corners marked ***BuTrans*** 5 µg/h

10 micrograms/hour: rectangular, beige coloured patch with rounded corners marked ***BuTrans*** 10 µg/h

20 micrograms/hour: square, beige coloured patch with rounded corners marked ***BuTrans*** 20 µg/h

BuTrans patches are available in cartons containing 2 or 4 pouches each containing a single patch.

Marketing Authorisation Holder and Manufacturer

Bard Pharmaceuticals Limited is the registered manufacturer for the marketing authorisation holder Napp Pharmaceuticals Limited, both at Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	*Norspan*®
Belgium	*Norspan*®
Czech Republic	*Norspan*®
Denmark	*Norspan*®
Estonia	*Norspan*®
Finland	*Norspan*®
Germany	*Norspan*®
Hungary	*Norspan*®
Iceland	*Norspan*®
Latvia	*Norspan*®
Lithuania	*Norspan*®
Luxembourg	*Norspan*®
Netherlands	*BuTrans*®
Norway	*Norspan*®
Poland	*Norspan*®
Portugal	*Norspan*®
Republic of Ireland	*BuTrans*®
Slovak Republic	*Norspan*®
Sweden	*Norspan*®
United Kingdom	*BuTrans*®

For UK only:

This leaflet is also available in large print, Braille or as an audio CD.
To request a copy, please call the RNIB Medicine Information line (free of charge) on:

0800 198 5000

You will need to give details of the product name and reference number. These are as follows:
Product name: BuTrans patches
Reference number: 16950/0136

This leaflet was last revised in January 2009

You can also get support and information about arthritis from Arthritis Care:
Phone free: 0808 800 4050 12pm to 4pm Monday to Friday
(or 020 7380 6555 10am to 4pm standard call charges apply).
Or write to: Helplines, Arthritis Care, 18 Stephenson Way, London, NW1 2HD.
Or email helplines@arthritiscare.org.uk

NAPP

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Cefalexin Capsules 250mg
Cefalexin Capsules 500mg
(cefalexin)

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. WHAT CEFALEXIN CAPSULES ARE AND WHAT THEY ARE USED FOR

Cefalexin Capsules contain cefalexin as the active ingredient, which belongs to a class of antibiotics called 'cephalosporins'. The capsules are used to treat a variety of bacterial infections. These include infections of the airways from nose to lungs, ear, bones and joints, and urine or reproduction systems, including inflammation of the prostate gland. They are also used to treat dental infections.

2. BEFORE YOU TAKE CEFALEXIN CAPSULES

Do not take Cefalexin Capsules if you have:
- an allergy (hypersensitivity) to the cephalosporin or penicillin group of antibiotics, or to any of the ingredients in the product *(see Section 6)*.
- porphyria; a hereditary metabolic disorder.

Take special care with Cefalexin Capsules if you have:
- kidney problems
- inflammation of the large intestine, symptoms include: diarrhoea, pain and fever.

You should be aware that Cefalexin Capsules may give a false result for:
- certain blood tests
- tests for glucose in the urine.

Taking other medicines
Please inform your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription.
In particular, tell your doctor if you are taking any of the following:
- other antibiotics, especially amphotericin, capreomycin, vancomycin, or an aminoglycoside –a broad spectrum antibiotic (for example, gentamicin or neomycin)
- diuretics (water tablets) such as furosemide, bumetanide or probenecid for gout.

Taking Cefalexin Capsules with food and drink
These capsules may be taken before, during or after your meals.

Pregnancy and breast-feeding
Ask your doctor for advice before taking any medicine if you are pregnant or planning to become pregnant.
Cefalexin passes into breast milk, so tell your doctor if you are breast-feeding.

Driving and using machines
Cefalexin Capsules are not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Cefalexin Capsules
Lactose - if you know you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE CEFALEXIN CAPSULES

The doctor will decide on the most appropriate dose for you, based on the nature and severity of your infection. The label will tell you how many capsules you need to take as well as how often to take them.

Swallow the Capsules whole with water.

Adults: The usual dose is 500mg every 8 hours, although your doctor may tell you to take 1g to 4g a day, split up into smaller doses.

Elderly: You should take the normal adult dose, unless you have severe kidney problems, when the maximum daily dose will be 500mg.

Children over 5 years: Your doctor will calculate the correct dose, depending on the child's weight. The usual daily dose is 250mg to 500mg for each kilogram of their weight, and is usually split up into smaller amounts taken every 8 or 12 hours. If your child is taking Cefalexin Capsules for ear infections, he or she may have to take 75mg to 100mg for each kilogram of their weight, split up into smaller doses throughout the day.

This medicine is not recommended for use in children under 5 years of age.

Use all the capsules your doctor has given you. **Do not stop taking** them, even if you feel better

If you take more Cefalexin Capsules than you should
Contact your doctor or nearest hospital casualty department immediately for advice if you or a child have swallowed too many capsules. Take this leaflet, the pack or any capsules with you, if you can.

If you forget to take Cefalexin Capsules
If you miss a dose, take it as soon as you remember. If it is almost time to take the next dose, skip the missed dose and carry on as before. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cefalexin Capsules can cause side effects, although not everyone gets them.

Tell your doctor at once if you notice any of these rare side effects:
- rash, fever, itchy skin, swelling of the lips, eyes, tongue, or difficulty in breathing normally are signs of an **allergic reaction. Stop taking the capsules immediately.**
- flaky skin, red or purple inflamed skin patches; pus in your eyes; blisters in your nose or mouth.
- blood disorders (if you bruise more easily, have a sore throat, fever or a chill).
- lower gut pain, nausea, vomiting, severe diarrhoea containing blood or mucus. Colitis (inflammation of the colon) can also occur during or after treatment.
- liver damage, for example jaundice (yellowing of the skin and whites of eyes).
- nephritis (inflamed kidneys).

Tell your doctor if you suffer from any of the following for more than a few days:
- feeling or being sick, heartburn, stomach pain, diarrhoea
- skin rashes
- dizziness, tiredness, headache, sleep disorders,nervousness
- feeling confused or agitated, hallucinations, extreme restlessness
- painful or swollen joints, extreme muscle tension
- itching around the anus or genitals, inflamed vagina, discharge from the vagina.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE CEFALEXIN CAPSULES

Keep out of the reach and sight of children.

Do not store above 25°C.

Store Cefalexin Capsules in their original package and keep containers tightly closed.

Do not use the capsules after the expiry 'EXP' date which is printed on the carton (the expiry date refers to the last day of the month stated).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Cefalexin Capsules contain
The **active** ingredient is cefalexin, 250mg or 500mg.
The **other** ingredients are lactose, magnesium stearate. The capsule shell contains black iron oxide (E172), titanium dioxide (E171), erythrosin (E127), quinoline yellow (E104) and gelatin.

What Cefalexin Capsules look like and contents of the pack
Cefalexin Capsules are grey/orange capsule containing white powder and printed with 'CHX 250' (250mg) or 'CHX 500' (500mg).
They are available in blisters pack of 7, 14, 20, 21, 28, 30, 50, 56, 60, 100, or 500 capsules (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Milpharm Limited
Ares, Odyssey Business Park,
West End Road,
South Ruislip HA4 6QD,
United Kingdom.

Manufacturers:
Milpharm Limited
Ares, Odyssey Business Park,
West End Road,
South Ruislip HA4 6QD,
United Kingdom.

APL Swift Services (Malta) Ltd.,
Hf26, Hal Far Industrial Estate,
Hal Far, Birzebbugia, BBG 3000.

This leaflet was last approved in {10/2009}

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Celluvisc® 0.5% w/v, Eye drops, solution, unit dose

(carmellose sodium)

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to use Celluvisc carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicines is Celluvisc 0.5% w/v, Eye drops, solution, unit dose but will be referred to as Celluvisc throughout the remainder of the leaflet.

In this leaflet:

1. What Celluvisc is and what it is used for

Celluvisc is a tear substitute and contains the lubricant called carmellose sodium. It is used for the treatment of the symptoms of dry eye (such as soreness, burning, irritation or dryness) caused by your eye not producing enough tears to keep the eye wet.

2. Before you use Celluvisc

Do not use Celluvisc

- If you are hypersensitive (allergic) to carmellose sodium or any of the other ingredients of Celluvisc. These are listed at the end of this leaflet in section 6 "Further information".

Take special care with Celluvisc

- If irritation, pain, redness or changes in vision occur or if you feel your condition is getting worse, stop taking this medicine and consult your doctor or pharmacist.

Using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are using other eye drops, leave at least 15 minutes between putting in the other drops and Celluvisc.

Pregnancy and breast-feeding
Celluvisc can be used during pregnancy and breast-feeding.

Driving and using machines
Celluvisc is not expected to cause blurred vision. If you do experience temporary blurring, do not drive or use machines until your sight is clear.

Read all the information in this leaflet for guidance.
Discuss with your doctor, nurse or pharmacist if you are unsure about anything.

3. How to use Celluvisc

Follow these instructions unless the pharmacist or your doctor gave you different advice.
The usual dose is 1-2 drops of Celluvisc in the affected eye/each affected eye, 4 times a day as needed.
You do not need to remove contact lenses before using Celluvisc.
Make sure that the single-dose container is intact before use. The solution should be used immediately after opening. To avoid contamination, do not let the open-end of the single-dose container touch your eye or anything else. Wash your hands before use.

1. Tear one single-dose container from the strip.

2. Hold the single-dose container upright (with the cap uppermost) and twist off the cap.

3. Gently pull down the lower eyelid to form a pocket. Turn the single-dose container upside down and squeeze it to release one drop into each eye. Blink your eyes a few times.

Do not re-use the single-dose container even if there is some solution left.

If you use more Celluvisc than you should, it will not cause you any harm. If you are worried, talk to your doctor or pharmacist.

If you forget to use Celluvisc, use a single drop in each eye that needs treatment as soon as you remember, and then go back to your regular routine. Do not take a double dose to make up for forgotten individual doses.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Celluvisc can cause side effects, although not everybody gets them.

Common side effects (occuring in between 1 and 10 patients in every 100) are:
Irritation of the eye

Uncommon side effects (occuring in between 1 and 10 patients in every 1,000) are:
Pain/stinging of the eye, blurred vision, eye watering and redness of the eye/eyelid.

If this side effect gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Celluvisc

Keep out of the reach and sight of children
Do not store above 25°C
Do not use Celluvisc after the expiry date stated on the labels and carton. The expiry date refers to the last day of that month.
If the medicine shows any signs of discolouration or deterioration consult your pharmacist for advice.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Celluvisc contains
Each 1ml contains 5mg carmellose sodium
The other ingredients are sodium chloride, sodium lactate, potassium chloride, calcium chloride, magnesium chloride and purified water

The ingredients in Celluvisc were designed to match your natural tear composition.

What Celluvisc looks like and contents of the pack
Celluvisc is a clear, colourless to pale yellow solution in a small, plastic and see-through (bubble-like) casing (known as a single-dose container).

The single dose container has a twist-off cap. Each single-dose container contains 0.4ml of eye drops solution.
Each pack contains 30 or 90 single dose containers.

PL 20774/1159 Celluvisc 0.5% w/v, Eye drops, solution, unit dose

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Manufactured by Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, Co. Mayo, Ireland. Procured from within the EU. Product Licence Holder: Quadrant Pharmaceuticals Ltd, Lynstock House, Lynstock Way, Lostock, Bolton, BL6 4SA. Repackaged by Maxearn Ltd, Bolton, BL6 4SA.

Leaflet Revision date: 1st July 2011

Celluvisc is a registered trademark of Allergan Inc.

PP1/1159/V4

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- **Very common** (occurs in more than 1 in 10 users): feeling sick, dry mouth, sleepiness, difficulty in sleeping, problems sleeping, tiredness, increased sweating.
- **Common** (occurs in less than 1 in 10 users): tingling (pins and needles), anxiety, agitation, nervousness, problems with concentration, confusion, ringing in the ears, abnormal dreams, yawning, shakiness of the arms and legs, dizziness, weakness, loss of appetite, weight loss, vomiting, diarrhoea, constipation, impotence and problems with ejaculation, reduced libido, problems in reaching orgasm (women), rash, muscle and joint pain.
- **Uncommon** (occurs in less than 1 in 100 users): aggression, false sense of wellbeing, irregular heart beats/pulse rate, hallucinations (seeing things, hearing things or feelings that are not there), mania, feeling of unreality, sensitivity to sunlight, slow heart rate, fainting, visual disturbances, fast heart rate, increase in appetite, increase in weight, problems with passing water, passing water frequently, period pains, hair loss, itching.
- **Rare** (occurs in less than 1 in 1,000 users): bleeding (in the skin, bruising, stomach and from the vagina), changes in the salt balance in your body, abnormalities of taste, jerky movements, fits, fever.
- **Not known:** bone fractures, abnormalities of vision, feeling faint after standing, changes in liver function, production of breast milk in men, psychomotor restlessness, panic attacks, thoughts of suicide and suicidal behaviour (see: 'section 2'). The syndrome of inappropriate anti-diuretic hormone secretion (SIADH, symptoms are confusion, hallucinations, drowsiness, fits, coma and breathing difficulties).

If you notice any side effects, they get worse, or if you notice any not listed, please tell your doctor or pharmacist.

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5 How to store

Keep out of the reach and sight of children.
No special precautions for storage.
Do not use Citalopram tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Citalopram tablets contain

- The active substance (the ingredient that makes the tablet work) is citalopram (as hydrobromide). Each tablet contains either 10mg, 20mg or 40mg of the active ingredient.
- The other ingredients are mannitol (E421), microcrystalline cellulose (E460), colloidal silica anhydrous, magnesium stearate. The film-coat contains hypromellose (E464), macrogol, titanium dioxide (E171).

What Citalopram tablets look like and contents of the pack

Citalopram tablets are round, white film-coated tablets.
Pack size of 28.

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK

Date of revision: July 2010

actavis

Actavis, Barnstaple, EX32 8NS, UK

Citalopram 10mg, 20mg and 40mg tablets

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Index

1 What Citalopram tablets are and what they are used for

Citalopram is one of a type of antidepressants known as Selective Serotonin Re-uptake Inhibitors (SSRIs). It increases the effects of the body's naturally occurring hormone, serotonin, by inhibiting its re-uptake in the nerve cells.
Citalopram is used to treat major episodes of depression.

2 Before you take

Do not take Citalopram tablets and **tell** your doctor if you:

- are **allergic** (hypersensitive) to citalopram or any of the other ingredients (see section 6).
- are taking, or have taken within the last two weeks, any **monoamine oxidase inhibitors** (MAO- inhibitors). These are medicines used depression or Parkinson's disease (e.g. selegiline or moclobemide).
- are taking **pimozide** (an antipsychotic medicine) or linezolide (an antibiotic).

Check with your doctor or pharmacist before taking Citalopram tablets if you:

- suffer from **mania** (great excitement, hallucinations, difficulty in concentrating or staying still).
- suffer from any **mental illnesses** such as depression and panic attacks.
- are **diabetic**.
- suffer from **epilepsy**. If you start having more fits than usual stop taking citalopram and see your doctor immediately.
- suffer from **liver** damage or liver disease.
- suffer from **severe kidney** disease.
- suffer from **heart** problems or an abnormal heart rhythm.
- are having electro-convulsive therapy (**ECT**).
- have a history of **bleeding disorders**.
- are taking herbal products containing **St. John's wort** (hypericum perforatum) used to treat depression.
- are taking **sumatriptan** or **other triptans** (for migraines), **oxitriptan** or **tryptophan** (substances that may influence the level of serotonin in the brain) or **tramadol** (to treat moderate to severe pain).

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Especially:

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Dexcel® pharma

PACKAGE LEAFLET: INFORMATION FOR THE USEF

CLOPIDOGREL 75 mg FILM-COATED TABLETS

Clopidogrel

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT CLOPIDOGREL TABLETS ARE AND WHAT THEY ARE USED FOR

Clopidogrel Tablets belong to a group of medicines called antiplatelet medicinal products. Platelets are very small structures in the blood, smaller than red or white blood cells, which clump together during blood clotting By preventing this clumping, antiplatelet medicinal products reduce the chances of blood clots forming (a process called thrombosis).

Clopidogrel Tablets are taken to prevent blood clots (thrombi) forming in hardened blood vessels (arteries), a process known as atherothrombosis, which can lead to atherothrombotic events (such as stroke, heart attack, or death).

You have been prescribed Clopidogrel Tablets to help prevent blood clots and reduce the risk of these severe events because:
- You have a condition of hardening of arteries (also known as atherosclerosis), and
- You have previously experienced a heart attack, stroke or have a condition known as peripheral arterial disease

Clopidogrel which is contained in Clopidogrel Tablets may also be authorised to treat other conditions which are not mentioned in this leaflet. Ask your doctor or pharmacist if you have further questions.

2. BEFORE YOU TAKE CLOPIDOGREL TABLETS

Do not take Clopidogrel Tablets:
- If you are allergic (hypersensitive) to clopidogrel or any of the other ingredients of Clopidogrel Tablets (listed in section 6 'What Clopidogrel Tablets contain')
- If you have a medical condition that is currently causing bleeding such as a stomach ulcer or bleeding within the brain
- If you suffer from severe liver disease

If you think any of these apply to you, or if you are in any doubt at all, consult your doctor before taking Clopidogrel Tablets.

Take special care with Clopidogrel Tablets:
If any of the situations mentioned below apply to you, you should tell your doctor before taking Clopidogrel Tablets:
- if you have a risk of bleeding such as
  - a medical condition that puts you at risk of internal bleeding (such as a stomach ulcer)
  - a blood disorder that makes you prone to internal bleeding (bleeding inside any tissues, organs or joints of your body)
  - a recent serious injury
  - a recent surgery (including dental)
  - a planned surgery (including dental) in the next seven days
- if you have had a clot in an artery of your brain (ischemic stroke) which occurred within the last seven days
- if you are taking another type of medicine (see 'Taking other medicines')
- if you have kidney or liver disease

While you are taking Clopidogrel Tablets:
- You should tell your doctor if a surgery (including dental) is planned
- You should also tell your doctor immediately if you develop a medical condition that includes fever and bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness confusion, yellowing of the skin or eyes (jaundice) (see section 4 'POSSIBLE SIDE EFFECTS')
- If you cut or injure yourself, it may take longer than usual for bleeding to stop. This is linked to the way you medicine works as it prevents the ability of blood clots to form. For minor cuts and injuries e.g., cutting yourself, shaving, this is usually of no concern. However, if you are concerned by your bleeding, you should contact your doctor straightaway (see section 4 'POSSIBLE SIDE EFFECTS')
- Your doctor may order blood tests
- You should tell your doctor or pharmacist if you notice any side effect not listed in section 4 'POSSIBLE SIDE EFFECTS' or if you notice that a side effect gets serious

Clopidogrel Tablets are not intended for use in children or adolescents.

Taking other medicines:
Some other medicines may influence the use of clopidogrel or vice versa.
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
The use of oral anticoagulants (medicines used to reduce blood clotting) with clopidogrel is not recommended
You should specifically tell your doctor if you take a non steroidal anti-inflammatory drug, usually used to treat painful and/or inflammatory conditions of muscle or joints, or if you take heparin or any other medicine used to reduce blood clotting, or if you take a proton pump inhibitor (e.g, omeprazole) for upset stomach.

Taking Clopidogrel Tablets with food and drink
Clopidogrel Tablets may be taken with or without food.

Pregnancy and breast-feeding
If you are pregnant or suspect that you are pregnant, you should tell your doctor or your pharmacist before taking Clopidogrel Tablets.
If you become pregnant while taking Clopidogrel Tablets, consult your doctor immediately as it is recommended not to take clopidogrel while you are pregnant.
While taking Clopidogrel Tablets, consult your doctor about the breast-feeding of a baby.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:
Clopidogrel Tablets are unlikely to affect your ability to drive or to use machines.

Important information about some of the ingredients of Clopidogrel Tablets:
Clopidogrel Tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE CLOPIDOGREL TABLETS

Always take Clopidogrel Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
The usual dose is one 75 mg tablet per day to be taken orally with or without food, and at the same time each day.
You should take Clopidogrel Tablets for as long as your doctor continues to prescribe it.

If you take more Clopidogrel Tablets than you should:
Contact your doctor or the nearest emergency department because of the increased risk of bleeding.

If you forget to take Clopidogrel Tablets:
If you forget to take a dose of Clopidogrel Tablets, but remember within 12 hours of your usual time, take your tablet straightaway and then take your next tablet at the usual time.
If you forget for more than 12 hours, simply take the next single dose at the usual time. Do not take a double dose to make up for the forgotten individual doses.

If you stop taking Clopidogrel Tablets:
Do not stop the treatment. Contact your doctor or pharmacist before stopping.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Clopidogrel Tablets can cause side effects, although not everybody gets them.

Contact your doctor immediately if you experience:
- fever, signs of infection or extreme tiredness. These may be due to rare decrease of some blood cells
- signs of liver problems such as yellowing of the skin and/or the eyes (jaundice), whether or not associated with bleeding which appears under the skin as red pinpoint dots, and/or confusion (see 'Take special care with Clopidogrel Tablets')
- swelling in the mouth or skin disorders such as rashes and itching, blisters of the skin. These may be the signs of an allergic reaction

The most common side effect (affects 1 to 10 patients in 100) reported with Clopidogrel is bleeding.
Bleeding may occur as bleeding in the stomach or bowels, bruising, haematoma (unusual bleeding or bruising under the skin), nose bleed, blood in the urine. In a small number of cases, bleeding in the eye, inside the head, the lung or the joints has also been reported.

If you experience prolonged bleeding when taking Clopidogrel Tablets
If you cut or injure yourself, it may take longer than usual for bleeding to stop. This is linked to the way your medicine works as it prevents the ability of blood clots to form. For minor cuts and injuries e.g., cutting yourself, shaving, this is usually of no concern. However, if you are concerned by your bleeding, you should contact your doctor straightaway (see 'Take special care with Clopidogrel Tablets').

Other side effects reported with Clopidogrel are:
Common side effects (affects 1 to 10 patients in 100): Diarrhoea, abdominal pain, indigestion or heartburn.
Uncommon side effects (affects 1 to 10 patients in 1,000): Headache, stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines, rashes, itching, dizziness, abnormal touch sensation.
Rare side effect (affects 1 to 10 patients in 10,000): Vertigo.
Very rare side effects (affects less than 1 patient in 10,000): jaundice; severe abdominal pain with or without back pain; fever, breathing difficulties sometimes associated with cough; generalised allergic reactions; swelling in the mouth; blisters of the skin; skin allergy; inflammation of the mouth (stomatitis); decrease in blood pressure; confusion; hallucinations; joint pain; muscular pain; changes in the way things taste.
In addition, your doctor may identify changes in your blood or urine test results.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CLOPIDOGREL TABLETS

Keep out of the reach and sight of children.
Do not use Clopidogrel Tablets after the expiry date which is stated on the carton and on the blister after EXP.
The medicinal product does not require any special storage conditions.
Do not use Clopidogrel Tablets if you notice any visible sign of deterioration.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Clopidogrel Tablets contain
- The active substance is clopidogrel. Each film-coated tablet contains 75 mg of clopidogrel (as besilate).
- The other ingredients are:

Core: Cellulose, microcrystalline, hydroxypropylcellulose (E463), mannitol (E421), crospovidone (type A), citric acid monohydrate, macrogol 6000, stearic acid (type 50), talc
Coating: Hypromellose (E464), iron oxide red (E172), lactose monohydrate, triacetin (E1518), titanium dioxide (E171)

What Clopidogrel Tablets look like and contents of the pack
Clopidogrel film-coated tablets are pink, round and biconvex.
They are supplied in PVC/PE/PVDC-Alu blisters or in PA/ALL/PVC-Alu blisters packed in cartons containing 14, 28, 30, 50, 84, 90 or 100 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Dexcel®-Pharma Limited, 1 Cottesbrooke Park, Heartlands Business Park, Daventry, Northamptonshire NN11 8YL, England.

This leaflet was last approved in July 2010.

771-6624F

PACKAGE LEAFLET : INFORMATION FOR THE USER

CoAprovel® 150 mg/12.5 mg film-coated tablets

irbesartan/hydrochlorothiazide

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT COAPROVEL IS AND WHAT IT IS USED FOR

CoAprovel is a combination of two active substances, irbesartan and hydrochlorothiazide.
Irbesartan belongs to a group of medicines known as angiotensin-II receptor antagonists.
Angiotensin-II is a substance produced in the body that binds to receptors in blood vessels causing them to tighten. This results in increase in blood pressure. Irbesartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower.
Hydrochlorothiazide is one of a group of medicines (called thiazide diuretics) that causes increased urine output and so causes a lowering of blood pressure.
The two active ingredients in CoAprovel work together to lower blood pressure further than if either was given alone.

CoAprovel is used to treat high blood pressure, when treatment with irbesartan or hydrochlorothiazide alone did not provide adequate control of your blood pressure.

2. BEFORE YOU TAKE COAPROVEL

Do not take CoAprovel
- if you are **allergic** (hypersensitive) to irbesartan or any of the other ingredients of CoAprovel
- if you are **allergic** (hypersensitive) to hydrochlorothiazide or any other sulfonamide-derived medicines
- if you are **more than 3 months pregnant.** (It is also better to avoid CoAprovel in early pregnancy - see pregnancy section)
- if you have **severe liver** or **kidney problems**
- if you have **difficulty in producing urine**
- if your doctor determines that you have **persistently high calcium or low potassium levels in your blood.**

CoAprovel should not be given to children and adolescents (under 18 years).

Take special care with CoAprovel
Tell your doctor if any of the following apply to you:
- if you **get excessive vomiting or diarrhoea**
- if you suffer from **kidney problems** or have a **kidney transplant**
- if you suffer from **heart problems**
- if you suffer from **liver problems**
- if you suffer from **diabetes**
- if you suffer from **lupus erythematosus** (also known as lupus or SLE)
- if you suffer from **primary aldosteronism** (a condition related to high production of the hormone aldosterone, which causes sodium retention and, in turn, an increase in blood pressure).

You must tell your doctor if you think you are (or might become) pregnant. CoAprovel is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

You should also tell your doctor:
- if you are on a **low-salt diet**
- if you have signs such as **abnormal thirst, dry mouth, general weakness, drowsiness, muscle pain or cramps, nausea, vomiting,** or an **abnormally fast heart beat** which may indicate an excessive effect of hydrochlorothiazide (contained in CoAprovel)
- if you experience increased **sensitivity of the skin to the sun** with symptoms of sunburn (such as redness, itching, swelling, blistering) occurring more quickly than normal
- if you are **going to have an operation** (surgery) or **be given anaesthetics**

The hydrochlorothiazide contained in this medicine could produce a positive result in an anti-doping test.

Using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Diuretic agents such as the hydrochlorothiazide contained in CoAprovel may have an effect on other medicines. Preparations containing lithium should not be taken with CoAprovel without close supervision by your doctor.
You may need to have blood checks if you take:
- potassium supplements
- salt substitutes containing potassium
- potassium sparing medicines or other diuretics (water tablets)
- some laxatives
- medicines for the treatment of gout
- therapeutic vitamin D supplements
- medicines to control heart rhythm
- medicines for diabetes (oral agents or insulins)
- carbamazepine (a medicine for the treatment of epilepsy)

It is also important to tell your doctor if you are taking other medicines to reduce your blood pressure, steroids, medicines to treat cancer, pain killer, arthritis medicines, or colestyramine and colestipol resins for lowering blood cholesterol.

Taking CoAprovel with food and drink
CoAprovel can be taken with or without food.
Due to the hydrochlorothiazide contained in CoAprovel, if you drink alcohol while on treatment with this medicine, you may have an increased feeling of dizziness on standing up, specially when getting up from a sitting position.

Pregnancy and breast-feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking CoAprovel before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of CoAprovel. CoAprovel is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. CoAprovel is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed. CoAprovel is unlikely to affect your ability to drive or use machines. However, occasionally dizziness or weariness may occur during treatment of high blood pressure. If you experience these, talk to your doctor before attempting to drive or use machines.

Important information about some of the ingredients of CoAprovel
CoAprovel contains lactose. If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine.

3. HOW TO TAKE COAPROVEL

Always take CoAprovel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage
The usual dose of CoAprovel is one or two tablets a day. CoAprovel will usually be prescribed by your doctor when your previous treatment did not reduce your blood pressure enough. Your doctor will instruct you how to switch from the previous treatment to CoAprovel.

Method of administration
CoAprovel is for **oral use.** Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take CoAprovel with or without food. Try to take your daily dose at about the same time each day. It is important that you continue to take CoAprovel until your doctor tells you otherwise.
The maximal blood pressure lowering effect should be reached 6-8 weeks after beginning treatment.

If you take more CoAprovel than you should
If you accidentally take too many tablets, contact your doctor immediately.

Children should not take CoAprovel
CoAprovel should not be given to children under 18 years of age. If a child swallows some tablets, contact your doctor immediately.

If you forget to take CoAprovel
If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

number 2875 engraved on the other side.

CoAprovel 150 mg/12.5 mg film-coated tablets are supplied in blister packs of 14, 28, 30, 56, 84, 90 or 98 film-coated tablets. Unit dose blister packs of 56 x 1 film-coated tablets for delivery in hospitals are also available.
Not all pack sizes may be marketed.

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Manufacturer
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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/

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CoAprovel is a registered trademark of sanofi-aventis

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Talk to your doctor straight away if you notice the following serious side effect:
- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is a very rare side effect

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:
- Constipation, feeling sick (nausea), being sick (vomiting)
- Dizziness, light-headedness, drowsiness, confusion
- Difficulty in passing water
- Becoming dependent on codeine
- You get infections or bruise more easily than usual. This could be because of a blood problem.

If any of the side effects gets serious, lasts longer than a few days or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CO-CODAMOL

Keep this medicine in a safe place out of the reach and sight of children.

Do not use this medicine after the expiry date shown on the pack.

Store your medicine in the original packaging.

Do not store above 25°C.

6. FURTHER INFORMATION

What Co-codamol 15/500 Tablets contain
- Each Co-codamol 15/500 Tablet contains 15mg of codeine phosphate and 500mg of paracetamol as the active ingredients.
- The other ingredients are maize starch, povidone, potassium sorbate, microcrystalline cellulose, stearic acid, magnesium stearate, talc, pregelatinised starch and purified water.
- Co-codamol 15/500 Tablets are white to off-white capsule-shaped tablets, marked PRO 15 and scored on one side with a plain reverse. They come in cartons of 100 tablets.

The Marketing Authorisation Holder is
Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

The Manufacturer is
Fawdon Manufacturing Centre, Edgefield Avenue, Fawdon, Newcastle upon Tyne, NE3 3TT, UK.

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4

PATIENT INFORMATION LEAFLET

CO-CODAMOL 15/500 TABLETS

Codeine Phosphate and Paracetamol

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

In this leaflet:

1. WHAT CO-CODAMOL IS AND WHAT IT IS USED FOR

The name of your medicine is Co-codamol 15/500 Tablets (called co-codamol throughout this leaflet). Co-codamol contains two different medicines called codeine phosphate and paracetamol. It belongs to a group of medicines called analgesics (painkillers) and is used to treat moderate pain.

2. BEFORE YOU TAKE CO-CODAMOL

Important things you should know about co-codamol
- **Do not take for longer than your doctor tells you to**
- **Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets**
- **Taking a painkiller for headaches too often or for too long can make them worse**

Do not take co-codamol and tell your doctor if:
- You are allergic (hypersensitive) to codeine, paracetamol or any of the other ingredients in your medicine (listed in Section 6: Further information)
  Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue
- You have severe asthma attacks or severe breathing problems
- You have recently had a head injury
- You have been told by your doctor that you have increased pressure in your head. Signs of this include: headaches, being sick (vomiting) and blurred eyesight
- You have recently had an operation on your liver, gallbladder or bile duct (biliary tract)
- You are taking medicine to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine or tranylcypramine (see 'Taking other medicines')
- You consume excessive amounts of alcohol on a regular basis
- You are pregnant or breast-feeding
- The person going to take the tablets is under 12 years of age. Co-codamol must not be given to children under 12 years of age

Do not take co-codamol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking co-codamol.

1

Take special care and check with your doctor before taking co-codamol if:
- You have severe kidney or liver problems
- You have problems passing water or prostate problems
- You have a bowel problem such as colitis or Crohn's disease or a blockage of your bowel
- You have a disease of the adrenal gland called Addison's disease
- You have a condition called myasthenia gravis which weakens the muscles
- You are elderly

If you are not sure if the above applies to you, talk to your doctor or pharmacist before taking co-codamol.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because co-codamol can affect the way some other medicines work. Also, some other medicines can affect the way co-codamol works.

While taking co-codamol you should not take any other medicines which contain paracetamol.
This includes some painkillers, cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

Do not take this medicine and tell your doctor or pharmacist if you are taking the following:
- Medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine, tranylcypramine

Tell your doctor if you are taking any of the following medicines:
- Medicines which make you drowsy or sleepy (CNS depressants)
- Medicines used to thin the blood such as warfarin
- Chloramphenicol - an antibiotic used for infections
- Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting)
- Colestyramine - for lowering blood cholesterol levels
- The oral contraceptive pill

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking co-codamol.

Taking co-codamol with food and drink
You should not drink alcohol while you are taking these tablets. This is because taking co-codamol can change the way alcohol affects you.

Pregnancy and breast-feeding
Talk to your doctor before taking these tablets if:
- You are pregnant, think you may be pregnant or plan to get pregnant
- You are breast-feeding or planning to breast-feed

Usually it is safe to take Co-codamol while breast feeding as the levels of codeine in breast milk are too low to cause your baby any problems. However, some women who are at increased risk of developing side effects at any dose may have higher levels of codeine in their breast milk. If any of the following side effects develop in you or your baby, stop taking this medicine and seek immediate medical advice; feeling sick, vomiting, constipation, decreased or lack of appetite, feeling tired or sleeping for longer than normal and shallow or slow breathing.

2

Driving and using machines
You may feel dizzy or sleepy while taking co-codamol. If this happens, do not drive or use any tools or machines.

Changing or stopping treatment
Taking co-codamol for a long time may lead to tolerance and dependence. Do not increase the dose or suddenly stop treatment without discussing this with your doctor.

3. HOW TO TAKE CO-CODAMOL

Always take co-codamol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- **Do not take more than the recommended dose**
- **Do not take for longer than your doctor tells you to**

Adults and children over 15 years:
- Swallow the tablets whole with a drink of water
- The usual dose of co-codamol is 2 whole tablets, taken together
- Wait at least 4 hours before taking another dose
- Do not take more than 8 tablets in any 24-hour period
- Elderly people may be prescribed a lower dose

Children aged 12 – 15 years:
- 1 whole tablet every 4 hours
- Do not take more than 4 tablets in any 24-hour period.

Children under 12 years: Co-codamol should not be given to children under 12 years of age.

If you take more co-codamol than you should
- Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage
- Remember to take any remaining tablets and the pack with you. This is so the doctor knows what you have taken

If you have forgotten to take co-codamol
If you forget to take a dose at the right time, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take two doses at or near the same time. Remember to leave at least 4 hours between doses.

4. POSSIBLE SIDE EFFECTS

As with all medicines, co-codamol can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Important side-effects you should know about co-codamol
- Taking a painkiller for headaches too often or for too long can make them worse.
- Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop taking the tablets.

Stop taking co-codamol and see a doctor or go to a hospital straight away if:
- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria)
  This may mean you are having an **allergic reaction** to co-codamol

3

PACKAGE LEAFLET: INFORMATION FOR THE USER

Detrusitol® XL 4 mg

prolonged-release capsules, hard

PHARMACIA

Tolterodine

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What DETRUSITOL XL is and what it is used for

The active substance in Detrusitol XL is tolterodine. Tolterodine belongs to a class of medicinal products called antimuscarinics.
Detrusitol XL is used for the treatment of the symptoms of overactive bladder syndrome. If you have overactive bladder syndrome, you may find that:
- you are unable to control urination,
- you need to rush to the toilet with no advance warning and/or go to the toilet frequently.

2. Before you take DETRUSITOL XL

Do not take Detrusitol XL if you:
- are allergic (hypersensitive) to tolterodine or any of the other ingredients in Detrusitol XL
- are unable to pass urine from the bladder (urinary retention)
- have an uncontrolled narrow-angle glaucoma (high pressure in the eyes with loss of eyesight that is not being adequately treated)
- suffer from myasthenia gravis (excessive weakness of the muscles)
- suffer from severe ulcerative colitis (ulceration and inflammation of the colon)
- suffer from a toxic megacolon (acute dilatation of the colon).

Take special care with DETRUSITOL XL
- If you have difficulties in passing urine and/or a poor stream of urine
- If you have a gastro-intestinal disease that affects the passage and/or digestion of food
- If you suffer from kidney problems (renal insufficiency)
- If you have a liver condition
- If you suffer from neuronal disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system)
- If you have a hiatal hernia (herniation of an abdominal organ)
- If you ever experience decreased bowel movements or suffer from severe constipation (decreased gastro-intestinal motility)
- If you have a heart condition such as:
  - an abnormal heart tracing (ECG);
  - a slow heart rate (bradycardia);
  - relevant pre-existing cardiac diseases such as:
    - cardiomyopathy (weak heart muscle)
    - myocardial ischaemia (reduced blood flow to the heart)
    - arrhythmia (irregular heartbeat)
    - and heart failure
- If you have abnormally low levels of potassium (hypokalaemia), calcium (hypocalcaemia) or magnesium (hypomagnesaemia) in your blood.

Talk to your doctor or pharmacist before starting your treatment with Detrusitol XL if you think any of these might apply to you.

Taking other medicines

Tolterodine, the active substance of Detrusitol XL, may interact with other medicinal products.

It is not recommended to use tolterodine in combination with:
- some antibiotics (containing e.g. erythromycin, clarithromycin)
- medicinal products used for the treatment of fungal infections (containing e.g. ketoconazole, itraconazole)
- medicinal products used for the treatment of HIV.

Detrusitol XL should be used with caution when taken in combination with:
- medicines that affect the passage of food (containing e.g. metoclopramide and cisapride)
- medicines for the treatment of irregular heartbeat (containing e.g. amiodarone, sotalol, quinidine, procainamide)
- other medicines with a similar mode of action to Detrusitol XL (antimuscarinic properties) or medicines with an opposite mode of action to Detrusitol XL (cholinergic properties). Ask your doctor if you are unsure.

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Detrusitol XL with food and drink

Detrusitol XL can be taken before, after or during a meal.

Uncommon side effects (occurs in less than 1 in 100 patients) are:
- Allergic reactions
- Nervousness
- Sensation of pins and needles in the fingers and toes
- Vertigo
- Palpitations, heart failure, irregular heartbeat
- Inability to empty the bladder
- Chest pain
- Memory impairment

Additional reactions reported include severe allergic reactions, confusion, hallucinations, increased heart rate, flushed skin, heart burn, vomiting, angioedema dry skin, and disorientation. There have also been reports of worsening symptoms of dementia in patients being treated for dementia.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store DETRUSITOL XL

Keep Detrusitol XL out of the reach and sight of children.

Do not use Detrusitol XL after the expiry date which is stated on the label/carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Bottle: Store in the original container.

Blisters: Keep the blister in the outer carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Detrusitol XL contains

The active substance in Detrusitol XL 4 mg prolonged-release capsules is 4 mg of tolterodine tartrate, equivalent to 2.74 mg of tolterodine.

The other ingredients are:
Capsule contents: Sugar spheres (containing sucrose and maize starch), hypromellose and Surelease E-7-19010 (containing ethylcellulose, medium chain triglycerides and oleic acid).

Capsule shell: Gelatine and colourants.

Colourants:
Blue 4 mg prolonged-release capsule: Indigo carmine (E132) and titanium dioxide (E171).

Printing ink: Shellac glaze, titanium dioxide (E171), propylene glycol and simeticone.

What Detrusitol XL looks like and contents of the pack

Detrusitol XL is a hard prolonged-release capsule designed for once daily dosing.

Detrusitol XL 4 mg prolonged-release capsules are blue and marked with white printing (symbol and 4).

Detrusitol XL 4 mg prolonged-release capsules are available in the following pack sizes:
Blister packs containing:
- 7 prolonged-release capsules
- 14 prolonged-release capsules
- 28 prolonged-release capsules
- 49 prolonged-release capsules
- 84 prolonged-release capsules
- 98 prolonged-release capsules
- 280 prolonged-release capsules

And bottles containing 30, 100 and 200 capsules.
Hospital packs are available in packs of 80, 160 and 320 capsules.
Please note that not all the above pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing authorisation holder:
Pharmacia Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ
UK

Manufacturer:
Pfizer Italia S.r.l
Località Marino del Tronto
63100 - Ascoli Piceno (AP)
Italy

This medicinal product is authorised in the Member States of the EEA under the following names:
Detrusitol retard: Austria, Belgium, Luxembourg, Denmark, Germany, Iceland, Italy and Portugal
Detrusitol SR: Finland Greece, Ireland, Netherlands, Norway, Sweden
Detrusitol L.P. France,
Detrusitol Neo: Spain
Detrusitol XL: UK

This leaflet was last approved in September 2010

DX 13 0 UK

Dulcolax®

5 mg Gastro-resistant Tablets
bisacodyl

Package leaflet:
Information for the user

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. You need to take DULCOLAX Tablets as instructed in this leaflet to get the best results from it.
- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact your pharmacist or doctor if your symptoms worsen or do not improve after five days treatment
- If a side effect occurs and gets troublesome, or seems serious to you, or if you experience any side effect not listed in this leaflet, please tell your pharmacist or doctor

In this leaflet:

1. WHAT DULCOLAX TABLETS ARE AND WHAT THEY ARE USED FOR

- DULCOLAX Tablets contain a medicine called bisacodyl. This belongs to a group of medicines called laxatives
- DULCOLAX Tablets are used for relief of constipation
- DULCOLAX Tablets can also be used in a hospital to empty a person's bowel before child birth, surgery or radiological investigations
- DULCOLAX Tablets gently stimulate the muscles of the bowel (large intestine). This brings predictable, overnight relief from constipation, helping to return the body to its natural rhythm
- DULCOLAX Tablets are gastro-resistant tablets which have a special coating that helps to ensure the medicine works only where it is needed

What is constipation?
Normal and regular bowel movement is important for most people. However, what is "normal and regular" varies from person to person. Some may have a bowel movement every day, others less often. Whatever it is like for you, it is best that your bowel movement has a regular pattern.

- Constipation is an occasional problem for some people. For others, it may happen more often
- It happens when the normal muscle actions in the bowel (large intestine) slow down. This can mean that material is not easily eliminated from the body

The cause of constipation is often not known. It can be associated with:
- Sudden change of diet
- A diet with not enough fibre
- Loss of 'tone' of the bowel muscles in older people
- Pregnancy
- Medicines such as morphine or codeine
- Having to stay in bed for a long time
- Lack of exercise

Whatever the cause, constipation can be uncomfortable. It may make you feel bloated and heavy or generally "off colour". Sometimes it causes headaches.

These healthy tips are recommended to try to prevent constipation happening:
- Eat a balanced diet including fresh fruit and vegetables
- Drink enough water so that you do not become dehydrated
- Keep up your exercise and stay fit
- Make time to empty your bowels when your body tells you

2. BEFORE YOU TAKE DULCOLAX TABLETS

Do not take DULCOLAX Tablets if:
- You are allergic (hypersensitive) to bisacodyl or any of the other ingredients in the product (listed in Section 6: Further information)
- You are intolerant to or cannot digest some sugars (as the tablet contains a small amount of lactose and sucrose)
- You have severe dehydration
- You have a bowel condition called "ileus" (in the small intestine)
- You have a serious abdominal condition such as appendicitis
- You have severe abdominal pain with nausea and vomiting
- You have a blocked bowel (intestinal obstruction)
- You have inflammation of the bowel (small or large intestine)

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your pharmacist or doctor before taking this medicine.

Taking other medicines
Please tell your pharmacist or doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because DULCOLAX Tablets can affect the way some other medicines work. Also, some other medicines can affect the way DULCOLAX Tablets works.

In particular, tell your doctor or pharmacist if you are taking:
- Water tablets (diuretics) such as bendrofluazide or furosemide (frusemide)
- Steroid medicines such as prednisolone

If you are not sure if any of the above applies to you, talk to your pharmacist or doctor before taking DULCOLAX Tablets

Pregnancy and breast feeding
Talk to your pharmacist or doctor before taking DULCOLAX Tablets if you are pregnant, planning to become pregnant or are breast feeding.

Driving and using machines
Some people may feel dizzy or faint while taking this medicine. If this happens to you, wait until these feelings go away before driving or using machines.

3. HOW TO TAKE DULCOLAX TABLETS

If this medicine is from your doctor or pharmacist, do exactly as they have told you. Otherwise, follow the instructions below. If you do not understand the instructions, or you are not sure, ask your pharmacist or doctor.

As with all laxatives, DULCOLAX Tablets should not be taken every day for more than five days. If you need laxatives every day, or if you have abdominal pain which does not go away, you should see your doctor.

Taking this medicine
- Swallow the tablets whole with water
- Milk, antacids or proton pump inhibitors (medicines which reduce stomach acid) should not be taken within one hour before or after taking DULCOLAX Tablets. This is because they will stop the DULCOLAX Tablets from working properly

Adults and children over 10 years
- Take one or two tablets (5 to 10 mg) daily before bedtime
- If you have not taken DULCOLAX Tablets before, start with one tablet and increase to two if necessary
- When your bowel regularity has returned to normal, the dose can usually be stopped

Children aged between 4 and 10 years
DULCOLAX Tablets should only be given to children between the ages of 4 and 10 if recommended by a doctor. The usual dose for children is:
- One tablet (5 mg) daily before bedtime

Children under 4 years
DULCOLAX Tablets are not recommended for children under 4 years.

How much to take
If you take more DULCOLAX Tablets than you should
If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you; this is so the doctor knows what you have taken.

If you have any questions on the use of this product, ask your pharmacist or doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DULCOLAX Tablets can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Rare side effects (affect less than 1 in 1000 people)
- Severe allergic reactions which may cause swelling of the face or throat and difficulty in breathing or dizziness. If you have a severe allergic reaction, stop taking this medicine and see a doctor straight away.
- Colitis (inflammation of the large intestine which causes abdominal pain and diarrhoea)
- Dehydration
- Allergic reactions which may cause a skin rash
- Fainting

Uncommon side effects (affect less than 1 in 100 people)
- Blood in the stools
- Vomiting
- Abdominal discomfort
- Discomfort inside and around the back passage
- Dizziness

Common side effects (affect less than 1 in 10 people)
- Abdominal cramps or pain
- Diarrhoea
- Nausea

If a side effect occurs and gets troublesome or seems serious to you, or if you experience any side effect not listed in this leaflet, please tell your pharmacist or doctor.

5. HOW TO STORE DULCOLAX TABLETS

- Keep this medicine out of the sight and reach of children
- Do not take DULCOLAX Tablets after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month
- Do not store above 25°C
- Keep the blister strip within the outer carton
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. FURTHER INFORMATION

What DULCOLAX Tablets contain
- Each tablet contains 5 mg of bisacodyl as the active ingredient
- The other ingredients are: lactose monohydrate, maize starch, sucrose (approximately 21 mg per tablet), glycerol, magnesium stearate, talc (E553b), acacia (powdered), white beeswax (E901), shellac (E904), carnauba wax (E903), titanium dioxide (E171), yellow iron oxide (E172), methacrylic acid-methyl methacrylate copolymer, castor oil and macrogol 6000

What DULCOLAX Tablets looks like and contents of the pack
DULCOLAX Tablets are yellow. They are available in packs of 10, 20, 30, 40, 50, 60, 80 and 100. Not all pack sizes may be marketed.

The Marketing Authorisation is held by:
Boehringer Ingelheim Limited,
Consumer Healthcare,
Ellesfield Avenue, Bracknell, Berkshire
RG12 8YS, United Kingdom.

DULCOLAX Tablets are manufactured at:
Delpharm Reims S.A.S.
10 Rue Colonel Charbonneaux
51100 Reims,
France.

This leaflet was revised in February 2011.

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Boehringer Ingelheim

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Boehringer Ingelheim

PACKAGE LEAFLET: INFORMATION FOR THE USER

EZETROL® 10 mg Tablets

Ezetimibe

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT EZETROL IS AND WHAT IT IS USED FOR

EZETROL is a medicine used to lower levels of total cholesterol, "bad" cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, EZETROL raises levels of "good" cholesterol (HDL cholesterol). It is used for patients who cannot control their cholesterol levels by diet alone. You should stay on a cholesterol-lowering diet while taking this medicine.

EZETROL works by reducing the cholesterol absorbed in your digestive tract. EZETROL does not help you lose weight.

EZETROL adds to the cholesterol-lowering effect of statins, a group of medicines that reduce the cholesterol your body makes by itself.

EZETROL is used in addition to diet if you have:
- a raised cholesterol level in your blood (primary hypercholesterolaemia [heterozygous familial and non-familial])
  - together with a statin, when your cholesterol level is not well controlled with a statin alone
  - alone, when statin treatment is inappropriate or is not tolerated
- a hereditary illness (homozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood. You will also be prescribed a statin and may also receive other treatments
- a hereditary illness (homozygous sitosterolaemia, also known as phytosterolaemia) that increases the levels of plant sterols in your blood.

2. BEFORE YOU TAKE EZETROL

If you use EZETROL together with a statin, please read the package leaflet of that particular medicine.

Do not take EZETROL if:
- you are allergic (hypersensitive) to ezetimibe or any of the other ingredients of EZETROL Tablets (see Section 6: Further Information).

Do not take EZETROL together with a statin if:
- you currently have liver problems.
- you are pregnant or breast-feeding.

Take special care with EZETROL
- Tell your doctor about all your medical conditions including allergies.
- Your doctor should do a blood test before you start taking EZETROL with a statin. This is to check how well your liver is working.
- Your doctor may also want you to have blood tests to check how well your liver is working after you start taking EZETROL with a statin.

If you have moderate or severe liver problems, EZETROL is not recommended.

The safety and efficacy of the combined use of EZETROL and fibrates (medicines for lowering cholesterol) have not been established.

Children
EZETROL is not recommended for children under age of 10.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including those obtained without a prescription. In particular, tell your doctor if you are taking any of the following:
- ciclosporin (a medicine often used in organ transplant patients)
- medicines to prevent blood clots, such as warfarin, phenprocoumon, acenocoumarol or fluindione (anticoagulants)
- colestyramine (a medicine for lowering cholesterol), because it affects the way EZETROL works
- fibrates (medicines for lowering cholesterol)

Pregnancy and breast-feeding

Do not take EZETROL with a statin if you are pregnant, are trying to get pregnant or think you may be pregnant. If you get pregnant while taking EZETROL with a statin, stop taking both medicines immediately and tell your doctor. There is no experience from the use of EZETROL without a statin during pregnancy. Ask your doctor for advice before using EZETROL if you are pregnant.

Do not take EZETROL with a statin if you are breast-feeding, because it is not known if the medicines are passed into breast milk. EZETROL without a statin should not be used if you are breast-feeding. Ask your doctor for advice.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
EZETROL is not expected to interfere with your ability to drive or to use machinery. However, it should be taken into account that some people may get dizzy after taking EZETROL.

Important information about some of the ingredients of EZETROL
EZETROL tablets contain a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE EZETROL

Always take EZETROL exactly as your doctor has told you. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop. You should check with your doctor or pharmacist if you are not sure.
- Before starting EZETROL, you should be on a diet to lower your cholesterol.
- You should keep on this diet whilst taking EZETROL.

Adults and adolescents (10 to 17 years of age): The dose is one EZETROL 10 mg Tablet by mouth once a day.

Take EZETROL at any time of the day. You can take it with or without food.

If your doctor has prescribed EZETROL along with a statin, both medicines can be taken at the same time. In this case, please read the dosage instructions in the package leaflet of that particular medicine.

If your doctor has prescribed EZETROL along with colestyramine or any other bile acid sequestrant (medicines for lowering cholesterol), you should take EZETROL at least 2 hours before or 4 hours after taking the bile acid sequestrant.

If you take more EZETROL than you should:

Please contact your doctor or pharmacist.

If you forget to take EZETROL:

Do not take an extra dose, just take your normal amount of EZETROL at the usual time the next day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, EZETROL can cause side effects, although not everybody gets them.

The following terms are used to describe how often side effects have been reported:
- Very common (occurring in 1 or more of 10 patients treated)
- Common (occurring in 1 or more of 100 and less than 1 of 10 patients treated)
- Uncommon (occurring in 1 or more of 1000 and less than 1 of 100 patients treated)
- Rare (occurring in 1 or more of 10000 and less than 1 of 1000 patients treated)
- Very rare (occurring in less than 1 of 10000 patients treated including isolated reports).

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems, including muscle breakdown resulting in kidney damage, can be serious and may become a potentially life-threatening condition.

Allergic reactions, including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing (which requires treatment right away) have been reported in general use.

When used alone, the following side effects were reported:
Common: abdominal pain; diarrhoea; flatulence; feeling tired.
Uncommon: elevations in some laboratory blood tests of liver (transaminases) or muscle (CK) function; cough; indigestion; heartburn; nausea; joint pain; muscle spasms; neck pain; decreased appetite; pain; chest pain; hot flush; high blood pressure.

Additionally, when used with a statin, the following side effects were reported:
Common: elevations in some laboratory blood tests of liver function (transaminases); headache; muscle pain; tenderness or weakness.
Uncommon: tingling sensation; dry mouth; itching; rash; hives; back pain; muscle weakness, pain in arms and legs; unusual tiredness or weakness; swelling, especially in the hands and feet.

When used with fenofibrate, the following common side effect was reported: abdominal pain.

Additionally, the following side effects have been reported in general use:
dizziness; muscle aches; liver problems; allergic reactions including rash and hives; raised red rash, sometimes with target shaped lesions; muscle pain, tenderness or weakness; muscle breakdown; gallstones or inflammation of the gallbladder (which may cause abdominal pain, nausea, vomiting); inflammation of the pancreas often with severe abdominal pain; constipation; reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopaenia); tingling sensation; depression; unusual tiredness or weakness; shortness of breath.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE EZETROL

- Keep out of the reach and sight of children.
- Do not use EZETROL after the expiry date stated on the carton or container after "EXP". The expiry date refers to the last day of that month.
- Do not store EZETROL above 30°C.

Blisters: Store in the original package. Bottles: Keep bottles tightly closed. These measures will protect the product from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What EZETROL contains
- The active substance is ezetimibe. Each tablet contains 10 mg ezetimibe.
- The other ingredients are: lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, sodium laurilsulfate, magnesium stearate

What EZETROL looks like and contents of the pack

EZETROL tablets are white to off-white, capsule-shaped tablets with code "414" on one side.

Pack sizes:
7, 10, 14, 20, 28, 30, 50, 98, 100 or 300 tablets in push-through blisters or unit dose peelable blisters;
84 or 90 tablets in push-through blisters;
50, 100 or 300 tablets in unit dose push-through blisters;
100 tablets in bottles.

Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
MSD-SP Limited
Hertford Road
Hoddesdon
Hertfordshire EN11 9BU, United Kingdom

Manufacturer:
SP Labo N. V.
Industriepark 30 – Zone A
B-2220 Heist-op-den-Berg
Belgium

This medicinal product is authorized under the name EZETROL in Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden and United Kingdom.

The leaflet was last approved in March 2010

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MSD Schering-Plough

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PACKAGE LEAFLET: INFORMATION FOR THE USER
Finasteride 5mg Tablets

Read all this leaflet carefully before you start taking this medicine:
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Are Finasteride 5mg Tablets And What They Are Used For

The name of this medicine is Finasteride 5mg Tablets (also referred to as finasteride in this leaflet). Finasteride is a type of medicine called a 5-alpha-reductase inhibitor. It is used to shrink an enlarged prostate in men. Your doctor has prescribed Finasteride 5mg Tablets for you because your prostate is bigger than normal (a condition known as Benign Prostatic Hyperplasia; BPH) which is making it more difficult for you to pass urine. Finasteride 5mg Tablets will help to reduce the risk of developing a sudden inability to pass urine, known as acute urinary retention. They will also reduce the need for prostatic surgery.

2. Before You Take Finasteride 5mg Tablets

Do not take Finasteride 5mg Tablets
- if you are allergic to any of the ingredients in these tablets, listed in Section 6.
- if you are a woman or a child
- If a woman carrying a male baby comes into contact with the active ingredient, finasteride, the normal development of the baby's sex organs may be affected.

Take special care with Finasteride 5mg Tablets
- If you have a lot of difficulty passing urine (water).
- If you suffer from liver problems
- Finasteride can affect a blood test called PSA. If you need a PSA test, you should tell the doctor that you are taking finasteride.
- Women who are pregnant or who might become pregnant should not come into contact with finasteride.
- If you have been told by your doctor that you have an intolerance to certain sugars – see below under 'Important information about some of the ingredients of Finasteride 5mg Tablets'.

If any of the above apply, you should inform your doctor before beginning treatment with Finasteride 5mg Tablets.

Taking other medicines
Finasteride 5mg Tablets do not usually interfere with other medicines, however, you should make sure you have told your doctor or pharmacist about any other medicines that you are taking, including any you have bought without a prescription.

Taking Finasteride 5mg Tablets with food and drink
Finasteride 5mg Tablets can be taken with or without food. The effectiveness of your medicine is not altered by food.

Pregnancy
Women MUST NOT use Finasteride Tablets. Women who are pregnant, or think they may be pregnant, should avoid any contact with finasteride, particularly if the tablets are crushed or broken.

If your sexual partner is, or could be, pregnant, you must avoid exposing her to your semen which could contain a small amount of finasteride – for example by using a condom during sexual activity. If a pregnant woman comes into contact with finasteride, a doctor should be consulted.

Driving and using machines
Driving and using of machinery is not known to be affected by this medicine.

Important information about some of the ingredients of Finasteride 5mg Tablets
This medicine contains lactose, so patients with rare hereditary problems of galactose intolerance, the

Always take your medicine exactly as your doctor has told you and according to the instructions printed on the label of the pack. You should check with your doctor or pharmacist if you are not sure.

Adults: The usual dose is one tablet every day with or without food. The tablets should be swallowed whole and must not be crushed or divided. Finasteride 5mg Tablets may be taken on their own or with another medicine called doxazosin, which will not affect the effectiveness of your medicine. You may experience more side effects if you also take doxazosin.

Children: Finasteride 5mg Tablets MUST NOT be used in children.

Elderly patients or those with kidney disorders: Usually no adjustment to the dose is necessary and the same dose as for adults should be used.

If you take more Finasteride 5mg Tablets than you should
If you take more than the recommended number of tablets, contact your doctor or pharmacist for advice straight away. No side effects have been reported under these circumstances.

If you forget to take Finasteride 5mg Tablets
Take the forgotten tablet when you remember then take your next tablet as usual the following day. Do not take a double dose to make up for the missed dose.

If you stop taking Finasteride 5mg Tablets
If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects

Like all medicines, Finasteride 5mg Tablets can cause side effects, although not everybody gets them. You should promptly report to your doctor any changes in your breast tissue such as lumps, pain, enlargement of the breast tissue or nipple discharge as these may be signs of a serious condition, such as breast cancer.

Common side-effects include: impotence (inability to maintain an erection); a reduced desire to have sex; producing a reduced amount of semen

Uncommon side-effects include: Swelling and/or tenderness of the breasts; problems with ejaculation; skin rashes

Rare side-effects include: Allergic reactions including itching, hives or swelling of the face and lips; pain in the testicles and a rapid and irregular heart beat

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store your Finasteride 5mg Tablets

Keep your Finasteride 5mg Tablets in a safe place out of the reach and sight of children. Do not store above 30°C and keep the blister strips in the box. Do not take this medicine after the expiry date which is stated on the blister.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Finasteride 5mg Tablets contains
The active substance in your medicine is finasteride. Your medicine also contains lactose monohydrate, cellulose microcrystalline (E460), starch pregelatinised, sodium starch glycolate (Type A), magnesium stearate (E470b), docusate sodium. The coating of these tablets contains hypromellose (E464), titanium dioxide (E171), macrogol and indigo carmine (E132). The sodium content of each tablet is 6.6mg.

What Finasteride 5mg Tablets looks like and contents of the pack
Finasteride 5mg Tablets are blue, oval, film-coated tablets with the following markings: 'FIN' on one side and '5' on the other side. The tablets are presented in blister strips containing 28, 30, 50 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer (also EU batch release site)
Dr. Reddy's Laboratories (UK) Ltd
6 Riverview Road, Beverley, HU17 0LD, UK
Tel: +44 (0) 1482 860228; Fax: +44 (0) 1482 872042

This medicine is authorised in Member States of the EEA under the following names:
UK: Finasteride 5mg Tablets (PL 08553/0261)
Spain: Finasterida 5mg Aphar Comprimidos Recubiertos EFG

150024825

This leaflet was last approved on July 2010

- Seeing or hearing things that are not there (hallucinations)
- Changes in mood (depression) or memory loss (amnesia)
- Feeling anxious or confused
- Headache
- You have ringing in the ears (tinnitus)
- Feeling giddy, faint or light-headed, sweating or flushing
- You get blurred or double vision
- Balance problems, feeling dizzy (vertigo)
- You have movements that you cannot control
- Feeling tired, faint, dizzy or having pale skin. These could be signs of anaemia
- Feeling numb or weak, tingling or burning feelings in any part of your body
- You may bleed or bruise more easily than usual. This could be because of a blood disorder (called 'thrombocytopenia')
- Changes in the amount of liver enzymes at the beginning of treatment. This can be seen in blood tests.

Talk to your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days or if you notice any side effects not listed in this leaflet.

5. HOW TO STORE FLECAINIDE

- Keep out of the reach and sight of children
- Store in original container in order to protect from light
- Do not use flecainide after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Store below 25°C
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What flecainide tablets contain
Each tablet contains 50mg or 100mg of flecainide acetate as the active substance. The other ingredients are microcrystalline cellulose, maize starch, pregelatinised maize starch, croscarmellose sodium and magnesium stearate.

What flecainide tablets look like and contents of the pack
50mg tablets: The tablets are white uncoated tablets marked C on one side and F1 on the other
100mg tablets: The tablets are white, circular, biconvex, uncoated tablets one side embossed with a breakline and the identifying letters "C" above the line and "FJ" below, the reverse side embossed with a breakline.

The tablets are available in blister-packs of 60 tablets.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

Manufacturer
Zentiva, One Onslow Street, Guildford , Surrey GU1 4YS, UK

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in 01/2011

LF00000181

PATIENT INFORMATION LEAFLET

FLECAINIDE ACETATE 50MG AND 100MG TABLETS

Flecainide Acetate

Read all of this leaflet carefully before you start taking this medicine
- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist
- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

In this leaflet:

1. WHAT FLECAINIDE IS AND WHAT IT IS USED FOR

What flecainide is
The name of your medicine is Flecainide Acetate 50mg or 100mg Tablets (called flecainide throughout this leaflet). This belongs to a group of medicines called anti-arrhythmics.

It works by controlling the uneven beating of your heart (called 'arrhythmias'). Taking the tablets helps your heartbeat to return to normal.

Flecainide can be used to
- Treat uneven heartbeats
- Treat an illness called Wolff-Parkinson-White Syndrome. This is where your heart beats unusually fast
- Treat other types of fast or uneven heartbeats known as 'atrial flutter' or 'atrial fibrillation'.
- Treat fast heartbeats which may happen suddenly and may be uneven.

2. BEFORE YOU TAKE FLECAINIDE

Do not take this medicine and tell your doctor if:
- You are allergic (hypersensitive) to flecainide or any of the other ingredients of this medicine (listed in Section 6 below)
  Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You suffer or have suffered from heart failure
- You have had a heart attack
- You have any heart disease or damage
- You have a slower than usual heartbeat (called 'sinus bradycardia') or an illness called 'sino-atrial' heart block

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking flecainide.

Patient Information Leaflet

FLUCLOXACILLIN 250MG CAPSULES BP
FLUCLOXACILLIN 500MG CAPSULES BP

Read all of this leaflet carefully before you start taking your medicine. Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or pharmacist (chemist). This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

IN THIS LEAFLET

1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

The name of your medicine is Flucloxacillin Capsules BP. It belongs to a group of medicines called penicillinase-resistant antibiotics. It is a penicillin antibiotic used to treat infections in different parts of your body caused by bacteria; it can also be used to prevent infections during surgery.

2. BEFORE YOU TAKE YOUR MEDICINE

Do not take this medicine if:
- You have ever had an allergic reaction to flucloxacillin or any other penicillin antibiotics (see symptoms section 4).
- You have ever had an allergic reaction to any of the other ingredients of this medicine - see list of ingredients in section 6, Further Information.
- You have had liver problems in the past as a result of taking flucloxacillin.

Important information about some of the ingredients in your medicine:
This medicine contains approximately 54.3mg **sodium** per g. Check with your doctor before taking this medicine if you are on a sodium restricted diet.

Check with your doctor or pharmacist before taking this medicine if:
- You suffer from kidney problems, as you may require a lower dose than normal
- You suffer from liver problems, as this medicine could cause them to worsen
- You are on a sodium restricted diet.

Check with your doctor or pharmacist before taking this medicine if you are taking any other medicines, especially:
- Probenecid (used to treat gout).
- Methotrexate (used to treat leukemia, solid tumours and severe skin disease)

Some medicines may affect the way others work. Always tell your doctor about all the medicines you are taking. This means medicines you have bought yourself as well as medicines on prescription from a doctor.

Pregnancy and breastfeeding
Before you take your medicine, tell your doctor if you are pregnant, breastfeeding or trying to become pregnant.

3. HOW TO TAKE YOUR MEDICINE

Follow all directions given to you by your doctor or pharmacist. Their directions may differ from the information contained in this leaflet. The pharmacist's label should tell you how much to take and how often. If it does not, or you are not sure, check with your doctor or pharmacist.

How much of your medicine to take and when to take it:
The dose will depend on the patient and will be decided by your doctor. However, the usual doses for each age group are -

Adults (including the elderly):	250mg four times a day
In cases of bone or heart infection:	Up to 8g daily, in divided doses six to eight hourly
Surgical prophylaxis:	1 to 2g IV at induction of anaesthesia followed by 500mg six hourly for up to 72 hours
Children (2-10 years of age):	Half the adult dose
Children under 2 years of age:	Quarter the adult dose

If you suffer from severe kidney failure your doctor will give you lower or fewer doses.

When to take your medicine:
Take your medicine on an empty stomach, at least thirty minutes to one hour before meals/food. It is important that you take your medicine at the right times.

How long to take your medicine for:
Keep taking your medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, your infection may return or get worse. If you are still unwell after taking all the medicine, go and see your doctor.

Overdose: If you take more of your medicine than you should:
If you (or somebody else) accidentally takes too much of your medicine, speak to your doctor or pharmacist immediately.

If you forget to take your medicine:
If you forget to take a dose, take it as soon as you remember, then carry on as before. Do not take a double dose to make up for the dose you have missed.

4. POSSIBLE SIDE EFFECTS OF YOUR MEDICINE

Like all medicines, Flucloxacillin capsules may cause unwanted side-effects. If they occur, they are likely to be temporary, and not serious. However, some may be serious and need medical attention.

Most common side effects
Allergic reactions especially skin rash. Other reactions include nettle rash; fever; joint pains; rashes; swelling of the lips, face, mouth, tongue or throat; anaphylaxis; breathing difficulties; anaemia; and blood in your urine. **Discontinue medicine immediately** and contact your doctor.

- Diarrhoea, stomach ache and feeling sick

Should be mild and wear off after a few days. If severe or lasting longer, tell your doctor

Occasional side effects:
- Sore mouth

Rare side effects:
- Pseudomembranous colitis (bloody diarrhoea) - usually associated with the use of flucloxacillin in combination with other antibiotics.
- Hepatitis (inflammation of the liver), and jaundice (yellowing of the skin and eyes) - these are reversible when treatment is discontinued.
- Unexplained bleeding, bruising or skin discolouration; occurrence of an infection additional to the infection being treated.

Very rare side effects:
- Jaundice can develop some weeks after taking this medicine. If this happens, tell your doctor immediately.

In cases with high doses or severe kidney problems
- Anaemia, blood clotting disorders and convulsions - talk to your doctor.

Check with your doctor if you have any problems while taking this medicine, even if you think the problems are not connected with the medicine, or are not listed in this leaflet.

5. HOW TO STORE YOUR MEDICINE

Do not use this medicine after the expiry date shown on the label.
Keep this medicine in a safe place where children cannot see or reach it.
Securitainers: Store below 25ºC. Store in the original container. Keep the container tightly closed to protect from light and moisture.
Blister Packs: Store below 25ºC. Store in the original package. Keep the blister in the outer carton to protect from light and moisture.
Return any left-over medicine to the pharmacist.

6. FURTHER INFORMATION

What Flucloxacillin Capsules BP contain

Active ingredient: flucloxacillin as flucloxacillin sodium
Other ingredients: Sodium starch glycollate, magnesium stearate, red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172), titanium dioxide (E171) and gelatin.
Please see further information on sodium in section 2.

What Flucloxacillin Capsules BP look like

250mg Capsules are opaque caramel and grey printed with 'FXN 250' in black ink. The capsules contain a granular off white powder.

500mg Capsules are opaque caramel and grey printed with 'FXN 500' in black ink. The capsules contain a granular off white powder.

Both strengths are available in the following pack sizes:
Securitainers are available in pack sizes of 15, 18, 20, 21, 28, 30, 50, 100, 250 & 500 capsules.
Blister packs are available in pack sizes of 15, 18, 20, 21, 28, 30, 50, 100, 250 & 500 capsules.
Not all pack sizes may be marketed.

The licence holder and manufacturer is:

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

PL06453/0015
PL06453/0016

This leaflet was revised January 2009.

HALF SINEMET® CR Tablets
(levodopa / carbidopa)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.
- **Keep this leaflet.** You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **This medicine has been prescribed for you.** Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1) WHAT IS HALF SINEMET CR TABLETS AND WHAT IS IT USED FOR?

Half Sinemet CR Tablets improves the signs of Parkinson's disease. Parkinson's disease is a long-term illness where:
- you become slow and unsteady
- your muscles feel stiff
- you may develop shaking or trembling (called 'tremor').

If not treated, Parkinson's disease can make it hard for you to continue your normal daily activities.

Half Sinemet CR Tablets contains two different medicines called: levodopa and carbidopa.
- levodopa turns into a material called 'dopamine' in your brain. The dopamine helps to improve the signs of your Parkinson's disease.
- carbidopa belongs to a group of medicines called 'aromatic amino acid decarboxylase inhibitors'. It helps levodopa work more effectively by slowing the speed at which levodopa is broken down in your body.

2) BEFORE YOU TAKE HALF SINEMET CR TABLETS

Do not take Half Sinemet CR Tablets if:
- you are allergic (hypersensitive) to carbidopa or levodopa or any of the other ingredients of Half Sinemet CR Tablets (listed in Section 6)
- you have ever had skin cancer or you have any unusual moles which have not been examined by your doctor
- you are taking certain medicines called 'MAOIs' (Monoamine Oxidase Inhibitors) used for depression. You need to stop using these medicines at least two weeks before you start Half Sinemet CR Tablets (see also under '**Taking other medicines**' below).
- you have a condition called 'narrow-angle glaucoma' that may cause a sudden build up of pressure in the eye
- you have a severe mental disorder
- you are pregnant, might become pregnant, or are breast-feeding.

Do not take Half Sinemet CR Tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Half Sinemet CR Tablets.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Half Sinemet CR Tablets.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Half Sinemet CR Tablets can affect the way some other medicines work. Also some other medicines can affect the way Half Sinemet CR Tablets works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:
- Medicines for Parkinson's disease containing levodopa:
  - → If they are 'slow release', you will need to wait 24 hours after your last dose before starting Half Sinemet CR Tablets.
  - → If they are 'normal release', you will need to wait 12 hours after your last dose before starting Half Sinemet CR Tablets.
  - → Tell the doctor or pharmacist even if you have only taken them in the past.
- Medicines for Parkinson's disease which do not contain levodopa will usually be continued. However, your dose may be changed.
- Medicines for mental problems (including depression), tuberculosis (TB), high blood pressure, muscle spasms, epilepsy or to treat low iron. Your dose may need to be changed.
- Medicines called 'MAOIs' (see also '**Do not take Half Sinemet CR Tablets if**').
- Anticholinergic medicines (such as orphenadrine, trihexyphenidyl, benzatropine and procyclidine). Your dose may need to be changed.
- Phenytoin which is used to treat fits (convulsions).
- Papaverine which is used to treat impotence in men.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine. Your doctor or pharmacist has a more complete list of medicines to avoid while taking Half Sinemet CR Tablets.

Tests while you are taking Half Sinemet CR Tablets
This medication can affect some laboratory tests that your doctor may perform on blood or urine samples. Please remind your doctor if you are taking Half Sinemet CR Tablets and are having any tests.

Taking Half Sinemet CR Tablets with food and drink
Try to avoid taking your tablets with a heavy meal. If your diet contains too much protein (meat, eggs, milk, cheese) Half Sinemet CR Tablets may not work as well as it should.

Pregnancy and breast-feeding
Do not take Half Sinemet CR Tablets if you are pregnant, might become pregnant or are breast-feeding. Levodopa, one of the substances in Half Sinemet CR Tablets, is passed into human milk.
Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

Driving and using machines
- Half Sinemet CR Tablets affects different people in different ways. Some people have side effects which affect their ability to drive or use tools or machines. (see Section 4 Possible side effects). Do not drive or use tools or machines if you get these effects.
- Half Sinemet CR Tablets can also make you sleepy or cause 'sudden sleep attacks'. If this happens to you, you must not drive or use tools or machines. Your doctor will tell you if you can start driving again if these attacks stop.

3) HOW TO TAKE HALF SINEMET CR TABLETS

Always take Half Sinemet CR Tablets exactly as your doctor has

If you have not had levodopa before
The usual starting dose for Sinemet CR Tablets is one tablet twice a day.

If you have had levodopa before
- your doctor will ask you to stop taking your medicine for Parkinson's disease for 8 hours before you start taking Half Sinemet CR Tablets.

The usual starting dose for Sinemet CR is one tablet twice a day. Your doctor may ask you to take Half Sinemet CR Tablets to help in determining the correct dose.

A combination of more than one Sinemet or Half Sinemet CR Tablets product may be prescribed by your doctor. If you have been given different Sinemet or Half Sinemet CR Tablets to take make sure that you are taking the correct one at the right time. Remember: Half Sinemet CR Tablets is a lower dose tablet than Sinemet CR.

Children under 18 years of age
Half Sinemet CR Tablets is not suitable for children under the age of 18 years.

If you take more Half Sinemet CR Tablets than you should
If you take too many tablets see your doctor immediately.

If you forget to take Half Sinemet CR Tablets
Do not take a double dose to make up for a forgotten dose.

If you stop taking Half Sinemet CR Tablets
Do not stop taking Half Sinemet CR Tablets or change your dose without talking to your doctor first. When you stop taking Half Sinemet CR Tablets the following can occur: stiff muscles, high temperature (fever) and mental changes.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4) POSSIBLE SIDE EFFECTS

Like all medicines, Half Sinemet CR Tablets can cause side effects, although not everybody gets them.

Stop taking Half Sinemet CR Tablets and see your doctor straight away, if you notice any of the following side effects:
- allergic reaction, the signs may include hives (nettle rash), itching, rash, swelling of your face, lips, tongue or throat. This may cause difficulty in breathing or swallowing
- chest pain
- uneven (irregular) heart beat or palpitations
- dizziness on standing-up quickly
- bleeding from your gut which may be seen as blood in your faeces or darkened faeces (gastro-intestinal bleeding)
- blood problems, the signs may include pale skin (pallor), tiredness, fever, sore throat or mild bruising and prolonged bleeding after injury
- stiff muscles, high fever
- mental changes including delusions, hallucinations and depression
- fits (convulsions).

The most common side effects are
- abnormal movements such as twitching or spasms (which may or may not be like your Parkinson's symptoms)
- nausea.

Other side effects include
- fainting, anorexia, high blood pressure
- inflammation of the veins, being sick (vomiting) diarrhoea, discoloration of urine, sweat or saliva
- on-off phenomenon, characteristic of some people with long-standing Parkinson's disease. This is when you can have unpredictable changes from being mobile - "on" - to a sudden inability to move - "off". "Off" to "on" can occur just
- difficulty sleeping, feeling anxious or high, falling over and abnormal walking patterns
- headache

Eyes:
- drooping eyelid and dilated pupil
- changes in vision, irregular movement of the eye

Digestive system:
- indigestion, dry mouth, bitter taste
- swelling of the salivary glands, difficulty swallowing, grinding of the teeth
- hiccups, abdominal pain and distress, constipation, wind
- burning sensation of the tongue.

Sexual:
- persistent abnormal erection of the penis

Urinary:
- difficulty passing urine or incontinence (inability to control urine flow);

Skin:
- changed patches of pigmented skin, including, irritated or irregular moles, or moles in which you have noticed changes (melanoma)

General:
- weight gain or loss, swelling in the limbs
- flushing, hot flushes, increased sweating
- feeling weak, faint or tired
- hoarseness, general feeling of being unwell
- increased energy or activity, unusual breathing pattern

If any symptoms persist or you experience any other side effects please tell your doctor or pharmacist. It will help if you make a note of what you experienced, when it started and how long it lasted.

5) HOW TO STORE HALF SINEMET CR TABLETS

- Do not use Half Sinemet CR Tablets after the expiry date which is stated on the blister and carton after 'EXP.' The expiry date refers to the last day of that month.
- If your doctor tells you to stop taking the tablets return the remaining tablets to the pharmacist for safe disposal. Only keep the tablets if your doctor tells you to.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will advice you what to do.
- Do not store above 30°C.
- Keep out of the reach and sight of children
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6) FURTHER INFORMATION

What Half Sinemet CR Tablets contain
- The active substances in Half Sinemet CR Tablets are carbidopa (equivalent to 25mg anhydrous carbidopa) and levodopa (100mg) in prolonged-release tablets.
- The other ingredients are magnesium stearate, hydroxypropylcellulose, copolymer of polyvinyl acetate, crotonic acid and red iron oxide (E172).

What Half Sinemet CR Tablets look like and contents of the pack
Half Sinemet CR Tablets are pink coloured oval shaped tablets marked and '601' one side. They are available in blister strips of 50 tablets.

Manufacturer
This product is manufactured by **Merck Sharp & Dohme (Italia) SpA, Via Emilia, 21-27100 Pavia, Italy.** Procured from within

PATIENT INFORMATION LEAFLET

HYDROCORTISONE OINTMENT 1%
1% Hydrocortisone

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. WHAT HYDROCORTISONE OINTMENT IS AND WHAT IT IS USED FOR

Hydrocortisone Ointment is a smooth off-white ointment for application to the skin only. It contains hydrocortisone which belongs to a group of medicines called corticosteroids. Hydrocortisone Ointment is used to reduce inflammation in a variety of inflammatory skin conditions including eczema and dermatitis of all types, such as:
- inherited skin inflammation, scaliness or itchiness (atopic eczema)
- light-sensitive skin (photodermatitis)
- dermatitis between folds of skin (intertrigo)
- dermatitis caused by irritants or allergens
- lumps in the skin with itching (prurigo nodularis)
- scaly or crusty skin, 'cradle cap' (seborrhoeic dermatitis)
- insect bite reactions.

2. BEFORE YOU USE HYDROCORTISONE OINTMENT

Do not use Hydrocortisone Ointment if you:
- are allergic to hydrocortisone or to any of the other ingredients of Hydrocortisone Ointment *(see Section 6 and end of Section 2)*.
- have a bacterial infection (e.g. impetigo), viral infection (e.g. herpes simplex) or fungal infection (e.g. tinea, also called 'athlete's foot', ringworm or thrush) of the skin.

Take special care with Hydrocortisone Ointment
Hydrocortisone Ointment is **not** suitable for use in the following:
- allergic skin reactions including temporary red or raised areas on your skin (short lived 'wheal and flare' reactions)
- conditions involving the deeper skin layers, such as granulomas
- psoriasis (long term scaly skin condition); only use this product on medical advice and with careful supervision by your doctor.

Take great care to apply the ointment sparingly to the skin of infants or children, especially in the nappy area which can be covered for long periods. Covering the treated area can increase absorption. Treatment for infants must not exceed 7 days.

Your doctor may advise the use of antimicrobial medicine at the same time as Hydrocortisone Ointment if the area has become infected.

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
Tell your doctor if you are or may be pregnant. Ask your doctor for advice before taking any medicine during pregnancy. There is a very small risk of abnormalities in the unborn child if this product is used during pregnancy.
If you are breast-feeding, do not apply the product to your chest area.

Important information about some of the ingredients
Hydrocortisone Ointment contains **wool fat** (lanolin) which may cause local skin reactions (e.g. contact dermatitis).

23LF00568PW

3. HOW TO USE HYDROCORTISONE OINTMENT

FOR EXTERNAL USE ONLY

Always use Hydrocortisone Ointment exactly as your doctor has told you. Your doctor will tell you how much to apply and how often but you must check with your doctor if you are not sure.

Do not exceed the stated dose.

For application to the **surface of the skin** only:
1. Wash your hands thoroughly before use.
2. Apply the ointment sparingly to the affected area, one to four times a day. Massage the ointment gently into the affected area to help absorption into the skin.
3. Once applied, **do not cover** the area with a dressing or plaster.

Increase the intervals between applications as the condition improves. Treatment may be reduced to two to three times a week, or restarted when your symptoms return.

If you use more Hydrocortisone Ointment than you should
If you or a child accidentally swallow the ointment, contact your doctor or nearest hospital immediately. Take the packet with you to help identification.

If you forget to use Hydrocortisone Ointment
If you miss a treatment, apply the ointment as soon as you remember, and apply the remaining doses for that day at evenly spaced intervals.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Hydrocortisone Ointment can cause side effects, although not everybody gets them.

You may notice the following:
- rash, itchy skin, swelling of the lips, eyes, tongue, or difficulty in breathing may be signs of an **allergic reaction**. **Stop using Hydrocortisone Ointment immediately.**
- 'stretch marks' may appear, especially in skin folds such as the groin or armpits.

If any of the side effects become severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE HYDROCORTISONE OINTMENT

Keep out of the reach and sight of children. Do not store above 25˚C. Store in the original package and keep the tube in the outer carton. Do not use Hydrocortisone Ointment after the expiry date which is stated on the tube/carton.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Hydrocortisone Ointment contains:
- The **active substance** is hydrocortisone and the ointment contains 10 mg in every 1g (1%).
- The **other ingredients** are wool fat (lanolin) liquid paraffin and white soft paraffin *(see end of Section 2 for further information)*.

What Hydrocortisone Ointment looks like and contents of the pack
The product is a smooth off- white ointment and is available in aluminium tubes containing 5g, 10g, 15g, 20g, 30g or 50g. No all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.
PL 04917/0020

This leaflet was last updated in 09/2009

23LF00568PW

PACKAGE LEAFLET: INFORMATION FOR THE USER

ISTIN™
(amlodipine as amlodipine besilate)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT ISTIN IS AND WHAT IT IS USED FOR

Istin is one of a group of medicines called calcium antagonists.

Your medicine is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina.

In patients with high blood pressure your medicine works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina Istin works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. Your medicine does not provide immediate relief of chest pain from angina.

2. BEFORE YOU TAKE ISTIN

Do not take Istin
- if you are allergic (hypersensitive) to Amlodipine, or any of the other ingredients of your medicine listed in section 6, or to any other calcium antagonists. This may be itching, reddening of the skin or difficulty in breathing.
- If you have narrowing of the aortic heart valve (aortic stenosis), unstable angina or cardiogenic shock.
- If you are pregnant or breast feeding.

Take special care with Istin
You should inform your Doctor if you have or have had any of the following conditions:
- Recent heart attack (within the last month).
- Severe increase in blood pressure (Hypertensive crisis)
- Liver disease

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Istin with food and drink
Your medicine can be used before or after food. Grapefruit juice and grapefruit should not be consumed by people who are taking Istin. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Istin.

UNITED KINGDOM

YOU WILL FIND MORE ABOUT ISTIN ON THE BACK OF THIS LEAFLET

ON ISTIN

If you forget to take Istin
Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a missed dose.

If you stop using Istin
Your doctor will advise you how long to take your medicine. Your condition may return if you stop taking your medicine before you are advised.

If you have any further questions on how to take this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Istin can cause side effects, although not everybody gets them.

Tell your doctor **immediately** if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.
- Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).

The following **Common side-effects** have been reported. If any of these cause you problems or if they **last for more than one week,** you should **contact your doctor.**

Common side-effects:
- Headache, dizziness, sleepiness
- Palpitations (awareness of your heart beat), flushing
- Abdominal pain, feeling sick (nausea)
- Ankle swelling (oedema), tiredness

Other side-effects that have been reported include the following list. If any of these get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

Uncommon side-effects:
- Mood changes, sleeplessness
- Trembling, taste abnormalities, fainting, weakness
- Visual disturbances, ringing in the ears
- Low blood pressure
- Shortness of breath, sneezing/running nose

MORE INFORMATION ON ISTIN

- Altered bowel habit, indigestion, dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on skin
- Increased need to urinate especially at night, inability to obtain an erection
- Chest pain, weakness, pain, feeling unwell
- Joint or muscle pain, muscle cramps, back pain
- Weight increase or decrease
- Enlargening of male breasts

Very rare side-effects reported:
- Unusual bruising and bleeding (red blood cell damage)
- Severe skin reactions
- Excess sugar in blood (diabetes)
- Increased sensitivity of the skin, pins and needles, loss of pain sensation
- Heart attack
- Hives
- Abdominal bloating (gastritis)
- Cough
- Inflamed pancreas
- Abnormal liver function, inflammation of the liver, yellowing of the skin (jaundice), liver enzyme increases

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ISTIN

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use your medicine after the expiry date which is stamped on the pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Istin contains
- The active substance is Amlodipine (as amlodipine besilate)
- The other ingredients are dibasic calcium phosphate, magnesium stearate, microcrystalline cellulose and sodium starch glycollate.

What Istin looks like and contents of the pack

Istin tablets come in two strengths, 5mg and 10mg.

The 5mg tablets are white; emerald shaped and marked AML-5 on one side and the Pfizer logo on the other. They contain 5mg amlodipine besilate.

The 10mg tablets are white; emerald shaped and marked AML-10 on one side and the Pfizer logo on the other. They contain 10mg amlodipine besilate.

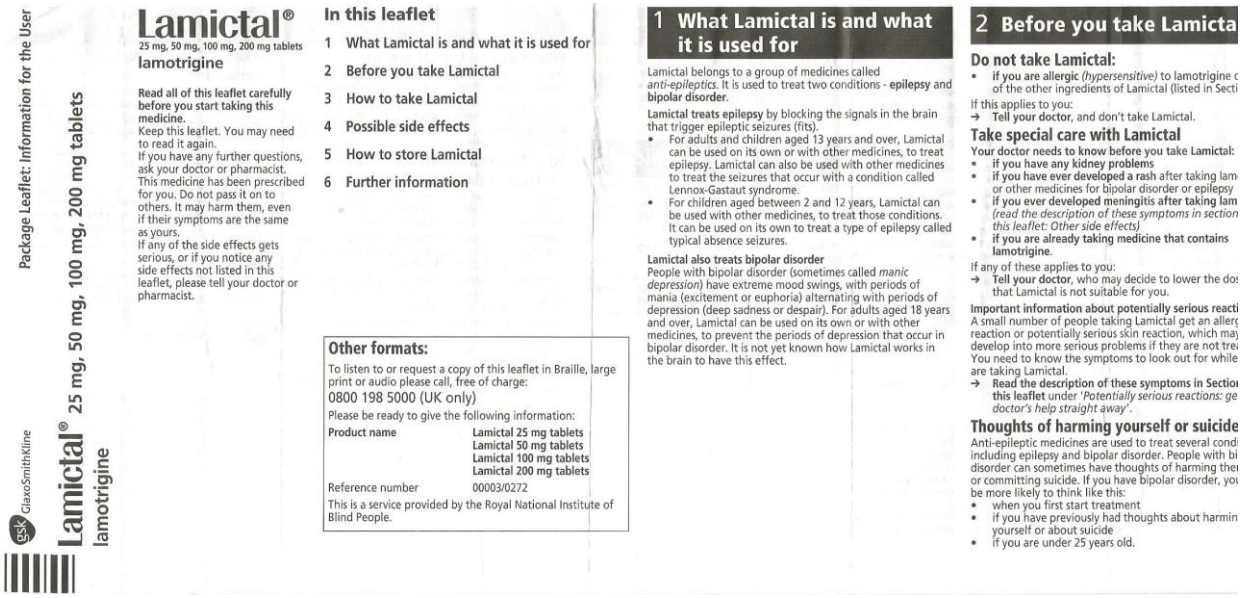
Istin comes in packs of 28 tablets.

Marketing Authorisation Holder
Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ
United Kingdom

Manufacturer
Pfizer Manufacturing Deutschland GmbH
Heinrich-Mack-Strasse 35
89257 Illertissen
Germany

This leaflet was approved in March 2010

Ref Code: IS14_0 UK



Package Leaflet: Information for the User

GlaxoSmithKline

Lamictal® 25 mg, 50 mg, 100 mg, 200 mg tablets
lamotrigine

Lamictal®
25 mg, 50 mg, 100 mg, 200 mg tablets
lamotrigine

Read all of this leaflet carefully before you start taking this medicine.
Keep this leaflet. You may need to read it again.
If you have any further questions, ask your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK only)
Please be ready to give the following information:

Product name	**Lamictal 25 mg tablets** **Lamictal 50 mg tablets** **Lamictal 100 mg tablets** **Lamictal 200 mg tablets**
Reference number	00003/0272

This is a service provided by the Royal National Institute of Blind People.

1 What Lamictal is and what it is used for

Lamictal belongs to a group of medicines called *anti-epileptics*. It is used to treat two conditions - **epilepsy** and **bipolar disorder**.

Lamictal treats epilepsy by blocking the signals in the brain that trigger epileptic seizures (fits).
- For adults and children aged 13 years and over, Lamictal can be used on its own or with other medicines, to treat epilepsy. Lamictal can also be used with other medicines to treat the seizures that occur with a condition called Lennox-Gastaut syndrome.
- For children aged between 2 and 12 years, Lamictal can be used with other medicines, to treat those conditions. It can be used on its own to treat a type of epilepsy called typical absence seizures.

Lamictal also treats bipolar disorder
People with bipolar disorder (sometimes called *manic depression*) have extreme mood swings, with periods of mania (excitement or euphoria) alternating with periods of depression (deep sadness or despair). For adults aged 18 years and over, Lamictal can be used on its own or with other medicines, to prevent the periods of depression that occur in bipolar disorder. It is not yet known how Lamictal works in the brain to have this effect.

2 Before you take Lamicta

Do not take Lamictal:
- **if you are allergic** *(hypersensitive)* to lamotrigine o
of the other ingredients of Lamictal (listed in Secti

If this applies to you:
→ **Tell your doctor**, and don't take Lamictal.

Take special care with Lamictal
Your doctor needs to know before you take Lamictal:
- **if you have any kidney problems**
- **if you have ever developed a rash** after taking lam
or other medicines for bipolar disorder or epilepsy
- **if you ever developed meningitis after taking lam**
(read the description of these symptoms in section this leaflet: Other side effects)
- **if you are already taking medicine that contains lamotrigine.**

If any of these applies to you:
→ **Tell your doctor**, who may decide to lower the dos
that Lamictal is not suitable for you.

Important information about potentially serious reacti
A small number of people taking Lamictal get an allerg
reaction or potentially serious skin reaction, which may
develop into more serious problems if they are not trea
You need to know the symptoms to look out for while
are taking Lamictal.
→ **Read the description of these symptoms in Sectio**
this leaflet under *'Potentially serious reactions: ge*
doctor's help straight away'.

Thoughts of harming yourself or suicide
Anti-epileptic medicines are used to treat several condi
including epilepsy and bipolar disorder. People with bi
disorder can sometimes have thoughts of harming the
or committing suicide. If you have bipolar disorder, yo
be more likely to think like this:
- when you first start treatment
- if you have previously had thoughts about harmin
yourself or about suicide
- if you are under 25 years old.

3 How to take Lamictal

Always use Lamictal exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

How much Lamictal to take

It may take a while to find the best dose of Lamictal for you. The dose you take will depend on:
- your age
- whether you are taking Lamictal with other medicines
- whether you have any kidney or liver problems.

Your doctor will prescribe a low dose to start, and gradually increase the dose over a few weeks until you reach a dose that works for you (called the *effective dose*). **Never take more Lamictal than your doctor tells you to.**

The usual effective dose of Lamictal for adults and children aged 13 years or over is between 100 mg and 400 mg each day.

For children aged 2 to 12 years, the effective dose depends on their body weight - usually, it's between 1 mg and 15 mg for each kilogram of the child's weight, up to a maximum of 400 mg daily.

Lamictal is not recommended for children aged under 2 years.

How to take your dose of Lamictal

Take your dose of Lamictal once or twice a day, as your doctor advises. It can be taken with or without food.

Your doctor may also advise you to start or stop taking other medicines, depending on what condition you're being treated for and the way you respond to treatment.

- **Swallow your tablets whole.** Don't break, chew or crush them.
- **Always take the full dose** that your doctor has prescribed. Never take only part of a tablet.

If you take more Lamictal than you should

→ **Contact a doctor or pharmacist immediately.** If possible, show them the Lamictal packet.

Someone who has taken too much Lamictal may have any of these symptoms:
- rapid, uncontrollable eye movements *(nystagmus)*
- clumsiness and lack of co-ordination, affecting their balance *(ataxia)*
- loss of consciousness or coma.

If you forget to take Lamictal

Don't take extra tablets or a double dose to make up for a forgotten dose.

If you have missed taking a dose of Lamictal:
→ **Ask your doctor for advice on how to start taking it again.** It's important that you do this.

Don't stop taking Lamictal without advice

Lamictal must be taken for as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you're taking Lamictal for epilepsy

To stop taking Lamictal, **it is important that the dose is reduced gradually**, over about 2 weeks. If you suddenly stop taking Lamictal, your epilepsy may come back or get worse.

If you're taking Lamictal for bipolar disorder

Lamictal may take some time to work, so you are unlikely to feel better straight away. If you stop taking Lamictal, your dose will not need to be reduced gradually. But you should still talk to your doctor first, if you want to stop taking Lamictal.

4 Possible side effects

Like all medicines, Lamictal can cause side effects, but not everyone gets them.

Potentially serious reactions: get a doctor's help straight away

A small number of people taking Lamictal get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated.

These symptoms are more likely to happen during the first few months of treatment with Lamictal, especially if the starting dose is too high or if the dose is increased too quickly, or if Lamictal is taken with another medicine called *valproate*. Some of the symptoms are more common in children, so parents should be especially careful to watch out for them.

Symptoms of these reactions include:

- **skin rashes or redness**, which may develop into severe skin reactions including widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals *(Stevens-Johnson syndrome)*, extensive peeling of the skin (more than 30% of the body surface - *toxic epidermal necrolysis)*
- **a sore mouth or eyes**
- **a high temperature** *(fever)*, flu-like symptoms or drowsiness
- **swelling around your face**, or **swollen glands in your neck, armpit or groin**
- **unexpected bleeding or bruising**, or the fingers turning blue
- **a sore throat**, or more infections (such as colds) than usual.

In many cases, these symptoms will be signs of less serious side effects. **But you must be aware that they are potentially serious and can develop into more serious problems**, such as organ failure, if they are not treated. If you notice any of these symptoms:

→ **Contact a doctor immediately.** Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking Lamictal.

Very common side effects

These may affect **more than 1 in 10 people:**

- headache
- feeling dizzy
- feeling sleepy or drowsy
- clumsiness and lack of co-ordination *(ataxia)*
- double vision or blurred vision
- feeling sick *(nausea)* or being sick *(vomiting)*
- skin rash.

Common side effects

These may affect **up to 1 in 10 people:**

- aggression or irritability
- rapid, uncontrollable eye movements *(nystagmus)*
- shaking or tremors
- difficulty in sleeping
- diarrhoea
- dry mouth
- feeling tired
- pain in your back or joints, or elsewhere.

Rare side effects

These may affect **up to 1 in 1,000 people:**

- itchy eyes, with discharge and crusty eyelids *(conjunctivitis)*
- a severe skin reaction *(Stevens-Johnson syndrome: see also the information at the beginning of Section 4)*.

Very rare side effects

These may affect **up to 1 in 10,000 people:**

- hallucinations ('seeing' or 'hearing' things that aren't really there)
- confusion or agitation
- feeling 'wobbly' or unsteady when you move about
- uncontrollable body movements *(tics)*, uncontrollable muscle spasms affecting the eyes, head and torso *(choreoathetosis)*, or other unusual body movements such as jerking, shaking or stiffness
- a severe skin reaction *(toxic epidermal necrolysis: see also the information at the beginning of Section 4)*
- in people who already have epilepsy, seizures happening more often
- changes in liver function, which will show up in blood tests, or liver failure
- changes which may show up in blood tests - including reduced numbers of red blood cells *(anaemia)*, reduced numbers of white blood cells *(leucopenia, neutropenia, agranulo-cytosis)*, reduced numbers of platelets *(thrombocytopenia)*, reduced numbers of all these types of cell *(pancytopenia)*, and a disorder of the bone marrow called *aplastic anaemia*
- a serious disorder of blood clotting, which can cause unexpected bleeding or bruising *(disseminated intravascular coagulation)*
- a high temperature *(fever)*
- swelling around the face *(oedema)* or swollen glands in the neck, armpit or groin *(lymphadenopathy)*
- in people who already have Parkinson's disease, worsening of the symptoms.

Other side effects

Other side effects have occurred in a small number of people but their exact frequency is unknown:
A group of symptoms together including: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover the brain and spinal cord *(meningitis)*.
These symptoms usually disappear once treatment is stopped however if the symptoms continue or get worse **contact your doctor.**

If you get side effects

→ If any of the side effects becomes severe or troublesome, or if you notice any side effects not listed in this leaflet **please tell your doctor or pharmacist.**

5 How to store Lamictal

Keep Lamictal out of the sight and reach of children.

Do not use Lamictal after the expiry date shown on the blisters, carton or bottle. The expiry date refers to the last day of that month.

Lamictal does not require any special storage conditions.

If you have any unwanted Lamictal tablets, don't dispose of them in your waste water or your household rubbish. Take them back to your pharmacist, who will dispose of them in a way that won't harm the environment.

6 Further information

What Lamictal tablets contain

The active substance is lamotrigine. Each tablet contains 25 mg, 50 mg, 100 mg or 200 mg lamotrigine.

The other ingredients are: lactose monohydrate, microcrystalline cellulose, povidone K30, sodium starch glycolate (Type A), iron oxide yellow (E172) and magnesium stearate.

What Lamictal tablets look like and contents of the pack

Lamictal tablets (all strengths) are square with rounded corners, and pale, yellowish brown in colour. Not all listed pack sizes may be marketed.

Lamictal 25 mg tablets are marked 'GSEC7' on one side and '25' on the other. Each pack contains blisters of 14, 21, 28, 30, 42, 50, 56 or 100 tablets.

Lamictal 50 mg tablets are marked 'GSEE1' on one side and '50' on the other. Each pack contains blisters of 14, 28, 30, 42, 56, 90, 98 or 100 tablets.

Lamictal 100 mg tablets are marked 'GSEE5' on one side and '100' on the other. Each pack contains blisters of 28, 30, 42, 50, 56, 60, 90, 98 or 100 tablets.

Lamictal 200 mg tablets are marked 'GSEE7' on one side and '200' on the other. Each pack contains blisters of 28, 30, 42, 56 or 100 tablets.

Marketing Authoris Manufacturer

Marketing Authorisation H
Stockley Park West, Uxbrid

Manufacturer: GlaxoSmithI
Ul. Grunwaldzka 189, 60-3

If you have any other ques contact a doctor or pharm the British Epilepsy Associa them for you. You can tel Information Centre free fr country on **0808 800 5050** Anstey House, Gate Way D LS19 7XY

Leaflet date: June 2011
Lamictal is a registered trac GlaxoSmithKline group of

GlaxoSmithKlin

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lercanidipine HCl 10 mg film-coated tablets
Lercanidipine HCl 20 mg film-coated tablets

lercanidipine hydrochloride

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TAKING THIS MEDICINE:

Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT LERCANIDIPINE HCl IS AND WHAT IT IS USED FOR

Lercanidipine HCl belongs to a group of medicines called Calcium Channel Blockers (dihydropyridine derivatives). Lercanidipine HCl is used to treat high blood pressure also known as hypertension in adults over the age of 18 years (it is not recommended for children under 18 years old).

2. BEFORE YOU TAKE LERCANIDIPINE HCL

DO NOT TAKE LERCANIDIPINE HCL AND TELL YOUR DOCTOR IF:

- You are allergic (hypersensitive) to lercanidipine hydrochloride or to any other ingredients of Lercanidipine HCl tablets
- You have had allergic reactions to drugs closely related to Lercanidipine HCl tablets (such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine)
- If you are suffering from certain heart diseases:
  - Untreated heart failure
  - Obstruction to flow of blood from the heart
  - Unstable angina (angina at rest or progressively increasing)
  - Within one month of heart attack
- You have severe liver or kidney problems
- You are taking drugs that are inhibitors of CYP3A4 isoenzyme:
  - Antifungal medicines (such as ketoconazole or itraconazole)
  - Macrolide antibiotics (such as erythromycin or troleandomycin)
  - Antivirals (such as ritonavir)
- You are taking another drug called ciclosporin or cyclosporin (used after transplants to prevent organ rejection)
- With grapefruit or grapefruit juice.

Do not use if you are pregnant or breastfeeding (see section Pregnancy and Breastfeeding for more information).

TAKE SPECIAL CARE WITH LERCANIDIPINE HCL AND TELL YOUR DOCTOR IF:

- You have certain other heart conditions or you have a pacemaker or have pre-existing angina
- You have problems with your liver or kidneys or you are on dialysis.

USING OTHER MEDICINES

Please tell your doctor or pharmacist if:
- You are taking or have recently taken any other medicines, including medicines obtained without a prescription
- You are taking beta-blockers e.g. metoprolol, diuretics (water tablets) or ACE-inhibitors (medicines to treat high blood pressure)
- You are taking cimetidine (more than 800 mg, a medicine for ulcers, indigestion, or heartburn)
- You are taking digoxin (a medicine to treat a heart problem)
- You are taking midazolam (a medicine that helps you sleep)
- You are taking rifampicin (a medicine to treat tuberculosis)
- You are taking astemizole or terfenadine (medicines for allergies)
- You are taking amiodarone or quinidine (medicines to treat a fast heart beat)
- You are taking phenytoin or carbamazepine (medicines for epilepsy). Your doctor will want to monitor your blood pressure more frequently than usual.

TAKING LERCANIDIPINE HCL WITH FOOD AND DRINK

- Patients should not consume alcohol during treatment with Lercanidipine HCl tablets since it may increase the effect of Lercanidipine HCl tablets
- Patients should not take grapefruit or grapefruit juice.

PREGNANCY AND BREAST FEEDING

Do not use Lercanidipine HCl if you are pregnant or breast-feeding, or you wish to become pregnant or if you are not using any contraceptive method.
If you are taking Lercanidipine HCl and think that you may be pregnant, consult your doctor.

DRIVING AND USING MACHINES

Caution should be exercised because of the possibility of dizziness, weakness and tiredness. Do not drive or use machines until you know how Lercanidipine HCl affects you.

INFORMATION ABOUT SOME INGREDIENTS OF LERCANIDIPINE HCL:

If you have been told by your doctor that you have an intolerance to some sugars, e.g. intolerance to lactose, galactosaemia or glucose/galactose malabsorption syndrome, contact your doctor before taking this medicinal product, as the tablets contain lactose.

3. HOW TO TAKE LERCANIDIPINE HCL

Always take Lercanidipine HCl exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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Adults: The usual dose is 10 mg film-coated tablet daily at the same time each day, preferably in the morning at least 15 minutes before breakfast, because a high fat meal significantly increases blood levels of the drug. Your doctor may advise you to increase the dose to one Lercanidipine HCl 20 mg film-coated tablet daily, if needed.
The tablets should preferably be swallowed whole with some water.

Elderly: No adjustment of the daily dose is required. However, special care should be exercised in starting treatment.

Patients with liver or kidney problems: special care is needed in starting treatment in these patients and an increase in daily dose to 20 mg should be approached with caution.

Children: This medicine should not be used in children under 18 years of age.

If you have any further questions on the use of this product ask your doctor.

IF YOU TAKE MORE LERCANIDIPINE HCL THAN YOU SHOULD

Do not exceed the prescribed dose

If you take more than the prescribed dose or in the event of overdose, seek medical advice immediately and, if possible, take your tablets and/or the container with you.

Exceeding the correct dosage may cause blood pressure to become too low, and the heart to beat irregularly or faster. It may also lead to unconsciousness.

IF YOU FORGET TO TAKE LERCANIDIPINE HCL

If you forget to take your tablet simply miss that dose and then go on as before. Do not take a double dose.

IF YOU STOP TAKING LERCANIDIPINE HCL

If you stop taking Lercanidipine HCl your blood pressure may increase again. Please consult your doctor before stopping the treatment.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lercanidipine HCl can cause side effects, although not everybody gets them.

Some side effects can be serious:

If you experience any of these side effects tell your doctor straight away.

Rare (affecting less than 1 out of 1000 patients): angina pectoris (chest pain due to lack of blood to your heart).

Very rare (affecting less than 1 out of 10,000 patients): chest pain, fall in blood pressure, fainting and allergic reactions (symptoms include itching, rash, hives).

If you suffer from pre existing angina pectoris, with the group of medicines to which Lercanidipine HCl belongs, you may experience increased frequency, duration or severity of these attacks. Isolated cases of heart attack may be observed.

Other possible side effects:

Uncommon (affecting less than 1 out of 100 patients): headache, dizziness, faster heart beats, palpitations (heart pounding or racing), sudden reddening of the face, neck or upper chest., ankle swelling.

Rare (affecting less than 1 out of 1000 patients): sleepiness, feeling sick, vomiting, heartburn, stomach pain, diarrhoea; skin rash, muscle pain, passage of large amounts of urine, tiredness.

Very rare (affecting less than 1 out of 10,000 patients): swelling of gums, changes in liver function (detected by blood tests), increase in the usual number of times one urinates.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LERCANIDIPINE HCL

Keep out of the reach and sight of children

Do not use Lercanidipine HCl after the expiry date, which is stated on the label, carton and on blister. The expiry date refers to the last day of that month.
Store in the original package in order to protect from light and moisture. The original package should be kept in a dry place.

Medicines should not be disposed of via wastewater of household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

WHAT LERCANIDIPINE HCL CONTAINS

The active substance is: lercanidipine hydrochloride 10 mg which is equivalent to 9.4 mg of lercanidipine or lercanidipine hydrochloride 20 mg which is equivalent to 18.8 mg of lercanidipine.
The other ingredients are:
Core tablet: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone K30, magnesium stearate
Film coating: hypromellose, talc, titanium dioxide (E171), macrogol 6000, and ferric oxide (E172).

WHAT LERCANIDIPINE HCL LOOKS LIKE AND CONTENTS OF THE PACK

Lercanidipine HCl 10 mg: yellow, circular, biconvex, film coated tablet scored on one side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
Lercanidipine HCl 20 mg: pink, circular, biconvex, film coated tablet scored on one side
Lercanidipine HCl is available in blister packs of 7, 14, 28, 35, 42, 50, 56, 98, 100 tablets. Not all pack sizes may be marketed.

MARKETING AUTHORISATION HOLDER AND MANUFACTURER

RECORDATI Industria Chimica e Farmaceutica S.p.A. - Via Matteo Civitali 1 - 20148 Milan, Italy.

Date of revision of the text: February 2009

RECORDATI
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PACKAGE LEAFLET: INFORMATION FOR THE USER

UNITED KINGDOM

Lipitor 10 mg, 20 mg, 40 mg & 80 mg

film-coated tablets

Atorvastatin

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT LIPITOR IS AND WHAT IT IS USED FOR

Lipitor belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

Lipitor is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, Lipitor can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

2. BEFORE YOU TAKE LIPITOR

Do not take Lipitor

- if you are hypersensitive (allergic) to Lipitor or to any similar medicines used to lower blood lipids or to any of the other ingredients of the medicine – see Section 6 for details.
- if you have or have ever had a disease which affects the liver
- if you have had any unexplained abnormal blood tests for liver function
- if you are a woman able to have children and not using reliable contraception
- if you are pregnant or trying to become pregnant
- if you are breast-feeding.

Take special care with Lipitor

The following are reasons why Lipitor may not be suitable for you:

- if you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes
- if you have kidney problems
- if you have an under-active thyroid gland (hypothyroidism)
- if you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems
- if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other '-statin' or '-fibrate' medicines)
- if you regularly drink a large amount of alcohol
- if you have a history of liver disease
- if you are older than 70 years.

Check with your doctor or pharmacist before taking Lipitor

- if you have severe respiratory failure.

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your Lipitor treatment to predict your risk of muscle related side effects. The risk of muscle related side effects e.g rhabdomyolysis is known to increase when certain medicines are taken at the same time (see Section 2 "Taking other medicines").

Taking other medicines

There are some medicines that may change the effect of Lipitor or their effect may be changed by Lipitor. This type of interaction could make one or both of the medicines less effective. Alternatively it could increase the risk or severity of side-effects, including the important muscle wasting condition known as rhabdomyolysis described in Section 4:

- Medicines used to alter the way your immune system works, e.g. ciclosporin
- Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampin, fusidic acid
- Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol
- Some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem,; medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone
- Medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, etc.
- Other medicines known to interact with Lipitor include ezetimibe (which lowers cholesterol), warfarin (which reduces blood clotting), oral contraceptives, stiripentol (an anti-convulsant for epilepsy), cimetidine (used for heartburn and peptic ulcers), phenazone (a painkiller) and antacids (indigestion products containing aluminium or magnesium)
- Medicines obtained without a prescription: St John's Wort

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Lipitor with food and drink

See Section 3 for instructions on how to take Lipitor. Please note the following:

Grapefruit juice
Do not take more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effects of Lipitor.

Alcohol
Avoid drinking too much alcohol while taking this medicine. See Section 2 "Take special care with Lipitor" for details

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Pregnancy and breast-feeding

Do not take Lipitor if you are pregnant, or if you are trying to become pregnant.
Do not take Lipitor if you are able to become pregnant unless you use reliable contraceptive measures.
Do not take Lipitor if you are breast-feeding.
The safety of Lipitor during pregnancy and breast-feeding has not yet been proven. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Normally this medicine does not affect your ability to drive or operate machines. However, do not drive if this medicine affects your ability to drive. Do not use any tools or machines if your ability to use them is affected by this medicine.

Important information about some of the ingredients of Lipitor

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE LIPITOR

Before starting treatment, your doctor will place you on a low-cholesterol diet, which you should maintain also during therapy with Lipitor.

The usual starting dose of Lipitor is 10 mg once a day in adults and children aged 10 years or older. This may be increased if necessary by your doctor until you are taking the amount you need. Your doctor will adapt the dose at intervals of 4 weeks or more. The maximum dose of Lipitor is 80 mg once daily for adults and 20 mg once daily for children.

Lipitor tablets should be swallowed whole with a drink of water, and can be taken at any time of day, with or without food. However, try to take your tablet at the same time every day.

Always take Lipitor exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You will find more about LIPITOR on the back of this leaflet

- allergic reactions
- increases in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels), increase in blood creatine kinase
- headache
- nausea, constipation, wind, indigestion, diarrhoea
- joint pain, muscle pain and back pain
- blood test results that show your liver function can become abnormal

Uncommon side effects (affects 1 to 10 users in 1000) include:

- anorexia (loss of appetite), weight gain, decreases in blood sugar levels (if you have diabetes you should continue careful monitoring of your blood sugar levels)
- having nightmares, insomnia
- dizziness, numbness or tingling in the fingers and toes, reductions of sensation to pain or touch, change in sense of taste, loss of memory
- blurred vision
- ringing in the ears and/or head
- vomiting, belching, abdominal pain upper and lower, pancreatitis (inflammation of the pancreas leading to stomach pain)
- hepatitis (liver inflammation)
- rash, skin rash and itching, hives, hair loss
- neck pain, muscle fatigue
- fatigue, feeling unwell, weakness, chest pain, swelling especially in the ankles (oedema), raised temperature
- urine tests that are positive for white blood cells

Rare side effects (affects 1 to 10 users in 10,000) include:

- visual disturbance
- unexpected bleeding or bruising
- cholestasis (yellowing of the skin and whites of the eyes)
- tendon injury

Very rare side effects (affects less than 1 user in 10,000) include:

- an allergic reaction – symptoms may include sudden wheezing and chest pain or tightness, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse
- hearing loss
- gynecomastia (breast enlargement in men and women).

Possible side effects reported with some statins (medicines of the same type):

- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LIPITOR

Keep out of the reach and sight of children.
This medicine does not require any special storage conditions.

Do not use Lipitor after the expiry date which is stated on the container and outer packaging after {EXP}. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Lipitor contains

- The active substance is atorvastatin.
  Each film-coated tablet contains 10 mg atorvastatin (as atorvastatin calcium trihydrate).
  Each film-coated tablet contains 20 mg atorvastatin (as atorvastatin calcium trihydrate).
  Each film-coated tablet contains 40 mg atorvastatin (as atorvastatin calcium trihydrate).
  Each film-coated tablet contains 80 mg atorvastatin (as atorvastatin calcium trihydrate).
- The other ingredients of Lipitor are:
  calcium carbonate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, polysorbate 80, hyprolose and magnesium stearate.

The coating of Lipitor contains hypromellose, macrogol 8000, titanium dioxide (E171), talc, simethicone, stearate emulsifiers, thickeners, benzoic acid and sorbic acid.

What Lipitor looks like and contents of the pack

Lipitor film-coated tablets are white with a round shape. They are marked with 10, 20, 40 or 80 on one side and "ATV" on the other side.

Each strength of Lipitor is supplied in blister packs of 28 tablets.

449687

This medicine is available as 5 mg, 10 mg, 20 mg and 40 mg chewable tablets and 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Pfizer Ireland Pharmaceuticals, Pottery Road, Dun Laoghaire, Co. Dublin, Ireland.

Manufacturer:
Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, D-79090 Freiburg, Germany.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Bulgaria, Czech Republic, Estonia, Germany, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia	Sortis
Belgium, Cyprus, Finland, Greece, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Sweden, UK	Lipitor
Denmark, Greece, Iceland, Portugal, Spain	Zarator
Finland	Orbeos
France	Tahor
Germany	Atorvastatin Pfizer, Liprimar
Greece	Edovin
Hungary	Obradon
Italy	Torvast, Totalip, Xarator
Portugal	Atorvastatina Parke-Davis, Texzor
Spain	Cardyl, Atorvastatina Nostrum, Atorvastatina Pharmacia, Prevencor

This leaflet was last approved in 03/2011.

Ref: LR 20_0

LIQUIFILM TEARS®

1.4% w/v, eye drops, solution
Polyvinyl alcohol

user

Read all of this leaflet carefully because it contains important information for you
This medicine is available without prescription. However, you still need to use LIQUIFILM TEARS carefully to get the best results from it.
- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- **while you are wearing soft contact lenses:** you must remove them before using LIQUIFILM TEARS eye drops. After using LIQUIFILM TEARS, wait at least 15 minutes before putting your lenses back in. See also in Section 2, "Important information about some of the ingredients of LIQUIFILM TEARS".

Take special care with LIQUIFILM TEARS:
Stop using LIQUIFILM TEARS and **contact** your doctor if:
- you experience long-lasting redness or irritation of the eye, eye pain, changes in vision
- your condition worsens or has not improved 3 days after having started treatment with LIQUIFILM TEARS.

Using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you have to use any other eye medicine during treatment with LIQUIFILM TEARS: first use the other eye medicine, wait 15 minutes, then use LIQUIFILM TEARS.

Pregnancy and breast-feeding
You can use LIQUIFILM TEARS if you are pregnant and when you are breast-feeding.

Driving and using machines
Your sight may become blurred for a short time just after using LIQUIFILM TEARS. You should not drive or use machines until your sight is clear again.

Important information about some of the ingredients of LIQUIFILM TEARS
If you wear soft contact lenses you must remove them before using LIQUIFILM TEARS eye drops. After using LIQUIFILM TEARS, you have to wait at least 15 minutes before putting your lenses back in. This is important because one of the ingredients of LIQUIFILM TEARS, called benzalkonium chloride, may cause eye irritation and can change the colour of soft contact lenses.

3. HOW TO USE LIQUIFILM TEARS

If LIQUIFILM TEARS has been recommended for you then use it exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The **usual dose** of LIQUIFILM TEARS is **1 or 2 drops** in **each eye** that needs treatment as often as you feel the need.

Instructions for use
Do not use the bottle if the **seal** around the cap is **broken** before you first open it.

Wash your hands before opening the bottle. Tilt your head back and look at the ceiling.

1. 	Gently pull down the lower eyelid of the eye that needs treatment until there is a small "pocket".
2. 	Turn the bottle upside down. Squeeze it to release 1 drop into the "pocket".
3. 	Let go of the lower lid, and blink your eyes a few times. For a second drop repeat the steps 2 and 3.
4.	Repeat the steps 1 to 3 for the other eye, if it also needs treatment.

If a drop misses your eye, try again.

To help prevent infection, do not let the tip of the bottle touch your eye, the surrounding tissue or anythi else. Put the screw-cap back on to close the bottle, straigh after you have used it. Once you have **opened the bottle**, you must **not use it longer than 28 days**; please see also Section 5, "How to store LIQUIFILM TEARS".

Package leaflet: Information for the user

LIQUIFILM TEARS®
1.4% w/v, eye drops, solution
Polyvinyl alcohol

LIQUIFILM TEARS than you should will not cause you any harm.

If you forget to use LIQUIFILM TEARS
If you have missed a dose of LIQUIFILM TEARS continue with your next dose as normal

If you have any further questions on the use of this product, ask your doctor or pharmacist.

everybody gets them.

Stop using LIQUIFILM TEARS and **contact** your doctor if:
- you experience long-lasting redness or irritation of the eye, eye pain, changes in vision
- your condition worsens or has not improved 3 days after having started treatment with LIQUIFILM TEARS.

If you experience any of the following side effects, talk to your doctor if they worry you:
- short-lived stinging, irritation or feeling of burning in the eye just after putting in the drops.

The above mentioned side effects are known to occur, but the number of people likely to be affected can vary.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LIQUIFILM TEARS

Keep out of the reach and sight of children.

Do not use LIQUIFILM TEARS after the expiry date which is stated on the bottle label and the carton after 'EXP.'. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not refrigerate or freeze.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What LIQUIFILM TEARS contains
- The active ingredient is polyvinyl alcohol 1.4% w/v.
- The other ingredients are benzalkonium chloride, sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic, edetate disodium, hydrochloric acid or sodium hydroxide (to adjust pH) and purified water.

What LIQUIFILM TEARS looks like and contents of the pack
LIQUIFILM TEARS is a solution in a plastic bottle with a screw-cap. Each bottle contains 15 ml of solution.

Each pack contains 1 bottle.

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Marketing Authorisation Holder Ireland:
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Castlebar Road
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Westport
Co Mayo
Ireland

This leaflet was last approved in the UK in July 2008.
This leaflet was last approved in Ireland in February 2009.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only). Please be ready to give the following information: Polyvinyl alcohol 1.4% w/v reference number PL 00426/0009R. This is a service provided by the Royal National Institute of the Blind.

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® marks owned by Allergan, Inc.

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PACKAGE INFORMATION LEAFLET

Please read all of this leaflet carefully before you start to take your medicine.
Keep this leaflet, you may need it again.
This medicine has been prescribed for you personally and you should not pass it to others.
It may harm them, even if their symptoms are the same as yours.
If you have any further questions, please ask your doctor or pharmacist.

The name of the medicine is
LISINOPRIL 2.5mg tablets / LISINOPRIL 5mg tablets
LISINOPRIL 10mg tablets / LISINOPRIL 20mg tablets

The tablets are available in four strengths and contain either 2.5mg, 5mg, 10mg or 20mg active ingredient lisinopril (as dihydrate). The tablets also contain: mannitol, calcium hydrogen phosphate, maize starch and magnesium stearate. The 5mg, 10mg and 20mg tablets also contain the colouring agent iron oxide (E172).
The product licence holder and manufacturer is Bristol Laboratories Ltd., Unit 3, Canalside, Northbridge Road, Berkhamsted, Herts, HP4 1 EG.

What the tablets are and what are they used for

Lisinopril belongs to a group of medicines called ACE inhibitors that work by widening blood vessels, making it easier for the heart to pump blood through them. This helps to lower blood pressure and can also help the heart to work better if it does not pump as well as required.
Lisinopril is recommended in children (above 6 years old) only for the treatment of high blood pressure (hypertension).
Lisinopril should not be used in children with severe kidney impairment.
The 2.5 mg tablets are round, white or almost white coloured, uncoated tablets with the markings "2.5" on one side and "BL" on the reverse.
The 5 mg tablets are round, light pink coloured, uncoated tablets with the markings "5" and a breakline on one side and "BL" on the reverse.
The 10 mg tablets are round, light pink coloured, uncoated tablets with the markings "10" on one side and "BL" on the reverse.
The 20 mg tablets are round, pink coloured, uncoated tablets with the markings "20" on one side and "BL" on the reverse.
The tablets are supplied to your pharmacist in packs containing 28, 30, 56, 60, 84, 250, 500 or 1000 tablets who will then provide you with the required number of tablets as prescribed by your doctor.
(Not all pack sizes may be marketed).

Before you take Lisinopril Tablets

DO NOT TAKE THIS MEDICINE IF:
- You are allergic to lisinopril, other ACE Inhibitors (e.g. enalapril) or to any of the other ingredients in the tablets which are listed above. (An allergic reaction may be which causes swelling of the face, lips, tongue, throat or extremities, or difficulty in swallowing or breathing).
- You have ever had an allergic reaction which caused swelling of the face, lips, tongue, throat or extremities or there is a family history of this (even when this is unrelated to ACE inhibitor medicines)
- You have chronic severe kidney failure
- You suffer from narrowing of the artery to one or both kidneys
- You are suffering from cardiogenic shock (shock caused when heart fails to supply enough blood to the body).
- You have had a heart attack and your blood pressure is unstable
- You are more than 3 months pregnant. (It is also better to avoid Lisinopril in early pregnancy - see pregnancy section.)
- You are breastfeeding

CHECK WITH YOUR DOCTOR BEFORE TAKING IF:
- You suffer from heart disease or problems with narrowing of the heart valve or blood flow from the heart.
- You suffer from kidney disease or you are undergoing dialysis
- You have had a heart attack and also suffer from kidney dysfunction.
- You are to undergo a procedure to remove lipoprotein from the blood or desensitisation treatment (e.g. to reduce the allergic reaction to a bee or wasp sting)
- You suffer from with your adrenal glands secreting too much of the aldosterone hormone.
- You are elderly
- In Afro-Caribbean patients taking lisinopril as the sole treatment for high blood pressure, some may have a reduced response to the medication. This may mean the dose prescribed by the doctor may need to be higher than the usual recommendations.

You must tell your doctor if you think you are (or might become) pregnant. Lisinopril is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).
TAKING OTHER MEDICINES
Please tell your doctor or pharmacist if you are taking, or have recently taken any of the following medicines:
- Potassium supplements, potassium containing salt substitutes, or potassium-sparing diuretics such as amiloride, spironolactone or triamterene as these are not recommended for use in patients also taking lisinopril.
- Other drugs for high blood pressure e.g. beta-blockers such as atenolol, propranolol or metoprolol vasodilators such as calcium channel blockers and moxonidine or other diuretic medicines (water tablets) such as hydrochlorothiazide.
- Insulin or antidiabetic medicines taken by mouth.
- Pain-killers (non-steroidal anti-inflammatory drugs- NSAIDs) such as indometacin, ibuprofen or aspirin.
- The drug lithium (used to treat depression) as your doctor will want you to have regular blood tests when this is taken in conjunction with lisinopril.
- Allopurinol (used to treat gout).
- Drugs used in the treatment of cancer or to prevent transplant rejection (immunosuppressants).

If you are taking any other medicines or supplements, including any you have bought without prescription, please check with your doctor before taking it with Lisinopril Tablets.
If you need to undergo an operation or have an anaesthetic, make sure your hospital doctor or dentist is aware you are taking Lisinopril Tablets.

MONITORING OF PATIENTS
Your doctor may wish to check your blood pressure or kidney function regularly
whilst you are taking this medicine particularly if you are elderly, have severe heart failure, have kidney problems, are dehydrated, have connective tissue disorders eg systemic lupus erythematosus and scleroderma, have a low immune response, are being treated with immunosuppressant drugs such as steroids, methotrexate, azathioprine or cancer treatments.
Driving Warning:
May cause dizziness or light-headedness which means you should not drive or operate machinery if affected. Also avoid alcoholic drink as this may increase these side-effects.

(front page

Taking your medicine

Swallow the tablets whole with a drink of water. You should take the tablets as a single dose at approximately the same time each day.
The dosage of lisinopril tablets required is dependent on the condition being treated and varies according to the need of each individual patient. Take the tablets exactly as directed by your doctor, which will be written on the pharmacists label. If you do not understand the directions, ask your pharmacist or doctor to explain you the same.
The usual dose is as follows:
Initially, a daily dose of 2.5 mg is recommended. This dose will gradually be increased by your doctor until control is achieved. The usual maintenance dose in patients suffering from high blood pressure and in those who are diabetic with kidney problems, is 10 to 20 mg per day, with a maximum daily dose of 40 mg. For patients suffering from heart failure, the usual effective dose is 5 to 20 mg per day.
If you are also taking a diuretic medicine, your doctor will if possible, have either stopped this diuretic medicine or reduced its dosage for 2 to 3 days before starting your treatment with Lisinopril Tablets. The diuretic may be resumed later if this is considered necessary by your doctor.
For use following heart attack, the initial dose is 5 mg daily for 2 days, increased to 10 mg daily thereafter for 6 weeks. Patients with low blood pressure may require a lower dose.
Patients with reduced renal function:
Lisinopril Tablets should be used with caution in patients with kidney problems. In those who are undergoing dialysis, the usual daily dose may be given on dialysis days, but on non-dialysis days the dose given will be dependent on the patients blood pressure.
Do not stop taking this medicine unless instructed by your doctor.
Children under 6 years: The use of Lisinopril is not recommended.
Children and adolescents aged 6 to 16 years:
The dose depends on your weight. The usual starting dose is between 2.5mg and 5mg once daily, which can be increased to a maximum of 20mg to 40mg once daily. Patients with kidney problems should take a lower dose. Your doctor will decide the correct dose for you.
If you miss a dose:
Take the missed dose as soon as you remember, however, if it is almost time for your next dose, skip the missed dose and then take your next dose when it is due. Do not take a double dose to make up for missed dose.
If you take too much:
If you take too many tablets, you must obtain urgent medical attention from your doctor or hospital casualty department.
Pregnancy and breast-feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Lisinopril before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lisinopril. Lisinopril is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.
Breastfeeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Lisinopril is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Possible Side-Effects

As with all medicines there is a possibility of unwanted effects whilst taking this medicine.
Studies suggest that lisinopril is generally well tolerated when given to hypertensive paediatric patients, but the same unwanted effects listed below for adults apply to paediatric patients.
If any of the following happens, stop taking the tablets and tell your doctor IMMEDIATELY or go to the nearest hospital casualty department.

- Swelling of your lips, tongue, throat, face, hands or feet, difficulty swallowing, shortness of breath, inflamed, red or itching skin. These are signs of a serious allergic reaction, which can occur rarely.
- Blistering of the skin, mouth, eyes or genitals.

If you notice any of the following tell your doctor straight away:

- Sudden or severe chest pain (sign of angina or a possible heart attack), slurred speech or paralysis (signs of a possible stroke), irregular or racing heartbeat.
- Dark urine with fever and nausea or yellowing of the skin and eyes (these may be symptoms of hepatitis or jaundice)
- Abnormally low or no urine output, sudden severe vomiting and loss of appetite (this could be a sign of kidney disease or failure).

The more common side-effects which may occur are:

- Low blood pressure (light-headedness is a symptom)
- Headache, dizziness
- Nausea or diarrhoea
- Unusual tiredness or weakness
- Persistent dry cough
- Skin rashes

Other more rare side-effects include:

- Anaemia and other blood cell disorders which may result in bruising/bleeding under the skin or signs of infection such as sore throat or fever, high blood levels of potassium which can cause abnormal heart rhythm, low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fit or coma.
- Confusion, mood changes, vertigo, numbness or tingling of the hands, feet, arms or legs, disturbed sleep, taste disturbances.
- Wheezing, runny, blocked nose or painful sinuses.
- Stomach pain, vomiting, indigestion, dry mouth, inflammation of the pancreas, which causes severe pain in the abdomen and back.
- Sweating, hair loss, flaking or peeling of the skin.
- Impotence, fever, sensitivity to light, joint pain or swelling, muscle pain, inflammation of blood vessels.
- Increased levels of waste products or liver enzymes in the body (laboratory tests have found increased levels in some cases).

If you do notice any of the above effects, or you notice any other unusual or unexpected effects and think your tablets may be causing them, please inform your doctor or pharmacist.

Storing the tablets

Keep out of the reach and sight of children.
Blisters: Do not store above 25°C. Store in the original package.
Tablet Containers: Do not store above 25°C. Keep the container tightly closed.
Do not use the tablets after the expiry date shown on the carton or label.
Unless your doctor tells you to, do not keep any tablets that you no longer need. Give them back to the pharmacist.
This leaflet was last revised in August 2010.

IABTNE

(back page)

PATIENT INFORMATION LEAFLET

LOSARTAN POTASSIUM 25mg, 50mg AND 100mg FILM-COATED TABLETS

losartan potassium

READ ALL OF THIS LEAFLET CAREFULLY before you start to take your tablets, even if you have just had a repeat prescription. Some of the information in your previous leaflet may have changed. Keep this leaflet. You may need to read it again. If you have any more questions, please ask your doctor or your pharmacist. This medication has been prescribed for you. You should not pass it on to anyone else. It may harm them, even if their symptoms are the same as yours. If any of the side effects get serious, or if you notice any side effects that are not listed in the leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET

The name of your medicine is Losartan potassium 25mg, 50mg or 100mg film-coated tablets. Your medication is referred to as Losartan potassium tablets or Losartan throughout this leaflet.

1. WHAT ARE LOSARTAN POTASSIUM TABLETS AND WHAT ARE THEY USED FOR

Losartan belongs to a group of medicines known as angiotensin-II receptor antagonists.
Angiotensin II is a chemical in your body, which tightens your blood vessels making it harder for the blood to pass through them and causes your blood pressure to increase.
Losartan blocks this effect, causing the blood vessels to relax and so lowers your blood pressure.
Your doctor has prescribed Losartan to:

- **treat hypertension** (high blood pressure)
- **reduce the risk of stroke in hypertension with left ventricular hypertrophy** (thickening of the heart muscle)
- **treat chronic heart failure** when treatment with ACE inhibitors (angiotensin-converting enzyme inhibitors (also used to lower blood pressure)) is not considered suitable by your doctor

If you have **hypertension (high blood pressure),** Losartan lowers your blood pressure.
If you have **hypertension with left ventricular hypertrophy**, Losartan can reduce the risk of a stroke.

2. BEFORE YOU TAKE THE TABLETS

DO NOT take Losartan if you:

- are allergic (hypersensitive) to losartan or any of the other ingredients
- are pregnant, think you may be pregnant or you are planning to become pregnant
- are breast-feeding
- have severe liver disease

If any of the above applies to you, do not take the tablets. Talk to your doctor first and follow their advice.
Before you take Losartan, tell your doctor if you:

- have a history of angioedema (swelling of the face, lips, throat and/ or tongue)
- suffer from liver or kidney problems
- have recently suffered from severe vomiting or diarrhoea
- receive diuretics (medicines that increase the amount of water that you pass out through your kidneys)
- received a kidney transplant recently
- suffer from problems with your heart valves or heart muscle (e.g. 'aortic stenosis' or 'outflow obstruction')
- suffer from heart failure, heart disease or stroke
- have narrowing or blockage of the blood vessels leading to your kidneys
- suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone)
- have a high level of potassium in your blood (hyperkalaemia), or, you are on a low-potassium diet

Taking other medicines
Before you start to take Losartan tell your doctor or pharmacist about any other medication that you are taking or plan to take, including medicines you have bought without a prescription, herbal medicines and natural products.
In particular tell your doctor if you are taking:

- other blood pressure lowering medicines as they may additionally reduce your blood pressure
- anti-depressants, anti psychotics, baclofen or amifostine as these may lower your blood pressure further
- lithium (used to treat certain types of mental illness)
- non-steroidal anti-inflammatory painkillers (for example, ibuprofen, Naproxen or Diclofenac); COX-2 inhibitors (for example, celecoxib, etoricoxib or lumiracoxib) or more than 3grams of aspirin a day
- high-dose diuretics (tablets to help you lose water) e.g. amiloride, triamterene, spironolactone
- potassium supplements, potassium sparing agents or potassium-containing salt substitutes

Your doctor will decide whether you should take these medicines with Losartan.
Taking losartan with food and drink
Losartan can be taken with or without food.
Pregnancy and Breast-feeding
You should not take losartan in the first 12 weeks of pregnancy, and you must not take them at all after the 13th week, as their use during pregnancy may possibly be harmful to the baby. If you become pregnant while taking Losartan, tell your doctor immediately. A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy. You must not take losartan if you are breast-feeding. Always ask your doctor or pharmacist for advice before taking any medicine.
Driving and using machines
You should not drive or operate machinery, until you know how you react to losartan potassium tablets as it may cause dizziness or drowsiness. If you experience dizziness or drowsiness, you should consult your doctor before attempting to drive or use machines.

3. HOW TO TAKE THE TABLETS

You should take the tablets with a drink of water. You must take your tablets every day exactly as your doctor has told you. It is important that you take the tablets for as long as your doctor prescribes them.
Dose for Adults
Hypertension (high blood pressure)
The usual dose of Losartan for most adult patients is one 50mg tablet once a day to control your blood pressure over the 24-hour period. If a 50mg daily dose is ineffective, your doctor may prescribe a higher dose of 100mg.
Hypertension with left ventricular hypertrophy (thickening of the heart muscle)
The usual dose of Losartan for most adult patients is one 50mg tablet taken once a day.
Your doctor may also prescribe a low dose of a diuretic or increase your daily dose of Losartan to 100mg.
Heart failure
The usual starting dose for most adult patients is one 12.5mg tablet once a day. Your doctor may gradually increase your dose weekly according to your condition up to the usual maintenance dose of 50mg daily.
Special Dosage Requirements
Your doctor may prescribe a lower dose of 25mg once a day if you:

- are over 75 years of age
- have liver problems

Children less than 6 years of age
Not recommended, as limited data is available in this age group.
Hypertension (high blood pressure) in children aged 6 to 16
For children who can swallow and who weigh:

- between 20 and 50kg- the recommended dose is 25mg once a day (your doctor may increase the dose up to 50mg once a day)
- 50kg or over- the starting dose is 50mg once a day (your doctor may increase the dose up to 100mg once a day).

The doctor will adjust the dose according to the weight of the child and how their blood pressure responds to the medicine. ALWAYS follow your doctor's instructions exactly.
If you take more Losartan potassium tablets than you should
If you take too many tablets, contact your doctor immediately or go to the nearest hospital casualty department. Symptoms of an overdose may be low blood pressure, fast heart beat or slow heart beat.
If you forget to take a Losartan potassium tablet
Try to take Losartan each day as prescribed. If you miss a dose, just carry on with the next dose as normal. **DO NOT** take an extra tablet to make up the dose.
If you stop taking losartan potassium tablets
Do not stop taking your medicine without talking to your doctor, even if you feel better. It is important to continue the course of treatment prescribed to you by your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines Losartan may cause side effects. They are generally mild and do not normally need treatment. **STOP taking Losartan and contact your doctor or pharmacist immediately if you develop any of these symptoms:**

- an allergic reaction, causing swelling of the face, lips, throat or tongue which may cause difficulty in breathing or swallowing

This is a serious but rare side effect, which affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients. You may need urgent medical attention.
Other side effects reported with losartan potassium tablets
Common (affects 1 in 10 patients to 1 in 100 patients):

- feeling dizzy
- low blood pressure
- weakness or feeling very tired
- too little sugar in the blood (hypoglycaemia)
- too much potassium in the blood (hyperkalaemia)- your doctor will take regular blood samples to monitor the levels of potassium in your blood

Uncommon (affects 1 in 100 patients to 1 in 1,000 patients):

- drowsiness
- headache
- nausea (feeling sick), vomiting (being sick)
- sleep disorders
- feeling of increased heart rate (palpitations)
- severe chest pain (angina pectoris)
- low blood pressure (due to excessive loss of water from the body) or a rapid drop in blood pressure- symptoms of which may be feeling light-headed or dizzy, particularly when standing up
- shortness of breath
- severe constipation
- abdominal pain
- localised swelling (oedema)
- diarrhoea
- hives, itching or rash

Rare (affects 1 in 1,000 patients to 1 in 10,000 patients):

- **inflammation of the blood vessels** including inflammation of small veins, causing hard, purple blotches on the skin
- numbness or tingling sensation (paraesthesia)
- fainting
- irregular or rapid heartbeat
- stroke
- inflammation of the liver (hepatitis)
- elevated liver enzyme levels (can be reversible upon stopping treatment)

Not known (cannot be estimated from the available data):

- anaemia – symptoms may be feeling tired or short of breath (a blood test will confirm this)
- thrombocytopenia – a reduction in the number of platelets in the blood. This may occasionally lead to abnormal (unexpected) bruising or bleeding
- migraine
- a cough
- muscle and joint pains
- liver problems – yellowing of the eyes and skin and flu-like symptoms
- changes in kidney function including kidney failure (may be reversible upon stopping treatment)
- flu like symptoms
- increase in blood urea, serum creatinine and serum potassium in patients with heart failure
- back pain and urinary tract infection

If you develop any of the side effects described, or if you have any other unusual symptoms or feelings not listed in this leaflet, contact your doctor or pharmacist as soon as possible.

5. HOW TO STORE THE TABLETS

Do not take the tablets after the expiry date shown on the carton.
KEEP YOUR TABLETS OUT OF THE REACH AND SIGHT OF CHILDREN.
Do not remove the tablets from the blister pack until you are ready to take them.
There are no special requirements to store the tablets at a particular temperature.

6. FURTHER INFORMATION

What Losartan contains
The active ingredient in Losartan potassium tablets is losartan potassium.
Losartan potassium 25mg film-coated tablets contain 25mg of losartan potassium.
Losartan potassium 50mg film-coated tablets contain 50mg of losartan potassium.
Losartan potassium 100mg film-coated tablets contain 100mg of losartan potassium.
Other ingredients include: microcrystalline cellulose, sodium stearyl fumarate, croscarmellose sodium, colloidal anhydrous silica, polyoxyethylene stearate, hypromellose and titanium dioxide (E171).
What Losartan looks like and the contents of the pack
Losartan comes in blister packs containing 28 tablets.
Losartan potassium 25mg tablet is available as a white, oblong, plain, film-coated tablet.
Losartan potassium 50mg tablet is available as a white, oval, score-line, film-coated tablet.
Losartan potassium 100mg tablet is available as a white, oblong, plain, film-coated tablet.
Marketing authorisation holder: Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland.
Manufacturer responsible for batch release: Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland
Distributor and manufacturer responsible for batch release: Kent Pharmaceuticals Limited, Watton Road, Ashford, Kent, TN23 6LL, UK
Product licence number: PL 30464/0049, PL 30464/0050 or PL 30464/0051
This leaflet was last revised January 2010.

Goldshield

868175C

PACKAGE LEAFLET: INFORMATION FOR THE USER

Macrodantin® 50mg and 100mg Capsules

(Nitrofurantoin)

Read all of this leaflet carefully before you start using this medicine.
Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT MACRODANTIN® CAPSULES ARE AND WHAT THEY ARE USED FOR

Nitrofurantoin (the active substance in Macrodantin® Capsules) is an antibiotic.
It is used to prevent and treat infections of the bladder, kidney and other parts of the urinary tract.

2. BEFORE YOU TAKE MACRODANTIN® CAPSULES

DO NOT TAKE Macrodantin® Capsules and talk to your doctor if:

- you are allergic (causing itching, reddening of the skin or difficulty in breathing) to nitrofurantoin or any of the ingredients of Macrodantin® Capsules (listed in Section 6 at the end of the leafet) or other medicines containing nitrofurantoin.
- you have a disease of the kidneys which is severely affecting the way they work (ask your doctor if you are not sure);
- you are in the final stages of pregnancy (labour or delivery) as there is a risk that it might affect the baby.

Tell your doctor if you are not sure about any of the above.

TAKE SPECIAL CARE with Macrodantin® Capsules and speak to your doctor or pharmacist before taking the capsules if:

- you have diabetes;
- you are suffering from any illness causing severe weakness;
- you have anaemia (a decrease in red blood cells causing pale skin, weakness and breathlessness); or a lack of vitamin B or abnormal levels of salts in your blood (your doctor will be able to advise you).
- you have a history of allergic reactions.

The above conditions may increase the chance of developing a side effect which results in damage to the nerves, causes altered sense of feeling, and pins and needles.

- you lack an enzyme (body chemical) called glucose-6-phosphate dehydrogenase, which causes your red blood cells to be more easily damaged (this is more common in black people and people of Mediterranean, Middle Eastern or Asian origin. Your doctor will know);
- you have any disease of the lungs, liver or nervous system. If you need to take Macrodantin® Capsules for a number of months, your doctor may want to regularly check how your lungs and liver are working.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If they are taken with Macrodantin® Capsules their effect or the effect of Macrodantin® Capsules may be changed.

- Antacids for indigestion (e.g. magnesium trisilicate);
- Medicines for gout (e.g. probenecid or sulfinpyrazone);
- Medicines which slow the passage of food through the stomach (e.g. atropine, hyoscine);
- Medicines for raised pressure in the eye (glaucoma), such as carbonic anhydrase inhibitors (e.g. acetazolamide);
- Medicines which make the urine less acid (e.g. potassium citrate mixture);
- Medicines for infections, known as quinolones.

If you are in doubt about any of these medicines ask your doctor or pharmacist.
Macrodantin® Capsules may interfere with the results of some tests for glucose in the urine.

Taking Macrodantin® Capsules with food and drink
Macrodantin® Capsules capsules should be taken at meal times with food or milk. This will help to avoid stomach upset and also to help the absorption.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine. As far as is known Macrodantin® Capsules may be used in pregnancy. However, it should not be used during labour or delivery because there is a possibility that use at this stage may affect the baby. If you want to breast feed, please consult your doctor first.

Driving and using machines
Macrodantin® Capsules may cause dizziness and drowsiness. You should not drive or operate machinery if you are affected this way until such symptoms go away.

Important information about some of the ingredients in Macrodantin® Capsules
This medicine contains lactose and sucrose (sugars). If you have been told by your doctor that you are intolerant to some sugars and have to avoid them, contact your doctor before taking this medicine.

3. HOW TO TAKE MACRODANTIN® CAPSULES

Follow your doctor's instructions exactly and **complete the course of treatment even if you feel better.** You should check with your doctor or pharmacist if you are not sure.
Do not forget to take your medicine.
Capsules should be swallowed whole.

Adults:
The normal dosage depends on the type of infection you have and instructions should be written on the label provided by the pharmacist. Consult your pharmacist or doctor if these instructions are not clear. The usual doses are:

- For treatment of infections: Either one 50mg capsule or one 100mg capsule four times a day for seven days.
- For prevention of further infections: Either one 50mg capsule or one 100mg capsule at bedtime.
- For prevention of infections during surgery: One 50mg capsule four times a day on the day of the operation and three days thereafter.

Children and infants over three months of age:
The dose depends on the weight of the child and will be provided by your doctor. Follow your doctor's instructions exactly.
Children below 3 months of age should not take Macrodantin® Capsules
Medical Checks
Your doctor will watch carefully for any effects on the liver, lungs, blood or nervous system.
Macrodantin® Capsules may interfere with the results of some tests for glucose in the urine.
If you TAKE MORE Macrodantin® Capsules than you should
Consult your doctor or pharmacist immediately or go to the emergency department of the nearest hospital. Always take any left over capsules with you, as well as the container and label, so that the medical staff know what you have taken.
If you FORGET TO TAKE Macrodantin® Capsules
Do not worry. If you remember later on that day, take that day's dose as usual. If you miss a whole day's dose take the normal dose on the next day. Do not take a double dose to make up for a forgotten capsule. If you are not sure ask your doctor or pharmacist.
If you STOP TAKING Macrodantin® Capsules
Your doctor will tell you how long to take the treatment. Do not stop earlier than you are told, even if you feel better.
If you have any further questions on the use of this product, ask your doctor or pharmacist

4. POSSIBLE SIDE EFFECTS

Like all medicines, Macrodantin® Capsules can cause side effects, although not everybody gets them. Most of them are mild and disappear when you stop taking Macrodantin® Capsules.
All medicines can cause allergic reactions although serious allergic reactions are rare. If you notice any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) STOP TAKING your medicine and go to a doctor immediately.
If you experience any of the side effects detailed below stop taking Macrodantin® Capsules and consult your doctor.

- Your lungs may react to Macrodantin® Capsules. This may develop quickly, within a week of starting treatment or very slowly, especially in elderly patients. This may produce fever, chills, cough and shortness of breath.
- Jaundice (inflammation of the liver causing yellowing of the skin or whites of the eyes).
- The nerves outside the spinal cord may be affected causing changes to the sense of feeling and the use of muscles. In addition headache, extreme changes of mood or mental state, confusion, weakness, blurred vision may occur. These effects may be severe and in some instances permanent.
- Raised pressure in the skull (causing severe headaches).

Please note that while taking Macrodantin® Capsules your urine may become coloured dark yellow or brown. This is quite normal and not a reason to stop taking the medicine.

Other side effects include:

- Feeling sick (nausea) and headache.
- Diarrhoea
- Loss of appetite, stomach ache, and being sick (vomiting).
- Dizziness,drowsiness.
- Blood cells have been affected in some patients. This may result in bruising, delayed clotting of the blood, sore throat, fever, anaemia, and a susceptibility to colds or persistent cold.
- A variety of skin rashes or reactions have occurred in some patients. These may appear as flaking skin, a red rash or fever accompanied by rapid heart rate and severe rash with blistering. Other reactions may include inflammation of salivary glands (causing facial pains), inflammation of the pancreas gland (causing severe abdominal pain) and joint pains.
- Short-term hair loss.
- Urinary infection by germs which are not sensitive to Macrodantin® Capsules.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Remember:
This medicine is only for you. Only a doctor can prescribe it for you. Never give this medicine to someone else. It could harm them, even if their symptoms seem the same as yours.

5. HOW TO STORE MACRODANTIN® CAPSULES

Keep out of the reach and sight of children.
Do not store above 30°C. Store in the original package to protect from light and moisture.
Do not use Macrodantin® Capsules after the expiry date which is stated on the carton (EXP). The expiry date refers to the last day of that month.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Macrodantin® Capsules contains
The active substance is Nirofurantoin. Macrodantin® Capsules are available in two strengths, containing either 50 mg or 100 mg Nirofurantoin. The other ingredients are talc, maize starch, lactose monohydrate. The capsule shell contains gelatin, sodium lauril sulfate and colourings quinoline yellow (E104) and titanium dioxide (E171). The printing ink contains Shellac and black iron oxide (E172).
What Macrodantin® Capsules looks like and contents of the pack
Appearance: The 50mg capsule is a no.3 size hard gelatin capsule with an opaque yellow cap and yellow opaque body. The capsules are printed in edible black ink and bears the monogram "Eaton 008".
The 100mg capsule is a no.2 size hard gelatin capsule with an opaque yellow cap and yellow opaque body. The capsules are printed in edible black ink and bears the monogram "Eaton 009".
Packaging: The capsules are available in blister packs of 30.
Marketing Authorisation Holder: Goldshield Pharmaceuticals Ltd., NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CRO OXT, UK.
Manufacturer: Lusomedicamenta S.A., Sociedade Técnica Farmacêutica, Estrada Consigilieri Pedroso, 69-B, Queluz de Baixo, 2730-055 Barcarena, Portugal.
This leaflet was last revised in April 2009 10206/LF/A 10207/LF/A

actavis

Metoprolol Tartrate 50mg and 100mg tablets

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Index:

1. What Metoprolol Tartrate tablets are and what they are used for

Metoprolol Tartrate belongs to a group of medicines called beta-blockers.

It is used to **treat:**
- high blood pressure
- angina pectoris (pain in the chest caused by blockages in the arteries to the heart)
- irregular heart rhythm (arrhythmia)
- the symptoms caused by an overactive thyroid gland (thyrotoxicosis)

It is used to **prevent:**
- migraine
- heart damage and death due to heart attacks.

2. Before you take

Do not take Metoprolol Tartrate tablets and **tell your doctor** if you:
- are **allergic** (hypersensitive) to metoprolol, other beta-blockers or any of the other ingredients in Metoprolol Tartrate tablets (see section 6)
- suffer with **heart conduction** or **rhythm problems**
- have severe or uncontrolled **heart failure**
- are in **shock** caused by heart problems
- suffer with **blocked blood vessels**, including **blood circulation problems** (which may cause your fingers and toes to tingle or turn pale or blue)
- have a **slow heart rate** or have suffered a heart attack which has been complicated by a significantly slow heart rate
- suffer from a tight, painful feeling in the chest in periods of rest (**Prinzmetal's angina**)
- suffer with **untreated phaeochromocytoma** (high blood pressure due to a tumour near the kidney)
- suffer from **increased acidity of the blood** (metabolic acidosis)
- have **low blood pressure**
- have or have had **breathing difficulties or asthma** including **COPD** (Chronic Obstructive Pulmonary Disease causing cough, wheezing or breathlessness, phlegm or increase in chest infections)
- suffer with **diabetes** associated with frequent episodes of **low blood sugar** (hypoglycaemia)
- have **liver** or **kidney disease** or **failure**
- have **difficulties** in **passing urine**
- have **low** levels of **potassium** (hypokalaemia) or **sodium** (hyponatraemia) in your blood
- have **high** levels of **calcium** (hypercalcaemia)
- suffer with **gout** due to high levels of uric acid (hyperuricaemia) in your blood causing crystals to deposit in joints of hands or feet causing pain.

Take special care with Metoprolol Tartrate tablets and **tell your doctor** if you:
- have a **history of allergic reactions**
- have **diabetes mellitus** (low blood sugar levels may be hidden by this medicine)
- suffer from treated **phaeochromocytoma** (high blood pressure du to tumour near the kidney)
- have an **overactive thyroid** (symptoms such as increased heart rat sweating, tremor, anxiety, increased appetite or weight loss may be hidden by this medicine)
- have or have suffered from **psoriasis** (severe skin rashes)
- have a **slow heart rate** or **blood vessel disorder**
- have controlled **heart failure**
- have **impaired liver or kidney function**
- have **liver cirrhosis**
- are **elderly.**

Taking other medicines

Do not take Metoprolol Tartrate tablets if you are already taking:
- **monoamine oxidase inhibitors** (MAOIs) for depression
- other **blood pressure lowering** medicines such as verapamil, nifedipine and diltiazem
- **disopyramide** or **quinidine** (to treat irregular heartbeat (arrhythmia)

Before taking Metoprolol Tartrate tablets, **tell your doctor if you are taking or have taken recently any of the following medicines** or ar taking any non prescribed medicines:
- **cimetidine** (to treat stomach ulcers)
- **hydralazine, clonidine** or **prazosin** (to treat high blood pressure)
- **amiodarone** and **propafenone** (for irregular heart rhythm)
- **tricyclic antidepressants** (to treat depression)
- **barbiturates** (to treat epilepsy)
- **phenothiazines** (for mental illness)
- **anaesthetics** such as cyclopropane or trichloroethylene
- **aldesleukin** (to treat some cancers, particularly cancer of the kidne
- **alprostadil** (to treat erectile dysfunction)
- **anxiolytics** or **hypnotics** (e.g. temazepam, nitrazepam, diazepam)
- **indometacin** (Non-Steroidal Anti-Inflammatory Drug (NSAID))
- **rifampicin** (antibiotics)
- **cocaine**
- **oestrogens** such as a contraceptive pill or hormone replacement therapy
- **corticosteroids** (e.g. hydrocortisone, prednisolone)
- other **beta-blockers** e.g. eye drops.
- **adrenaline** (epinephrine, used in anaphylactic shock) or other **sympathomimetics**
- medicines used to treat **diabetes**
- **lidocaine** (a local anaesthetic)
- **moxisylyte** (used in Raynaud's syndrome)
- **mefloquine** (to treat malaria)
- **tropisetron** (to prevent nausea and vomiting)
- **xanthines** such as aminophylline or theophylline (to treat asthma)
- medicines to treat **migranes** such as ergotamine
- **cardiac glycosides** e.g. digoxin (to treat heart conditions).

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Pregnancy and breast-feeding

Metoprolol Tartrate tablets are not recommended during pregnancy or breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Sugar intolerance

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

Alcohol

You are advised to avoid alcohol whilst taking this medicine. Alcohol may increase the blood pressure lowering effect of Metoprolol Tartrate tablets.

Driving and using machines

Metoprolol Tartrate tablets may make you feel tired and dizzy. Make sure you are not affected before you drive or operate machinery, particularly after changing to another medicine or if taken with alcohol.

Anaesthetics and surgery

If you are going to have an operation or an anaesthetic, please tell your doctor or dentist that you are taking Metoprolol Tartrate tablets, as your heart beat might slow down too much.

How to take

Always take Metoprolol Tartrate tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.
Swallow the tablet whole.
Usual doses:
- **High blood pressure:**
  Initially 100mg metoprolol tartrate daily. The dose may be increased to 200mg daily in single or divided doses.
- **Angina:**
  50-100mg metoprolol tartrate two or three times daily.
- **Irregular heart beats (arrhythmia):**
  50mg metoprolol tartrate two or three times daily. The dose may be increased to 300mg daily in divided doses.
- **Heart attacks:**
  50mg metoprolol tartrate every six hours. The usual maintenance dose is 200mg daily in divided doses.
- **Overactive thyroid gland (thyrotoxicosis):**
  50mg metoprolol tartrate four times daily.
- **Prevention of migraine:**
  100-200mg metoprolol tartrate daily in divided doses (in the morning and evening).
- **Children:**
  Not recommended.
- **Patients with impaired kidney or liver function:**
  In such cases the dose should be adjusted. Always follow your doctor's advice.

If you take more Metoprolol Tartrate tablets than you should

If you have accidentally taken more than the prescribed dose, contact your nearest casualty department or tell your doctor or pharmacist at once. Symptoms of overdose are low blood pressure (fatigue and dizziness), slow pulse, heart conduction problems, heart failure, shock caused by heart problems, cardiac arrest, shortness of breath, unconsciousness, coma, feeling and being sick, blue colouring of the skin, low blood sugar levels and high levels of potassium in the blood.

If you forget to take Metoprolol Tartrate tablets

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose. Then go on as before. Never double up on the next dose to make up for the one missed.

If you stop taking Metoprolol Tartrate tablets

Do not suddenly stop taking Metoprolol Tartrate tablets as this may cause worsening of heart failure and increase the risk of heart attack. Only change the dose or stop the treatment in consultation with your doctor.

4. Possible side effects

Like all medicines, Metoprolol Tartrate tablets can cause side effects, al not everybody gets them.

Stop treatment and contact a doctor at once if you have the follov symptoms of an:
- **allergic reaction** such as itching, difficulty breathing or swelling of lips, throat or tongue.

Tell your doctor if you notice any of the following side effects or n other effects not listed:
- **Nervous system:** tiredness, dizziness, headache, tingling or 'pins an needles', muscle cramps, depression, inability to think clearly, sleepi difficulty in sleeping, nightmares, changes in personality, hallucinati
- **Heart:** low blood pressure, worsening or development of a slow he feeling faint on standing due to low blood pressure, heart failure, im heart rate, heart conduction problems, limping, water retention cau swelling, palpitation, cold blue or tingling hands or feet (such as Ray phenomenon), chest pain, gangrene in patients with severe poor ci
- **Stomach and intestines:** feeling or being sick, diarrhoea or constip dry mouth, stomach pain.
- **Skin:** skin rash, sensitivity to light, increased sweating, hair loss, wor or new psoriasis.
- **Lungs:** shortness of breath with or without strenuous physical activ runny nose.
- **Hormones and metabolism:** weight gain
- **Urinary and genital:** disturbances of sexual desire and performanc
- **Senses:** visual disturbances, dry or irritated eyes, ringing in the ears, hearing with high doses.
- **Blood:** changes in the results of blood tests, effects on blood clottin causing easy or unexplained bruising, worsening or new blood vess disorders.
- **Other:** joint inflammation (arthritis), myasthenia gravis (muscle wea difficulty chewing or swallowing and slurred speech), hepatitis (sym include fever, sickness and yellowing of the skin or whites of the eye changes in liver function tests.

If you notice any of these effects, they get worse, or if you notice any si effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store

Keep out of the reach and sight of children.
Store below 25°C in a dry place. Protect from light.
Do not take the tablets after the expiry date which is stated on the carton.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Metoprolol Tartrate tablets contain

- the active substance (the ingredient that makes the tablets work) is metoprolol tartrate. Each tablet contains either 50mg or 100mg of the active substance.
- the other ingredients are silica colloidal anhydrous, lactose monohydrate, magnesium stearate, maize starch, cellulose microcrystalline, povidone.

What Metoprolol Tartrate tablets look like and contents of the pack

Metoprolol Tartrate 50mg and 100mg tablets are white to off-white, circular, biconvex, uncoated tablets.

Pack sizes are 28 and 56.

Marketing Authorisation Holder and Manufacturer
Actavis, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in January 2009

PACKAGE LEAFLET: INFORMATION FOR THE USER

MULTAQ® 400 mg

film-coated tablets

dronedarone

sanofi a

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT MULTAQ IS AND WHAT IT IS USED FOR

MULTAQ contains an active substance named dronedarone. It belongs to a group of medicines called anti-arrhythmics that help regulate your heart beat.
MULTAQ is used if you have had or are currently experiencing a problem with your heart beat (your heart beats out of time - atrial fibrillation).
MULTAQ prevents repetition of your problem of irregular heart beat and slows down your heart rate.

2. BEFORE YOU TAKE MULTAQ

Do not take MULTAQ if:
- you are allergic (hypersensitive) to dronedarone or to any of the other ingredients of MULTAQ (listed in section 6),
- you have a problem with the nerves in your heart (heart block). Your heart might beat very slowly or you may feel dizzy. If you have had a pacemaker fitted for this problem, you can use MULTAQ,
- you have a very slow heart beat (less th beats a minute),
- your ECG (electrocardiogram), shows a h problem called "prolonged QT correctec (this interval is more than 500 millisecc
- you have a problem where your heart c pump the blood round your body as we should (severe heart failure) and your p not controlled. You may have swollen fe trouble breathing when lying down or s or shortness of breath when moving arc
- you take medicines for infection (includ fungal infection or AIDS), allergies, hear problems, depression, after a transplant section below on "Taking other medicin This will give you more details on exactl medicines you cannot take with MULTAC
- you have a severe liver problem,
- you have a severe kidney problem.

If any of the above apply to you, do not take

Take special care with MULTAQ if:
- you have a problem that gives you a lov of potassium or magnesium in your blo problem should be corrected before star treatment with MULTAQ
- you have a problem where your heart d adequately pump the blood round your well as it should (heart failure). You may swollen feet or legs, trouble breathing w lying down or sleeping, shortness of bre when moving around, or weight increas your problem is controlled and your syn do not change.

If this applies to you (or you are not sure), talk to your doctor or pharmacist before t MULTAQ.

MULTAQ is not recommended in children adolescents below 18 years of age.

at CoAprovel looks like and contents of the pack

provel 150 mg/12.5 mg film-coated tablets are peach, biconvex, -shaped, with a heart debossed on one side and the number 2875 aved on the other side.
provel 150 mg/12.5 mg film-coated tablets are supplied in blister s of 14, 28, 30, 56, 84, 90 or 98 film-coated tablets. Unit dose er packs of 56 x 1 film-coated tablet for delivery in hospitals are available.

ll pack sizes may be marketed.

keting Authorisation Holder
FI PHARMA BRISTOL-MYERS SQUIBB SNC
venue de France
13 Paris - France

ufacturer

OIN PRIVATE CO. LTD.
u.5.
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This leaflet was last approved in January 2010

Detailed information on this medicine is available on the Medicines Agency (EMEA) web site: http://www.emea.europ

6

PACKAGE LEAFLET: INFORMATION FOR THE USER

NAPROXEN TABLETS 250mg and 500mg

[naproxen]

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Naproxen Tablets are and what they are used for

Naproxen is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Naproxen can relieve pain, stiffness and inflammation caused by: rheumatoid arthritis, osteoarthrosis, ankylosing spondylitis (arthritis of the spine and pelvis) and juvenile rheumatoid arthritis.

It is also used to treat acute gout and acute musculoskeletal disorders such as sprains, strains, trauma, lower back pain, neck pain and inflammation of tendons and muscles.

2. Before you take Naproxen Tablets

Do not take if you have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation.

If you suffer from any of the following at any time during your treatment STOP TAKING the medicine and seek immediate medical help:

- Pass blood in your faeces (stools/motions)
- Pass tarry black stools
- Vomit any blood or dark particles that look like coffee grounds
- STOP TAKING the medicine and tell your doctor if you experience: indigestion or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

Do not take Naproxen tablets and tell your doctor if you:

- Have a history of stomach bleeding or perforation which may be related to the use of NSAIDs (Mefenamic acid, ibuprofen, diclofenac) or aspirin.
- Are hypersensitive (allergic) to Naproxen or any other ingredients in this medicine (See section 6. Further information)
- Have a history of allergy to aspirin, ibuprofen or NSAIDs, which includes attacks of asthma, swelling of the nose and throat, skin rashes or a runny nose.
- Have inflammatory bowel disease
- Suffer from severe kidney, heart or liver disease
- Are in the last trimester of your pregnancy
- Are taking medicines for blood clots (for example warfarin)
- You have Systemic Lupus Erythematous (SLE or 'Lupus') or connective tissue disorders.
- If you develop problems with your vision, contact your doctor immediately.

Naproxen tablets may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Medicines such as Naproxen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, previous stroke or think you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Especially:

- Diuretics (water tablets)
- Medicines for high blood pressure
- Warfarin to thin the blood
- Digoxin for heart conditions
- Lithium or SSRIs (Selective Serotonin Reuptake Inhibitors) such as Fluoxetine or paroxetine used for treatment of depression
- Prednisolone a steroid treatment for inflammation
- Methotrexate used to treat rheumatoid arthritis
- Ciclosporin, tacrolimus which are medicines used to suppress the immune system
- Ciprofloxacin, sulphonamides such as sulphamethoxazole, antibiotics used to treat bacterial infections
- Mifepristone used in pregnancy terminations (at any time within the last 12 days)
- Zidovudine used for the treatment of AIDS and HIV infections
- Anti-inflammatory pain killers such as ibuprofen or ibuprofen preparations that can be bought without a prescription.
- Phenytoin used to treat epilepsy
- Gliclazide or glibenclamide (sulphonylureas) used to treat diabetes
- Probenecid used to treat gout
- Aspirin, clopidogrel, ticlopidine, dipyridamole which are anti-platelet agents used to prevent blood clots

Taking Naproxen with food and drink

Naproxen tablets should only be taken by mouth.

Always take the tablets with plenty of water, preferably with food.

Try to take them at the same time every day.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant, planning on becoming pregnant or are breast-feeding

Naproxen does pass into the mother's milk; therefore breast-feeding should be avoided if taking Naproxen tablets.

Driving and using machines

Undesirable effects such as dizziness, drowsiness and tiredness and visual disturbances are possible after taking NSAIDs. If you are affected do not drive or operate machinery.

Important information about some of the ingredients of Naproxen tablets

Naproxen tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

If you go into hospital or to see a doctor or dentist, tell them

(front page)

For rheumatoid arthritis, osteoarthritis and ankylosing spondylitis:
250-500mg taken at 12 hour intervals.

Acute musculoskeletal disorders: 500mg to start with, followed by 250mg every 6-8 hours. Do not take more than 1250mg (i.e. five 250mg tablets) in any 24 hour period.

Acute gout: 750mg to start with, followed by 250mg every 8 hours until the attack has passed.

The elderly:
Elderly patients are more likely to experience side effects. Therefore treatment should be started on the lowest possible dose for the shortest possible duration. Your doctor should monitor your condition regularly.

Children over 5 years of age:
If Naproxen tablets are prescribed for a child make sure that the tablets are taken as instructed by the doctor. Naproxen is not recommended for children under 16 years of age for use other than in the treatment of juvenile rheumatoid arthritis. For juvenile rheumatoid arthritis a dose of 10mg per kg body weight per day should be given in two doses, once every 12 hours.

If you take more Naproxen tablets than you should

If you accidently take too many Naproxen tablets, tell your doctor at once. If you can't do this, go to the nearest casualty department. Take along any tablets that are left, the container and the label so that the hospital staff can easily tell what medicine you have taken.

If you forget to take Naproxen tablets
If you forget to take a dose, take it as soon as you remember unless it is time for your next dose.
Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Naproxen can cause side effects, although not everybody gets them.

Serious side effects:
If you suffer from any of the following at any time during your treatment **STOP TAKING** the medicine and seek immediate medical help:

- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds
- **STOP TAKING** the medicine and tell your doctor if you experience: Indigestion or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms

Medicines such as Naproxen Tablets may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke.

If you experience any of the following stop taking Naproxen Tablets and contact your doctor immediately:

- All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eye lids, face or lips, rash, reddening of the skin or itching (especially affecting your whole body).
- Severe painful skin disorder with blisters and peeling skin. You may also have flu-like symptoms such as fever or sore throat (Steven Johnson Syndrome)
- Diarrhoea
- Rash or sensitivity to light
- Jaundice or hepatitis (yellowing of the skin and/or eyes).
- Persistent sore throat or high temperature
- Anaemia (feeling tired after exercising, giddiness, looking pale)
- Swollen feet or ankles
- High blood pressure
- Chest pain

The following side effects have also been reported, if they become troublesome contact your doctor:

The following side effects are common:

- Diarrhoea, flatulence (wind), constipation
- Nausea, Vomiting
- Headache
- Pins and needle
- Drowsiness or tiredness
- Ringing in the ears

Other side effects:

- Sleeping problems, dizziness, inability to concentrate, confusion, depression, hallucinations
- blood disorders, feeling unwell
- blood disorders, vasculitis (inflammation of a blood vessel),
- liver and kidney problems, blood in urine
- hair loss
- sore mouth

If any of the side effects gets serious or if you notice any side effects or symptoms not mentioned in this leaflet, please tell your doctor or pharmacist

5. How to store Naproxen Tablets

Keep out of the reach and sight of children.
Keep the tablets in a dry place at normal room temperature (below 25° C) in the packaging they come in.
Do not use Naproxen tablets 250mg and 500mg after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Do not use Naproxen tablets 250mg and 500mg if you notice visible signs of deterioration.
Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Naproxen tablets contains

The active substance(s) is	Naproxen
The other ingredients are:	Lactose Monohydrate Maize Starch Sodium lauryl sulphate Crospovidone Magnesium Stearate Quinoline yellow (E104) Sunset yellow (E110)

What Naproxen tablets look like and contents of the pack
Description:
Naproxen tablets 250 mg: Pale yellow flat tablet with a breakline on one side and plain on the reverse.
Naproxen tablets 500 mg: Pale yellow oblong tablet with a breakline on one side and plain on the reverse.

Contents of pack: Tubes
Naproxen tablets 250 mg: Packs of 28, 56 or 250 tablets
Naproxen tablets 500 mg: Packs of 28, 56, 100 or 500 tablets

Marketing Authorisation Holder and Manufacturer
Co-Pharma Limited
Unit 4, Metro Centre,
Tolpits Lane, Watford,
Herts.
UK, WD18 9SS
Tel: 01923 255580
Fax: 01923 255581

1010732

This leaflet was last amended: February 2010.

(back page

Neupro® 4 mg/24 h

transdermal patch

ROTIGOTINE

4013142 10995 2018

PACKAGE LEAFLET: INFORMATION FOR THE USER

Neupro® 4 mg/24 h

transdermal patch

Rotigotine

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT NEUPRO IS AND WHAT IT IS USED FOR

Neupro belongs to a group of medicines called dopamine agonists which stimulate a certain type of cells that bind with dopamine receptors in the brain.

Neupro is used to treat:

- the signs and symptoms of **Parkinson's disease** either alone or in combination with the medicine called levodopa.

2. BEFORE YOU USE NEUPRO

Do not use Neupro

- if you are **allergic** (hypersensitive) to rotigotine or any of the **other ingredients** of Neupro (see Section 6, **'Further information'**).
- if you need to have **magnetic resonance imaging** (method to visualise internal organs and tissues of the body) or **cardioversion** (treatment of abnormal heart rhythm). You must take your Neupro patch off before such procedures. You can put a new patch on after the procedure.

Take special care with Neupro

- This medicine may affect your **blood pressure**, so it should be measured regularly, especially at the beginning of your treatment.
- **Eye examinations** are recommended at regular intervals while using Neupro. However, if you notice any problems with your sight in between examinations, you should contact your doctor immediately.
- If you have serious **liver problems**, your doctor may need to adjust the dose. If during treatment your liver problems get worse, you should contact your doctor as soon as possible.
- If you **feel very drowsy** or find that you **fall asleep suddenly**, please contact your doctor (see also below in this section, under **'Driving and using machines'**).

Treatment of Parkinson's disease

Patients not taking levodopa (early stage of Parkinson's disease)

You will start by using one Neupro 2 mg/24 h patch daily. From the second week, the daily dose will be increased by 2 mg, on a weekly basis, until reaching the right (maintenance) dose for you.

For most patients, the right dose is between 6 mg and 8 mg per day (reached within 3 to 4 weeks).

The maximum dose is 8 mg per day.

Patients taking levodopa (advanced stage of Parkinson's disease)

You will start by using one Neupro 4 mg/24 h patch daily. From the second week, the daily dose will be increased by 2 mg, on a weekly basis, until reaching the right (maintenance) dose for you. For most patients, the right dose is between 8 mg and 16 mg per day (reached within 3 to 7 weeks).

The maximum dose is 16 mg per day.

If you have to stop taking this medicine, see Section 3, **'If you stop using Neupro'**.

FOLLOW THESE INSTRUCTIONS WHEN USING NEUPRO:

You should stick a new Neupro patch onto the skin **once a day**. Leave the patch on your skin for 24 hours, then remove it and apply a new one. Make sure that you take the old patch off before applying a new one; place the new patch on a different area of skin.

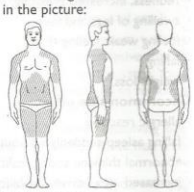
You should **change your patch** at around the **same time every day**.

Do not cut the Neupro patches into pieces.

Where to stick the patch

Put the sticky side of the patch onto clean, dry, healthy skin on the following areas, as indicated by the grey areas in the picture:

- shoulder
- upper arm
- belly
- thigh
- hip
- flank (your side, between your ribs and your hip).



To help avoid skin irritation:

- Stick the patch onto a different area of skin each day, for example on the right side of your body one day, then on the left side the next day; on your upper body one day, then on your lower body.
- Do not stick Neupro on the same area of skin twice within 14 days.
- Do not stick the patch on broken or damaged skin or on skin that is red or irritated.

If you still get problems with your skin because of the patch, please see in Section 4 **'Possible side effects'** the details about what you should do.

To prevent the patch becoming loose or falling off

- Do not put the patch in an area where it can be rubbed by tight clothing.
- Do not use creams, oils, lotions, powders or other skin products on the area of skin you will be sticking the patch on or near a patch you are already wearing.
- If you need to stick the patch to a hairy area of skin, you must shave the area at least 3 days before sticking the patch there.

If the patch falls off, a new patch should be applied for the rest of the day, then replace the patch at the same time as usual.

NOTE

- Bathing, showering and exercising should not affect how Neupro works. Nevertheless, check that the patch has not fallen off afterwards.
- You should avoid external heat (for example excessive sunlight, saunas, hot baths, heating pads or hot-water bottles) on the area of the patch.
- If the patch has irritated your skin, you should keep that area protected from direct sunlight, as it may cause changes in the colour of the skin.

How to use the patch

Each patch is packed in a separate sachet. You should stick Neupro onto your skin as soon as you have opened the sachet and removed the protective liner.

1. To open the sachet, hold the two sides of the sachet. Peel apart the foil and open the sachet.

If you have a skin reaction that lasts longer than a few days, is severe, or spreads outside the area of skin that was covered by the patch, you should contact your doctor.

The frequency of possible side effects listed below is defined using the following convention:

very common (affects more than 1 user in 10)

common (affects 1 to 10 users in 100)

uncommon (affects 1 to 10 users in 1,000)

rare (affects 1 to 10 users in 10,000)

very rare (affects less than 1 user in 10,000)

not known (frequency cannot be estimated from the available data)

If you are using Neupro for Parkinson's disease the following side effects may occur:

Very common side effects

- sleepiness, dizziness, headache
- feeling sick (nausea), vomiting
- skin irritations under the patch such as redness and itching

Common side effects

- seeing or hearing things that are not real (hallucinations)
- difficulty falling asleep, sleep disorder, difficulty sleeping, nightmare, unusual dreams
- loss of consciousness, involuntary movements related to Parkinson's disease (dyskinesia), feeling dizzy when standing up because of fall in blood pressure
- vertigo (sensation of whirling motion)
- feeling of heartbeat (palpitation)
- low blood pressure when standing up, high blood pressure
- hiccups
- constipation, dry mouth, heartburn
- redness, increased sweating, itching
- swelling of legs and feet
- feeling weak, feeling tired
- falling
- weight loss

Uncommon side effects

- allergic reaction
- falling asleep suddenly without warning
- abnormal thinking about reality and behaviour
- increased sex drive, inability to resist the impulse to perform an action that is harmful involving excessive gambling and repetitive meaningless actions
- confusion
- blurred vision
- visual disturbances such as seeing colours or lights
- abnormal heart rhythm
- low blood pressure
- stomach discomfort and pain
- generalised itching, skin irritation
- unable to achieve or maintain an erection
- increased or abnormal liver function test results
- weight increase
- increased heart rate

Rare side effects

- psychotic disorders
- unwanted and uncontrolled thoughts and behaviours
- involuntary muscle spasms (convulsion)
- generalised rash
- irritability

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE NEUPRO

- Keep out of the reach and sight of children.
- Do not use Neupro after the expiry date which is stated on the label and carton.
- Store in a refrigerator (2 °C – 8 °C).

What to do with the used and unused patches

Used patches still contain active substance, which may be harmful to others. Fold the used patch with the sticky side inwards. Put the patch in the original sachet and then throw it away safely, out of the reach of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines not longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Neupro contains

- The active substance is rotigotine.

  Each patch releases 4 mg of rotigotine per 24 hours. Each patch of 20 cm^2 contains 9.0 mg of rotigotine.
- The other ingredients are poly(dimethylsiloxane, trimethylsilyl silicate)-copolymerisate, povidone K90, sodium metabisulphite (E223), ascorbyl palmitate (E304) and DL-α-tocopherol (E307).

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This leaflet was last approved in 11/20

Detailed information on this medicine is able on the European Medicines Agency we http://www.ema.europa.eu.

NUROFEN

for Children
3 months to 9 years Strawberry
100mg / 5ml Oral Suspension

Contains Ibuprofen

Read all of this leaflet carefully before you use this medicine.
It contains important information.
Keep this leaflet: you might need it again.
If you have any further questions after you have read it ask your doctor or pharmacist.

- This medicine is designed to help bring down a high temperature (fever and post-immunisation fever) and relieves pain from headaches, sore throats, minor aches and sprains, teething and toothache.
- This medicine is suitable for most babies over 3 months of age, children and adults.
- **Follow the dose instructions carefully.** Section 3 shows the different amount that children need.
- **Speak to your doctor if your child:**
  - ▶ suffers from any of the conditions listed in Section 2 of the leaflet
  - ▶ is taking **aspirin** at a dose above 75 mg a day. See Section 2
  - ▶ is taking other medicines. See Section 2.
  - ▶ is not getting better, or you feel at all concerned. See Section 3
  - ▶ develops a rash, breathing problems or diarrhoea and gets very tired. See Section 3.
- **Do not use this medicine and speak to your doctor if you are pregnant, think you may be pregnant or trying to get pregnant or are breast feeding.** See Section 2.

In this leaflet:

1. What Nurofen for Children 3 months to 9 years Strawberry is and what it is used for

The active ingredient (which makes this medicine work) is ibuprofen which is a non-steroidal anti-inflammatory (NSAID) painkiller.
Ibuprofen is used as an analgesic (painkiller) for the relief of teething and toothache pain, muscular minor aches and sprains, sore throats as well as the symptomatic relief of headaches. Nurofen for Children 3 months to 9 years Strawberry also brings down a high temperature (fever) including post-immunisation fever.

Talk to your doctor or pharmacist if:

- your child has or has had **high blood pressure, heart problems** or a **stroke** because there is a small increased risk of heart problems with ibuprofen
- your child has a condition which may put them at risk of **heart problems**, such as **diabetes** or **high cholesterol**
- your child has **asthma** or any **allergic disease of the lungs**
- your child has, or has had **liver, kidney, heart or bowel problems**
- your child has **SLE** (Systemic Lupus Erythematosus, a condition of the immune system) or any similar disease
- your child suffers from **chronic inflammatory bowel disease** such as Crohn's disease or ulcerative colitis
- **You or your child are taking other medicines especially:**
  - o other **medicines containing ibuprofen or other NSAIDs,** including those you can buy over the counter
  - o **low dose aspirin** (up to 75 mg a day)
  - o **diuretics** (to help you pass water)
  - o **anticoagulants** (blood thinning medicines e.g. warfarin)
  - o **medicines for high blood pressure** (e.g.captopril, atenolol, losartan)
  - o **lithium** (for mood disorders)
  - o **methotrexate** (for psoriasis, arthritis and types of cancer)
  - o **zidovudine** (for HIV)
  - o **corticosteroids** (an anti-inflammatory drug)
  - o **cardiac glycosides** (for heart problems)
  - o **ciclosporin or tacrolimus** (to prevent organ rejection after transplant)
  - o **mifepristone** (for termination of pregnancy)
  - o **quinolone antibiotics** (for infections)
  - o **SSRI antidepressant drugs**
  - o **antiplatelet drugs** e.g. dipyridamole, clopidogrel.

Seek the advice of your doctor or pharmacist if any of the above apply.
If you are not sure what types of medicines your child is taking, show the medicine to the doctor or pharmacist.

If you are an adult taking this medicine
The warnings and information given in this section apply and in addition the following:

- ibuprofen belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. It is unlikely that this medicine, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant
- you should only take this product on a doctor's advice during the first 6 months of pregnancy
- DO NOT take Nurofen for Children if you

Fever and Pain Relief	
Age	**Dose**
3 months – 6 months Weighing over 5kg	**One 2.5ml dose 3 times a day.** Do not use for more than 24 hours
6 months – 12 months	**One 2.5ml dose 3 or 4 times in 24 hours**
1 year – 4 years	**One 5ml dose 3 times in 24 hours**
4 years – 7 years	**One 7.5ml (5ml + 2.5ml) dose 3 times in 24 hours**
Over 7 years	**One 10ml (5ml + 5ml) dose 3 times in 24 hours**

- Doses should be given every 6 – 8 hours. Leave at least 4 hours between doses.
- For **Short-term use only**
  - ▶ Do not give to babies aged 3 – 6 months for longer than 24 hours.
  - ▶ Do not give to children aged 6 months or over for longer than 3 days.

WARNING:
Do not exceed the stated dose

Talk to your doctor

- **If your child's symptoms do not go away as soon as possible or worsen.**
- **If you are not sure of your child's illness or it is accompanied by a rash, breathing difficulties, diarrhoea or excessive tiredness, speak to your doctor straight away.**

If anyone has taken too much medicine
If you accidentally give or take more than the recommended dose, contact your doctor straight away.

If you forget to give the medicine
If you forget a dose, give the next dose when needed, provided that the last dose was taken at least 4 hours ago. **Do not give a double dose.**

5. How to store Nurofen for Children 3 months to 9 years Strawberry

Do not use the medicine after the expiry date shown on the bottle label and carton.
Store below 25°C.

Keep all medicines out of the reach and sight of children

6. Further information

What is in this medicine?

The active ingredient is Ibuprofen 100 mg per 5 ml.

The other ingredients are:
Maltitol liquid, water, glycerol, citric acid, sodium citrate, sodium chloride, sodium saccharin, strawberry flavour, xanthan gum, polysorbate 80, domiphen bromide.

What the medicine looks like
Nurofen for Children 3 months to 9 years Strawberry is an off-white liquid available in 100ml bottles.
Each pack contains a dosing syringe (CE 0543
It contains 100mg of the active Ibuprofen in every 5 ml of medicine.
Product licence holder: Crookes Healthcare Limited, Nottingham, NG2 3AA
Syringe manufacturer: Crookes Healthcare Limited, Nottingham, NG2 3AA
Manufacturer of medicine: Reckitt Benckiser Healthcare UK Ltd, Hull, HU8 7DS
and
BCM Ltd, Nottingham NG2 3AA

Product license number: PL 00327/0157

This leaflet was revised: March 2010

The leaflet gives you the most important information. If you have any questions after you have read it, ask your doctor or pharmacist who will be able to help.

Package leaflet: Information for the user SZ36204LT03B

Nystatin Oral Suspension

Nystatin

Please read this leaflet carefully before you start to take your medicine. It contains important information.
- Keep the leaflet in a safe place because you may want to read it again.
- If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

SANDOZ

1 What Nystatin Oral Suspension is and what it is used for

Nystatin Oral Suspension contains the active ingredient nystatin which belongs to a group of medicines known as anti-fungal antibiotics.
It is used for the prevention and treatment of infections of the mouth, throat and intestinal tract caused by a fungus called Candida. It also provides effective protection against Candida infection in children born to mothers with vaginal Candida infection.

2 Before you take Nystatin Oral Suspension

Do not take Nystatin Oral Suspension if you are:
- allergic to Nystatin or any of the other ingredients in the product *(see Section 6: 'What Nystatin Oral Suspension contains').*

Take special care with Nystatin Oral Suspension
Children must not be given the medicine if they have a sugar intolerance.

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
Ask your doctor for advice before taking any medicine.

Driving and using machines
Nystatin Oral Suspension is not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Nystatin Oral Suspension
The product contains:
- **Sucrose -** contains 0.2g of sucrose per 1 ml dose. If you know you have an intolerance to some sugars, contact your doctor before taking this medicine. Nystatin Oral Suspension should not be given to children with disaccharide intolerance.
- **Propyl-p-hydroxybenzoate (E216) and methyl-p-hydroxybenzoate (E218) -** may cause allergic reactions such as nettle rash and wheezing, as well as delayed skin type reactions.
- **Sodium metabisulphite (E223) -** may rarely cause severe hypersensitivity reactions and bronchospasm (difficulty in breathing).
- **Sodium -** this medicinal product contains 0.3 mmol (or 1.3 mg) sodium per 1 ml dose. To be taken into consideration by patients on a controlled sodium diet.

3 How to take Nystatin Oral Suspension

Always take Nystatin Oral Suspension exactly as your doctor has told you. Do not use the suspension if the seal is broken. Do not dilute the medicine.

Shake the medicine well before use. **Hold the medicine in the mouth and keep in contact with the affected area(s) for as long as possible before swallowing.**

Continued on the next page

The usual doses are as follows:

Adults and the elderly	
Denture sores and mouth infections caused by Candida albicans:	1ml, 4 times a day.
Gut infections:	5ml, 4 times a day.
Prevent candidal infection/overgrowth:	If you are also taking other antibiotics, a total daily dosage of 10ml will probably be sufficient.
Children	
Intestinal and mouth infections caused by Candida albicans in infants and children:	1ml, 4 times a day.
Protection against infection in newborn babies	1ml, once a day.

You should continue to take Nystatin Oral Suspension for 48 hours after your infection has cleared. This is important to prevent the infection returning.

If you take more Nystatin Oral Suspension than you should
One extra dose is unlikely to be a cause for concern but if you, or someone else, have accidentally taken too much suspension, contact your doctor or local hospital accident and emergency department immediately.

If you forget to take Nystatin Oral Suspension
If you miss a dose, take the medicine as soon as you remember and continue your next dose as usual. Do not take a double dose to make up for the one forgotten.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Nystatin Oral Suspension can cause side effects, although not everybody gets them.

Side effects when taking nystatin are unusual, except if taking large doses of 40-50ml daily.

Stop taking this medicine and contact your doctor or the nearest hospital immediately if you experience any of the following:
- Severe itchy skin rash, swelling of the hands, face, lips or tongue, or difficulty breathing.
- Stevens-Johnson Syndrome (symptoms include cough, aches, headache, fever, vomiting, diarrhoea, rash and blisters).

Other reported symptoms:
- feeling sick (nausea), being sick (vomiting).
- mouth irritation and sensitisation.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5 How to store Nystatin Oral Suspension

Keep out of the reach and sight of children.

Store this product in a cool place, but do not freeze. Protect from light.

Do not take Nystatin Oral Suspension after the expiry date stated on the label. Do not use the suspension if the seal is broken or if you notice any visible signs of deterioration.

Ask your pharmacist how to dispose of medicines no longer required.

6 Further information

What Nystatin Oral Suspension contains
The **active ingredient** is nystatin. Each 1ml of suspension contains 100,000 International Units (IU) of nystatin.

The **other ingredients** are: sodium carboxymethylcellulose, methyl-p-hydroxybenzoate, propyl-p-hydroxybenzoate, sodium metabisulphite, sucrose, saccharin sodium, sodium citrate, aniseed flavour and purified water *(see also end of Section 2: 'Important information about some of the ingredients of Nystatin Oral Suspension').*

What Nystatin Oral Suspension looks like and contents of the pack
The medicine contains 30ml of suspension, in a brown glass bottle with either a plastic cap or a child-resistant cap.

Marketing Authorisation Holder and Manufacturer
Sandoz Ltd, 37 Woolmer Way, Bordon, Hampshire, GU35 9QE.

This leaflet was last approved in 08/2008 SZ36204LT03B

PACKAGE LEAFLET: INFORMATION FOR THE USER SZ90708LT04D

Omeprazole 10 mg, 20 mg and 40 mg Capsules

Omeprazole SANDOZ

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Omeprazole is and what it is used for

Omeprazole contains the active substance omeprazole. It belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Omeprazole is used to treat the following conditions:

In adults:
- 'Gastro-esophageal reflux disease' (GERD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Ulcers which are infected with bacteria called 'Helicobacter pylori'. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Omeprazole can also be used to stop ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

In children:
Children over 1 year of age and ≥ 10 kg
- 'Gastro-esophageal reflux disease' (GERD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
  In children, the symptoms of the condition can include the return of stomach contents into the mouth (regurgitation), being sick (vomiting) and poor weight gain.

2. Before you take Omeprazole

Do not take Omeprazole if:
- you are allergic to omeprazole or any other ingredients of this medicine (listed in section 6).
- you are allergic to medicines containing substituted benzimidazoles.

Do not take Omeprazole if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Omeprazole.

Take special care with Omeprazole
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Omeprazole
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- Tacrolimus (in cases of organ transplantation)
- St John's wort *(Hypericum perforatum)* (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Saquinavir (used to treat HIV infection)
- Clopidogrel (used to prevent blood clots (thrombi))

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Omeprazole to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

Taking Omeprazole with food and drink
You can take your capsules with food or on an empty stomach.

Pregnancy and breast-feeding
Before taking Omeprazole, tell your doctor if you are pregnant or trying to get pregnant. Your doctor will decide whether you can take Omeprazole during this time.

Your doctor will decide whether you can take Omeprazole if you are breastfeeding.

Driving and using machines
Omeprazole is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

Important information about some of the ingredients of Omeprazole
Omeprazole capsules contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Omeprazole

Always take Omeprazole exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many capsules to take and how long to take them for. This will depend on your condition and how old you are.
The usual doses are given below.

Adults:
To treat symptoms of GERD such as **heartburn and acid regurgitation:**
- If your doctor has found that your food pipe (gullet) has been slightly damaged, the usual dose is 20 mg once a day for 4-8 weeks. Your doctor may tell you to take a dose of 40 mg for a further 8

Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare:	affects less than 1 user in 10,000
Not known:	frequency cannot be estimated from the available data

Other side effects include:
Common side effects
- Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).

Uncommon side effects
- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as "pins and needles", feeling sleepy.
- Spinning feeling (vertigo).
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.

Rare side effects
- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth.
- An inflammation of the inside of the mouth.
- An infection called "thrush" which can affect the gut and is caused by a fungus.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (interstitial nephritis).
- Increased sweating.

Very rare side effects
- Changes in blood count including agranulocytosis (lack of white blood cells).
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint

isopropyl alcohol, propylene glycol, N-butyl alcohol, ammonium hydroxide, potassium hydroxide, black iron oxide (E172).

What Omeprazole Capsules look like and contents of the pack
Omeprazole 10 mg:
Light brown cap, light brown body, each imprinted with "OME 10" containing dull yellowish, brown granules.

Omeprazole 20 mg:
White cap, white body, each imprinted with "OME 20" containing dull yellowish, brown granules.

Omeprazole 40 mg:
White cap, light brown body, each imprinted with "OME 40" containing dull yellowish brown pellets.

Omeprazole 10 mg:
Aluminium/Aluminium blister in packs of 7, 14, 15, 28, 30, 56, 56x1 and 98 capsules.
White HDPE bottles with PP screw cap and desiccant: boxes containing 1 bottle of 7, 14, 15, 28, 30, 49, 50 and 168 capsules or boxes containing 2 bottles of 28, 49, 50 and 168 capsules.
Amber glass bottles with a HDPE screw cap with inserted desiccant agent containing silica gel in boxes of 15 and 168 capsules.

Omeprazole 20 mg:
Aluminium/Aluminium blister in packs of 7, 14, 15, 28, 30, 56, 56x1 and 98 capsules.
White HDPE bottles with PP screw cap and desiccant: boxes containing 1 bottle of 7, 14, 15, 28, 30, 49, 50, 100 and 168 capsules or boxes containing 2 bottles of 28, 30, 49, 50 and 168 capsules.
Amber glass bottles with a HDPE screw cap with inserted desiccant agent containing silica gel in boxes of 15 and 168 capsules.

Omeprazole 40 mg
Aluminium/Aluminium blister in packs of 7, 14, 15, 28, 30, 56 and 98 capsules.
White HDPE bottles with PP screw cap and desiccant: boxes containing 1 bottle of 7, 14, 15, 28, 30, 49, 50 and 168 capsules or boxes containing 2 bottles of 28, 30, 49, 50 and 168 capsules.
Amber glass bottles with a HDPE screw cap with inserted desiccant agent containing silica gel in boxes of 15 and 168 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing authorisation holder:
Sandoz Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR.

Manufacturer:
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

This leaflet was last approved in 11/2010.

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SZ90708LT04D

PACKAGE LEAFLET: INFORMATION FOR THE USER

One-Alpha® Capsules 0.25 microgram
One-Alpha® Capsules 0.5 microgram
One-Alpha® Capsules 1 microgram

alfacalcidol

Please read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.
- In this leaflet One-Alpha® capsules will be called One-Alpha®.

In this leaflet:

1. WHAT ONE-ALPHA® IS AND WHAT IT IS USED FOR

One-Alpha® belongs to a group of medicines called vitamin D analogues. It is a type of vitamin D.

Vitamin D controls the levels of two substances in your body. These substances are called calcium and phosphate. Your body needs both of these substances for healthy bones and teeth.

One-Alpha® works by increasing the amount of vitamin D in your body. This means the levels of calcium and phosphate in your body will increase too.

One-Alpha® is used to treat diseases where the amount of calcium in your body needs changing. It is used to treat:
- Changes in bone caused by kidney failure (osteodystrophy).
- Changes to your parathyroid glands. These are small glands found in your neck. They make a substance called the parathyroid hormone. This changes the amount of calcium in your body.
  - The glands may make the amount of calcium in your blood too high. (hyperparathyroidism).
  - The glands may make the amount of calcium in your blood too low (hypoparathyroidism).
- Low levels of calcium in the blood of newborn babies (hypocalcaemia).
- Softening and deformity of the bones due to lack of calcium (rickets or osteomalacia).

2. BEFORE YOU TAKE ONE-ALPHA®

Do not take One-Alpha®
- If you are allergic (hypersensitive) to alfacalcidol or any of the other ingredients. You can find a list of these ingredients in section 6 of this leaflet.
- If you know you have a condition called hypercalcaemia. This means you have high levels of calcium in your blood.
- If you know that you have a condition called calcification. This means you have high levels of calcium in your body tissues.

If you are unsure if any of the above apply to you, talk to your doctor before taking One-Alpha®.

Take special care with One-Alpha®
Before you take One-Alpha® tell your doctor:
- If you are taking another type of medicine called a cardiac glycoside, such as digoxin. These medicines are used to treat problems with your heart.
- If you have any problems with your kidneys. This includes if you have kidney stones.

You may get too much calcium or phosphate in your blood when you take this medicine. Please read section 4 of this leaflet so you can spot any signs this may be happening to you. Your doctor may need to change your dose.

While you are taking One-Alpha® your doctor will take regular blood tests. This is very important in children, patients with kidney problems, or patients on a high dose of medicine. This is to check the level of calcium and phosphate in your blood while you take your medicine.

Your doctor may prescribe another medicine called a phosphate binding agent to take as well as One-Alpha®. This will help to keep the right amount of phosphate in your blood.

Taking other medicines
Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription.

You must tell your doctor or pharmacist if you are taking any of the following medicines:
- Anticonvulsants: for epilepsy or fits. You may need a larger dose of One-Alpha®.
- Barbiturates: for sleeping disorders. You may need a larger dose of One-Alpha®.
- Cardiac glycosides, such as digoxin: for heart problems. You may get too much calcium in your blood. This may cause an abnormal heart beat.
- Colestyramine: for lowering your cholesterol level, or to help stop some types of diarrhoea or itching. Your One-Alpha® may not enter your blood as usual.
- Thiazide diuretics, often called "water pills": for increasing the amount of water (urine) that your body makes. You may get too much calcium in your blood.

Pregnancy and breast-feeding
Please ask your doctor or pharmacist for advice before taking One-Alpha®:
- If you are pregnant, or think you are pregnant.
- If you are breast-feeding.

Tell your doctor if you become pregnant while taking this medicine.

Driving and using machines
Usually your medicine may have very little effect on your ability to drive or use machines. Check with your doctor if you feel any side effect that may stop you from driving or using machines.

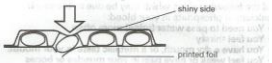
Important information about some of the ingredients of One-Alpha®
One-Alpha® contains:
- Sesame oil. Sesame oil is used to make your capsules. It may rarely give you severe allergic reactions. Please read section 4 of this leaflet so you can spot any signs this may be happening to you.

Please ask your doctor if you are worried about any of the ingredients in this medicine.

3. HOW TO TAKE ONE-ALPHA®

Always use One-Alpha® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How to take the capsule out of the blister
Press on the shiny side of the blister. The capsule will come out through the printed side of the foil. Please see the diagram.



How much One-Alpha® to take
Your doctor will tell you how many capsules to take, or to give your child.
At first you will have weekly blood tests to check the levels of some substances in your blood. These tests are to check the levels of calcium, an enzyme called alkaline phosphatase or the parathyroid hormone. This is so your doctor knows that you are taking the dose that is right for you. When you are getting the correct dose you will not need blood tests so often.
You may also have other tests such as X-rays. This is also so your doctor knows that the dose is right for you.

Your doctor may adjust your dose. Your doctor may ask you to take more or less capsules depending on your test results. You may get too much calcium or phosphate in your blood when you take this medicine. Please read section 4 of this leaflet so you can spot any signs this may be happening to you. Your doctor will tell you not to take any more medicine. You will need to have some blood

Adults:
The usual starting dose is 1 microgram each day. This is either 1 brown capsule, 2 red capsules or 4 white capsules. People usually take between 1 and 3 micrograms each day.

Most people take between 0.25 and 1 microgram each day once the blood test results show the medicine is working. This is usually one white capsule, or one red capsule or one brown capsule.
If you have very low levels of calcium in your blood, your doctor may prescribe between 3 and 5 microgram each day. Your doctor may prescribe another medicine called a calcium supplement to take as well as One-Alpha®. This will help to keep the right amount of calcium level in your blood.

Elderly:
The usual starting dose is 0.5 microgram each day. This is either 1 red capsule or 2 white capsules.

Children:
The dose depends on the weight of the child (called bodyweight).

- **Newborn and premature babies:**
  The usual starting dose is 0.05 to 0.1 microgram per kilogram of bodyweight each day.
  If the level of calcium in their blood is very low, up to 2 micrograms per kilogram of bodyweight may be needed each day.
  A dose of 0.1 microgram per kilogram bodyweight each day is used to stop low blood calcium levels in premature babies.
- **Children weighing less than 20 kilograms:**
  The usual starting dose is 0.05 microgram per kilogram bodyweight each day.
- **Children weighing more than 20 kilograms**
  The usual starting dose is 1 microgram each day.

If you take more One-Alpha® than you should
Tell your doctor straight away. You may need to stop taking this medicine.

You may get too much calcium or phosphate in your blood. Please read section 4 of this leaflet so you can spot any signs this may be happening to you.

If you forget to take One-Alpha®
If you forget to take your medicine, take it as soon as you remember. Then take the next dose at the usual time.

If you have any further questions about taking this medicine, please ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, One-Alpha® can cause side effects, although not everybody gets them.

Important side effects to look out for:
You must get urgent medical help if you have any of the following symptoms. You may be having an allergic reaction:
- **You have difficulty breathing**
- **Your face or throat swell**
- **Your skin develops a severe rash.**

You should tell your doctor straight away if you spot any of the following signs which may be due to too much calcium or phosphate in your blood:
- **You need to pass water (urine) more often**
- **You feel thirsty**
- **You have a dry mouth, or a metallic taste in your mouth.**
- **You feel weak or have pain in your muscles or bones**
- **You feel sick or have constipation.**

Other possible side effects:
Skin problems:
- Itching skin
- Rash
- Hives (urticaria)

Kidney problems:
- Needing to pass water (urine) less often.
- Swelling of any parts of your body.
- Fever with a pain in your side.

These are signs that there may be problems developing with your kidneys. Kidney stones may be forming. Kidney stones may cause a sharp spasm in one side of your lower back.

The possible side effects described in this section of the leaflet probably affect about 1 in 10,000 people. Skin problems or too much calcium in your blood are the side effects most people get.
If any of the side effects become serious, or you notice any

5. HOW TO STORE ONE-ALPHA®

- Keep out of the reach and the sight of children.
- Do not use the capsules after the expiry date on the carton. The expiry date is the last day of that month.
- Do not store above 25°C.

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need anymore. If you do this you will help protect the environment.

6. FURTHER INFORMATION

What One-Alpha® contains
- The active ingredient is alfacalcidol.
  One-Alpha® Capsules 0.25 microgram contain 0.25 microgram of alfacalcidol in each capsule.
  One-Alpha® Capsules 0.5 microgram contain 0.5 microgram of alfacalcidol in each capsule.
  One-Alpha® Capsules 1 microgram contain 1 microgram of alfacalcidol in each capsule.
- The other ingredients are sesame oil, all-*rac*-α-tocopherol, gelatin, glycerol, and potassium sorbate.
  The 0.25 microgram capsules also contain titanium dioxide (E171).
  The 0.5 microgram capsules also contain titanium dioxide (E171) and red iron oxide (E172).
  The 1 microgram capsules also contain black iron oxide (E172) and red iron oxide (E172).

You can find important information about some of the ingredients in your medicine near the end of section 2 of this leaflet.

What One-Alpha® looks like and contents of the pack
One-Alpha® Capsules 0.25 microgram are white capsules.
One-Alpha® Capsules 0.5 microgram are red capsules.
One-Alpha® Capsules 1 microgram are brown capsules.
One-Alpha® comes in blister packs of 30 capsules.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
LEO Laboratories Limited, Princes Risborough, Bucks., HP27 9RR, UK.
Manufacturer:
LEO Pharmaceutical Products, DK 2750, Ballerup, Denmark.

This leaflet was last revised in February 2009
®Registered Trade Mark

L E O

LEO

Patient Information Leaflet for

PARACETAMOL EXTRA CAPLETS

Read this leaflet carefully before taking these caplets. It does not contain all the information about your medicine that you may need to know, so please ask your doctor or pharmacist if you have any questions. This leaflet only applies to Paracetamol Extra Caplets.

1. What these caplets do

Paracetamol Extra Caplets contain paracetamol and caffeine and are used for the relief of headache, migraine, backache, fever, dental pain, period pain, the symptoms of cold and flu, sciatica and rheumatic and muscular aches and pains.

2. Check before you take

Do not take these caplets if you:

- Are allergic to Paracetamol, or any of the other ingredients listed in section 6 (See section 4 – Possible Side Effects)
- Have a peptic ulcer or have had one in the past
- Are pregnant

Take special care and tell your doctor if you:

- Have liver or kidney problems
- Have heart problems or high blood pressure
- Are breastfeeding
- Suffer from alcohol dependency
- Suffer from G6PD deficiency

Tell your doctor or pharmacist if you are already taking any of the following medicines:

- Colestyramine (used to help control cholesterol levels)
- Meprobamate (used to control anxiety)
- Metoclopramide and domperidone (prevent nausea and sickness)
- Chloramphenicol (an antibiotic)
- Blood thinning medicines such as warfarin
- Anti-inflammatory drugs (NSAIDs e.g. Ibuprofen or aspirin)
- Any drugs that affect the liver

3. How to take the caplets

Dosage in adults, the elderly and children over 12 years:

Take one to two caplets every four hours. Do not take more than a total of 8 caplets in 24 hours. Swallow the caplets whole with a drink of water. Do not chew.

When taking this medicine, it is important to remember the following:

- Do not give these caplets to children under 12 years of age unless told to by your doctor
- Do not exceed the stated dose
- Seek medical attention IMMEDIATELY if you accidentally take too many caplets, even if you feel well, because of the risk of delayed serious liver damage.
- If you miss a dose, do not take a double dose to make up for the missed dose
- Do not drink alcohol or take other Paracetamol containing products whilst taking this medicine
- If symptoms persist for more than 3 days consult your doctor

If you take more Paracetamol Extra Caplets than you should.

- Seek medical attention IMMEDIATELY if you accidentally take too many caplets, even if you feel well, because of the risk of delayed serious liver damage. Take the container and any remaining tablets with you. Symptoms of overdose include nausea, diarrhoea, vomiting, and abdominal pain.

If you forget to take Paracetamol Extra Caplets.

- Do not take a double dose to make up for a forgotten dose

If you have any further questions on the use of this product, ask your doctor or pharmacist

4. Possible side effects

Paracetamol Extra Caplets can cause side effects but not everybody gets them.

Serious side effects

If you experience any of the following symptoms after taking this medicine go to the nearest hospital IMMEDIATELY

- Skin rashes and itching
- Difficulty breathing
- Swollen face
- Unusual bruising or bleeding, throat and mouth ulcers or bleeding gums accompanied by tiredness and flu like symptoms

If you experience any of the above symptoms after taking this medicine go to the nearest hospital IMMEDIATELY.

Other side effects

- Pain in the lower back and groin
- Restlessness and excitement
- Blood disorders
- Pancreatitis
- Hepatitis
- Changes in your urine
- Stomach ulcers
- Nausea and vomiting
- Insomnia
- Headache
- Irritability and anxiety
- Rapid or irregular heartbeat

If you experience any of these or any other side effects and they get serious, contact your doctor or pharmacist.

5. Storing your medicine

Keep your medicine in a safe place where children cannot see or reach it.

Do not store above 25°C. Store in the original packaging to protect from light and moisture.

Do not use this medicine after the expiry date printed on the packaging.

6. More about your medicine

The active ingredients in Paracetamol Extra Caplets are Paracetamol 500mg and Caffeine Anhydrous 65mg. They are tablets with embossed 'ap and x' on one face on either side of a break line. The other ingredients are starch, povidone K-30, talc, stearic acid and magnesium stearate.

The product licence holder and manufacturer is Aspar pharmaceuticals Ltd, Capitol Way, Colindale, London NW9 0EQ.

PL 08977/0025

Paracetamol Extra Caplets are sold in blister packs of 8 and 16

Text Revised March 2010 PXT/1

'ACKAGE LEAFLET:
NFORMATION FOR THE USER

Phenergan 10 mg Tablets

promethazine hydrochloride

sanofi aventis

Is this leaflet hard to see or read?
Phone 01483 505515 for help

tead all of this leaflet carefully because it contains mportant information for you.
his medicine is available without prescription. However, ou still need to take Phenergan Tablets carefully to get the best esults from it.
- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact a doctor if your symptoms worsen or do not improve after 7 days
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

n this leaflet:

1. What Phenergan Tablets are and what they are used for

Phenergan Tablets contain a medicine called promethazine hydrochloride. This belongs to a group of medicines called phenothiazines. It works by blocking a natural substance (histamine) that your body makes during an allergic reaction. It also works directly on the brain to help you feel more relaxed.

What Phenergan Tablets are used for
Phenergan Tablets can be given to you either by a doctor or directly by a pharmacist depending on the condition you are being treated for.

Phenergan Tablets may be provided directly by a pharmacist for use in the following situations:
- To treat allergic conditions such as hay fever or rashes (like nettle rash or hives)
- To treat adults with difficulty sleeping (insomnia)
- To treat or stop you feeling sick (nausea) or being sick (vomiting) such as travel sickness

Phenergan Tablets may also be given to you by a doctor. This can be for use in any of the above situations or for use in the following additional situations:
- To help you feel more relaxed before an operation
- If you are having difficulty sleeping
- As a sedative for both adults and children. This is a medicine given to reduce awareness or make you feel relaxed and at ease

2. Before you take Phenergan Tablets

Do not take this medicine and tell your doctor if:
× The person taking the medicine is under 2 years of age
× You are allergic (hypersensitive) to promethazine hydrochloride or any of the other ingredients of Phenergan Tablets (listed in Section 6 below)
The signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
× You are taking a medicine for depression called a monoamine oxidase inhibitor (MAOI). Also do not take Phenergan Tablets if you have stopped taking one of these MAOI medicines within the last 14 days. If you are not sure ask your doctor or pharmacist (see "Taking other medicines" section below)
× The person is unconscious (in a coma) or suffers from severe dizziness, drowsiness or headache

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Phenergan Tablets.

Take special care with Phenergan Tablets
Check with your doctor or pharmacist before taking your medicine if
▲ You have difficulty breathing, wheezing, tightness in the chest (asthma) or an infection in your lungs (bronchitis)
▲ You have epilepsy
▲ You have any serious heart problems
▲ You have liver or kidney problems
▲ You have a stomach blockage or difficulty passing water (urine)
▲ You have increased pressure in the eye (narrow angle glaucoma)
▲ You have had something called Reye's Syndrome or possible Reye's Syndrome – signs include being sick and confused following a viral illness

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Phenergan Tablets.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you can buy without prescription, including herbal medicines. This is because Phenergan Tablets can affect the way some medicines work. Also some medicines can affect the way Phenergan Tablets work.

Do not take this medicine, and tell your doctor, if you are taking or have taken the following in the last 2 weeks:
- Some medicines for depression called monoamine oxidase inhibitors (MAOIs). If you are not sure ask your doctor or pharmacist

Tell your doctor or pharmacist if you are taking any of the following:
- Anticholinergic medicines - includes some medicines used for irritable bowel syndrome, asthma or weak bladder. These can increase the risk of dizziness, dry mouth and blurred eyesight
- Medicines for depression (such as amitriptyline)
- Medicines to help you to sleep or feel more relaxed (such as diazepam or zolpidem)
- Medicines such as aspirin (for arthritis and pain in your joints). Phenergan Tablets may hide the side effects of these medicines

Taking Phenergan Tablets with food and drink
Do not drink alcohol while you are taking Phenergan Tablets. This is because it can affect the way the medicine work

Pregnancy and breast-feeding
Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant. Phenergan Tablets should not be taken 2 weeks before birth.

You should not take Phenergan Tablets if you are breast-feeding. This is because small amounts may pass into mother milk. This can be harmful to your baby.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

Driving and using machines
You may feel drowsy or sleepy after taking this medicine or in the morning after taking this medicine. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Phenergan Tablets
This medicine contains:
- Lactose. This is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine

Turn Over

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3. How to take Phenergan Tablets

The amount you need to take depends on the reason you are taking Phenergan Tablets. The following information will help you to decide how much you need to take. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine
- Take this medicine by mouth
- Do not take for longer than 7 days. If your symptoms worsen or do not improve after 7 days talk to your doctor or pharmacist
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much to take
The usual dose is:
For allergies (such as hay fever, rashes and hives)
Children 2-5 years:
- Phenergan Elixir should be given in this age group

Children 5-10 years:
- A single dose of either one or two tablets (10mg or 20mg) given at night or one tablet (10mg) given twice a day
- DO NOT give more than two tablets (20mg) each day

Children over 10 years and adults (including the elderly):
- Start with one tablet (10mg) twice a day
- This may be increased to a maximum of two tablets (20mg) three times a day

For treatment and prevention of feeling sick or being sick (such as travel sickness)
Children 2-5 years:
- Phenergan Elixir should be given in this age group

Children 5-10 years:
- A single tablet to be taken the night before the journey
- This may be repeated after 6-8 hours if necessary

Children over 10 years and adults (including the elderly):
- Two tablets (20mg) to be taken the night before the journey
- This may be repeated after 6-8 hours if necessary

As a sedative (only under the advice of a doctor)
Phenergan Tablets may also be used as a short term sedative. This will normally have been prescribed by a doctor. The information below is a guide to the doses recommended
Children 2-5 years:
- Phenergan Elixir should be given in this age group

Children 5-10 years:
- Two tablets (20mg) given as a single dose at night time

Children over 10 years and adults (including the elderly):
- Two to five tablets (20mg to 50mg) as a single dose at night time

Exposure to sunlight
Phenergan Tablets can make your skin more sensitive to sunlight. Keep out of direct sunlight while taking this medicine.

If you take more Phenergan Tablets than you should
If you or your child takes more Phenergan Tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you or your child has taken.
The following effects may happen:
In children: Excitation, moving unsteadily or stumbling, uncontrolled writhing movements especially of the hands or feet, hallucinations, fits (seizures), loss of consciousness, uneven heart beat and breathing difficulties.
In adults: Feeling sleepy or drowsy, fits, loss of consciousness, uneven heart beat and breathing difficulties.

If you forget to take Phenergan Tablets
Do not take a double dose to make up for a forgotten dose
- If you are taking Phenergan Tablets for an allergic condition - take your medicine as soon as you remember, then carry on as before
- If you are taking Phenergan Tablets for sedation or sleeping problems - miss that dose and take the next evening's dose as usual

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Tests
Taking Phenergan Tablets may affect the results of certain tests. These include some pregnancy tests and skin tests. Phenergan Tablets should not be taken at least 3 days before the start of a skin test.

4. Possible side effects

Like all medicines, Phenergan Tablets can cause side effects, although not everybody gets them.

Stop taking Phenergan Tablets and see a doctor or go to a hospital straight away if you notice any of the following side effects:
- An allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- Liver problems that may cause the eyes or skin to go yellow (jaundice)
- Muscle stiffness or shaking
- Being unable to control some muscles in your head or face
- You notice unusual movements of the tongue, facial muscle spasms, rolling eyes and trembling
- Very fast, uneven or forceful heartbeat (palpitations)
- Tiredness which lasts for a long time. This may be due to a blood problem called anaemia
- Over-active behaviour in children

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet.
- Dry mouth, blurred vision or you cannot pass water (urine)
- Feeling drowsy or sleepy, tiredness, disorientation, having nightmares, headaches, feeling restless
- Loss of appetite (anorexia), indigestion
- Feeling dizzy, lightheaded, faint (hypotension)
- Feeling confused, especially in elderly people
- Being more sensitive to the sun than usual. If this happens keep out of direct sunlight and do not use sun lamps

5. How to store Phenergan Tablets

- Keep out of the reach and sight of children
- Do not take Phenergan Tablets after the expiry date which is stated on the carton and blister pack after EXP. The expiry date refers to the last day of that month
- Store below 30°C
- Store in the original carton in order to protect from light

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further Information

What Phenergan Tablets contains.
- Each tablet contains 10mg of the active substance, promethazine hydrochloride
- The other ingredients are lactose, maize starch, povidone, magnesium stearate, polyethylene glycol, Opaspray (contains titanium dioxide-E171, hypromellose-E464, indigo carmine aluminium lake blue-E132) and hypromellose

What Phenergan Tablets look like and contents of the pack
A pale blue film coated tablet marked PN 10 on one side. The tablets are available in blister packs of 56.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Sanofi-aventis
One Onslow Street
Guildford
Surrey
GU1 4YS
UK
Tel: 01483 505515
Fax: 01483 535432
email:uk-medicalinformation@sanofi-aventis.com

Manufacturer
Aventis Pharma SA
Avenida de Leganes 62
28925 Alcoron

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in 04/2008

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Goldshield

PATIENT INFORMATION LEAFLET
PHORPAIN® GEL MAXIMUM STRENGTH
(Ibuprofen)

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet.You may need to read it again. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1.WHAT IS PHORPAIN® GEL MAXIMUM STRENGTH AND WHAT IT IS USED FOR

Phorpain® Gel Maximum Strength contains ibuprofen and belongs to a group of medicines called non-steroid anti-Inflammatory drugs (NSAIDs). These medicines reduce pain and inflammation, and bring down a high temperature.

Phorpain® Gel Maximum Strength is used to treat a number of painful conditions affecting the joints and muscles such as back pain, sprains, strains and other sport injuries. It is also used for the relief of pain caused by mild to moderate arthritic conditions and nerve pain (neuralgia).

2. BEFORE YOU USE PHORPAIN® GEL MAXIMUM STRENGTH

DO NOT use Phorpain® Gel Maximum Strength if:

- You are allergic to ibuprofen, aspirin or similar medicines or any of the other ingredients in this gel (listed at the end of this leaflet).
- Aspirin or similar medicines have given you asthma, itchy rash or hayfever-like symptoms.

Take special care with Phorpain® Gel Maximum Strength

- Protect treated areas from direct sunlight to avoid any sensitivity reaction, e.g. a rash.
- You have had an ulcer or some other problem affecting your stomach, or intestines in the past.
- You have asthma or wheezing attacks (or if you have had asthma in the past)
- You have any kidney problems.
- If you develop a rash after using the gel stop using it any further.
- If you suffer from bronchial asthma or any allergic disease.

PHORPAIN® GEL IS FOR EXTERNAL USE ONLY

Taking / Using other medicines:

Can you take Phorpain® Gel with other medicines?

Please inform your doctor or pharmacist if you are taking, or have recently taken any other medicine, even those not prescribed by a doctor.

The effect of this medicine may affect or be affected by taking the following medicines at the same time:

- Medicines to lower your blood pressure (e.g. atenolol)
- Medicines used to thin the blood (e.g. warfarin)
- Aspirin or other NSAIDs, used for pain and inflammation

Please tell your doctor or pharmacist if you are taking any of the above, or have recently taken any other medicine - even those not prescribed.

Pregnancy and breast feeding

If you are pregnant or planning to become pregnant, or are breast feeding, please tell your doctor or pharmacist before taking Phorpain® Gel Maximum Strength.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Phorpain® Gel Maximum Strength should not affect the ability to drive or use machines.

3.HOW TO USE PHORPAIN® GEL MAXIMUM STRENGTH

Phorpain® Gel Maximum Strength is designed for topical (on the skin) application only. Never take the gel by mouth. If you do accidentally swallow some of the gel, rinse your mouth thoroughly. In the case of an upset stomach, speak to your doctor or pharmacist for advice.

Always use Phorpain® Gel Maximum Strength exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Check the seal is intact before first use (invert cap to break seal).

Adults: Squeeze 50 to 125mg (2 to 5cm) of gel from the tube on affected area. Massage until absorbed. This dose should not be repeated more frequently than every four hours and no more than four times a day in any 24 hour period.

Phorpain® Gel Maximum Strength should only be used on healthy, unbroken skin. Do not use it on or near cuts or grazes or under dressings such as plasters.

Do not let any gel come in contact with your eyes. If it does, rinse your eyes with cold water and consult your doctor. Hands should be washed after applying Phorpain® Gel Maximum Strength, unless they are the site of treatment. Do not use the gel on the genital area.

If the condition does not improve after two weeks use, or becomes worse at any time, speak to your doctor or pharmacist.

Children: Phorpain® Gel Maximum Strength is not recommended for use in children under 14 years.

If you use more than you should:

If you accidentally swallow any Phorpain® Gel Maximum Strength, contact your doctor, or nearest hospital, as soon as possible.

If you forget to use your Phorpain® Gel Maximum Strength:

If you miss a dose, just carry on with the next dose as normal. Do not apply a double dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines Phorpain® Gel can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Other side effects include:

- Itching or reddening of the skin.
- Abdominal Pain (pains in your stomach) or other abnormal stomach symptoms.
- A burning feeling.
- Sore or weeping spots.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PHORPAIN® GEL MAXIMUM STRENGTH

Keep out of the reach and sight of children.

Do not use Phorpain® Gel Maximum Strength after the expiry date which is stated on the tube. It should be stored in a cool, dry place, below 25°C. Keep the tube tightly closed.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Remember:

This medicine is for you. Never give this medicine to someone else, it could harm them, even if their symptoms seem the same as yours.

6. FURTHER INFORMATION

What Phorpain® Gel Maximum Strength contains:

The active substance is Ibuprofen. Other ingredients are hydroxyethylcellulose, sodium hydroxide, benzyl alcohol, isopropyl alcohol, purified water.

What Phorpain® Gel Maximum Strength looks like and contents of the pack:

Phorpain® Gel Maximum Strength is supplied in aluminium tubes containing 100g gel.

Marketing Authorisation Holder

Goldshield Group Limited trading as Goldshield Pharmaceuticals,
NLA Tower, 12 – 16 Addiscombe Road,
Croydon, Surrey CR0 0XT, UK.

Manufacturer:

Goldshield Pharmaceuticals Limited,
NLA Tower, 12 – 16 Addiscombe Road,
Croydon, Surrey CR0 0XT, UK.

Alternate Manufacturer:

Farmasierra Manufacturing S.L.
Carretera De Irun KM 26,200 28700,
SAN Sebastian De Los Reyes, Madrid, Spain.

This leaflet was last revised in July 2010.

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piriton® allergy tablets

Chlorphenamine Maleate

Please read right through this leaflet before you start using this medicine.
This medicine is available without prescription, but you still need to use Piriton Allergy Tablets carefully to get the best results from them.
- Keep this leaflet, you may need to read it again.
- If you have any questions, or if there is anything you do not understand, ask your pharmacist.

In this leaflet:

1. What Piriton Allergy Tablets do

Piriton Allergy Tablets are used to treat the allergic symptoms of hayfever and other allergies.
The active ingredient is chlorphenamine maleate, an antihistamine which can help to relieve the symptoms of some allergies and itchy skin rashes. It can be used to treat the itchiness, redness, swelling, tenderness and irritation that can be caused by:
- hayfever and other allergies e.g. pet, house dust mite and mould spore allergies
- nettle rash and hives
- skin allergies and dermatitis
- prickly heat and heat rash
- reactions to food, food additives or medicines
- insect bites and stings
- the itchy rash of chickenpox.

2. Check before you take Piriton Allergy Tablets

Do not take Piriton Allergy Tablets:

- **if you have ever had an allergic reaction** to antihistamines or to any of the other ingredients (listed in Section 6)
- if you have taken **monoamine oxidase inhibitors** (MAOIs) prescribed for **depression** in the **last two weeks**
- if you are **under 6 years.**

Take special care with Piriton Allergy Tablets

- Talk to your doctor before you take these tablets if you have **very high blood pressure, epilepsy, overactive thyroid, glaucoma, enlarged prostate, heart** or **liver disease, bronchitis, asthma** or other **similar respiratory problems.**
- **Be careful when drinking alcohol** while using Piriton Allergy Tablets. They can increase the effects of drinking.
- **Do not drive or operate machinery** if the tablets make you feel drowsy.
- If you have been told by your doctor that you have an **intolerance to some sugars,** contact your doctor before using Piriton Allergy Tablets.

If you are taking other medicines

Talk to your doctor or pharmacist before using this medicine if you are taking any prescribed medicines; particularly **phenytoin** (for **epilepsy**) or medicines for **anxiety** or to **help you sleep.**

Pregnancy and breast feeding

Talk to your doctor before taking Piriton Allergy Tablets if you are **pregnant** or **breast feeding.**

3. How to take Piriton Allergy Tablets

Adults and children aged 12 years and over:
Swallow one tablet every 4 to 6 hours as needed.
Do not take more than 6 tablets in 24 hours.

Children aged 6 to 12 years:
Give ½ tablet every 4 to 6 hours as needed.
Do not give more than 6 half tablets in 24 hours.

- **Do not take more than the recommended dose.**

If you take too many tablets

Contact your doctor or casualty department. Do not drive if you have taken too many tablets.

If you forget to take the tablets

Take one as soon as you remember, unless it is nearly time to take the next one. Never take two doses together.

If your symptoms persist, **see your doctor.**

4. Possible side effects

Like all medicines, Piriton Allergy Tablets can have side effects, but not everybody gets them. Children and older people are more prone to side effects.

- The most common side effect is drowsiness. This drowsiness can be helpful if symptoms are particularly troublesome at night.

The following side effects may occur:
- Difficulty concentrating, feeling tired, dizziness or blurred vision.
- Loss of appetite, indigestion or upset stomach, feeling or being sick, diarrhoea or tummy pain.
- Liver inflammation (which may make you feel weak, sick and turn yellow).
- Headache.
- Dry mouth or difficulty passing water.
- Palpitations (feeling your heart beat), fast or irregular heart beat, or low blood pressure (you may feel faint).
- Chest tightness or thickening of the phlegm.
- Blood disorders such as anaemia.
- Allergic reactions including itchy rash, skin peeling and sensitivity to the sun.
- Twitching, muscular weakness and un-coordination.
- Ringing in the ears.
- Depression (low mood), irritability or nightmares.
- Children may become excited and older people may become very confused.

If you do get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

5. How to store Piriton Allergy Tablets

Keep out of the reach and sight of children.
Do not use this medicine after the 'Use by end of' date shown on the pack.
Store below 30°C.

6. Further information

Active ingredient Each tablet contains Chlorphenamine Maleate 4 mg.
Other ingredients Lactose, maize starch, yellow iron oxide (E 172), magnesium stearate and water.

Packs of Piriton Allergy Tablets contain 30 or 60 tablets.

The marketing authorisation holder is GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K. and all enquiries should be sent to this address.

The manufacturer is Haupt Pharma Wülfing GmbH, Bethelner Landstrasse 18, D-31028 Gronau/Leine, Germany.

This leaflet was last revised in May 2010.
Piriton and the trigger device are registered trade marks of the GlaxoSmithKline group of companies.

GlaxoSmithKline

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PREDNISOLONE 1 mg AND 5 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

PREDNISOLONE LEAFLET – HEADLINES

- **Prednisolone is a steroid medicine,** prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor - you may need to reduce the dose gradually.
- **Prednisolone can cause side effects in some people** (read section 4 below). Some problems such as mood changes (feeling depressed, or 'high'), or stomach problems can happen straight away. If you feel unwell in any way, keep taking your tablets, but **see your doctor straight away.**
- **Some side effects only happen after weeks or months.** These include weakness of arms and legs, or developing a rounder face (read section 4 for more information).
- **If you take it for more than 3 weeks, you will get a blue 'steroid card':** always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chicken-pox or shingles,** if you have never had them. They could affect you severely. If you do come into contact with chicken pox or shingles, **see your doctor straight away.**

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you. This leaflet was last updated in July 2010

IN THIS LEAFLET:

1 WHAT PREDNISOLONE IS AND WHAT IT IS USED FOR

Prednisolone – benefit information.

Prednisolone belongs to a group of medicines called steroids. Their full name is *corticosteroids*. These corticosteroids occur naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroid (such as Prednisolone) is an effective way to treat various illnesses involving inflammation in

Prednisolone tablets are used in a wide range of inflammatory and auto-immune conditions including:
- allergies, including severe allergic reactions
- inflammation affecting the: lungs, including asthma, blood vessels and heart, bowel or kidneys, muscles and joints, including rheumatoid, arthritis, eye and nervous system
- skin conditions
- some infections
- some cancers, including leukaemia, lymphoma and myeloma
- to prevent organ rejection after a transplant

Also:
- to make up the difference when the body's production of cortisone is too low to maintain good health.
- to treat high calcium levels.

2 BEFORE YOU TAKE PREDNISOLONE

DO NOT take Prednisolone and talk to your doctor if you:
- are allergic (hypersensitive) to prednisolone or any of the other ingredients of this medicine
- have an infection unless it is being treated with a specific antibiotic
- are suffering from herpes infection of the eye.

Take special care with Prednisolone

Check with your doctor first:
- **If you have ever had severe depression** or manic-depression (bipolar disorder). This includes having had depression before while taking steroid medicines like Prednisolone
- **If any of your close family** has had these illnesses.

If either of these applies to you, **talk to a doctor before taking Prednisolone.**

Talk to your doctor before you start to take this medicine if you:
- have osteoporosis (weakened bones), particularly if you are past the menopause (the change of life), or have you suffered from muscle weakness during previous treatment with corticosteroids
- have stomach ulcers
- have heart, liver or kidney problems, or have high blood pressure
- have ever suffered from tuberculosis
- suffer from diabetes, or if anyone in your family suffer from diabetes
- have glaucoma (abnormally high pressure in the eyes), or if any of your family suffer from glaucoma
- are epileptic
- have ever had any psychiatric problems, or there is a family history of such problems
- are receiving treatment for a condition called myasthenia gravis (a rare muscle weakness disorder)
- have ever had blood clots (for example deep vein thrombosis (DVT), or, thromboembolism)
- are elderly and have low potassium levels in your blood or are susceptible to infections or thinning of the skin
- have had a recent immunisation or vaccination
- have never had measles, chickenpox or shingles
- have Cushing's disease (a hormone disorder which can cause symptoms including gaining weight very quickly, especially on the trunk and face, thinning
- abnormal feeling of well being, feeling of dependency on treatment
- depression, difficulty sleeping
- dizziness
- worsening of schizophrenia
- pressure on the nerve to the eye (sometimes in children after stopping treatment)
- abnormally high pressure in the eye (glaucoma), swelling of the optic disc
- whitening or clouding of the lens (cataracts), thinning of the eye tissue (sclera and cornea)
- worsening of viral and fungal eye infections
- worsening of epilepsy
- fatigue and general feeling of being unwell.

Withdrawal Symptoms: anorexia, nausea, vomiting, lethargy, headache, fever, joint pain, peeling of skin, muscle pain, inflammation of nose, conjunctivitis, painful itchy skin nodules, loss of weight and/or hypotension.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 HOW TO STORE PREDNISOLONE

Keep out of the reach and sight of children.
Do not store above 25°C. Store in the original package. Do not transfer them to another container.
Do not use Prednisolone after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION

What Prednisolone tablets contain:
- The active ingredient is prednisolone 1 mg or 5 mg.
- The other ingredients are lactose monohydrate, dextrin, maize starch and stearic acid (E570).

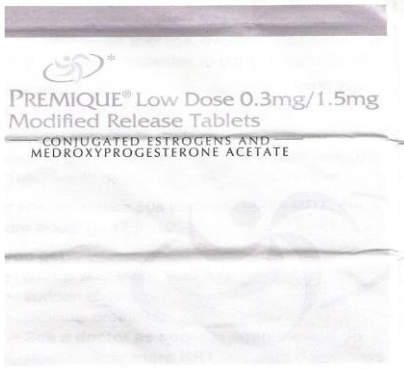
What Prednisolone tablets looks like and contents of the pack:
- Prednisolone 1 mg are white biconvex tablets, marked 'APS' on one side and '1/2401' on the reverse; or marked 'APS 2401' on one side and plain on the reverse.
- Prednisolone 5 mg are white biconvex tablets, marked 'APS' on one side and '5/2402' on the reverse; or marked 'APS' breakline '2402' on one side and plain on the reverse.

- The 1 mg tablets are available in packs of 28, 56, 60, 84, 90, 100, and 500.
- The 5 mg tablets are available in packs of 28, 30, 500, 1000 and 10 x 50
  Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation holder and company responsible for manufacture:
TEVA UK Limited, Eastbourne, BN22 9AG.

This leaflet was last revised: July 2010

PACKAGE LEAFLET:
INFORMATION FOR THE USER



Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT PREMIQUE LOW DOSE IS AND WHAT IT IS USED FOR

Premique Low Dose is one of a group of medicines known as Hormone Replacement Therapy (HRT). It is used to treat some of the symptoms and conditions associated with the menopause. Premique Low Dose 0.3mg/1.5mg Modified Release Tablets is a period-free HRT (an HRT product where you do not have a monthly bleed). Your periods will stop once menopause is reached.

This change is due to lowered levels of the hormones estrogen and progesterone. You may experience a number of unpleasant symptoms, including hot flushes, night sweats and vaginal dryness, around the time of menopause. Premique Low Dose can relieve some of these symptoms by replacing some of the lost estrogen.

2. BEFORE YOU TAKE PREMIQUE LOW DOSE

2.1 Do not take Premique Low Dose if:

- you have or have had breast cancer
- you have endometrial cancer (cancer of the lining of the womb) or have been told you have another type of estrogen-dependent cancer
- you have been told you have a blood circulation disorder or have had a blood clot
- you have a heart condition such as angina or have had a heart attack
- you are allergic to any of the ingredients in Premique Low Dose; the ingredients are listed in Section 6 of this leaflet
- you have porphyria (a rare inherited metabolic disorder)
- you have recently had unexpected or very heavy vaginal bleeding
- you have been told that you have endometrial hyperplasia (abnormal growth of the lining of the womb)
- you have or have previously had liver disease
- you are pregnant, or you are breast-feeding.

Before you start taking HRT, your doctor should ask about your own and your family's medical history. Your doctor may decide to examine your breasts and/or your abdomen, and may do an internal examination — but only if these examinations are necessary for you, or if you have any special concerns.

Once you've started on HRT, you should see your doctor for regular check-ups (at least once a year). At these check-ups, your doctor may discuss with you the benefits and risks of continuing to take HRT.

You are advised to:

- go for regular breast screening and cervical smear tests
- regularly check your breasts for any changes such as dimpling of the skin, changes in the nipple, or any lumps you can see or feel.

- headache, migraine
- blood clots in the veins
- dizziness
- changes in mood including anxiety
- changes in your interest in sex (increased or decreased libido)
- visible swelling of the face or ankles
- itchiness, acne
- difficulty wearing contact lenses
- gallbladder disease (e.g. gallstones)
- hair loss

Rare (affect less than 1 in 1000 women)

- vomiting
- changes in breast tissue, milky secretion from the breasts
- irritability
- allergic reactions including swelling, rash or red patches on the skin
- increase in hair growth
- an intolerance to glucose
- a worsening of asthma
- increased size of fibroids
- ovarian cancer
- worsening of epilepsy
- heart attack, stroke
- inflammation of veins just under the skin
- inflammation of the pancreas
- irregular dark spots (usually on the face)

Very rare (affect less than 1 in 10000 women)

- jaundice (e.g. yellowing of the skin)
- a worsening of chorea (an existing neurological disorder characterised by involuntary spasmodic movements of the body)
- a worsening of hypocalcaemia (low blood levels of calcium)
- blurred vision or loss of vision
- worsening of porphyria (a rare inherited metabolic disorder)
- growth of benign liver tumours

These side effects are usually temporary and should get better over time.

Other side effects that may occur while taking an estrogen-progesterone combined HRT are:

- memory loss (dementia)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PREMIQUE LOW DOSE

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date stated on the carton and blister. This date refers to the last day of the month.

Do not store above 25°C. Keep the blister in the outer carton to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measurements will help to protect the environment.

6. FURTHER INFORMATION

6.1 What Premique Low Dose contains

The active substances are conjugated estrogens (an estrogen) and medroxyprogesterone acetate (a progestogen).

Each tablet contains 0.3mg of conjugated estrogens and 1.5mg of medroxyprogesterone acetate (MPA). The tablets are cream coloured and marked with "W 0.3/1.5" in black ink.

The other ingredients in your tablets are lactose monohydrate, methylcellulose, magnesium stearate, calcium phosphate, macrogol, glyceryl mono-oleates, shellac, calcium sulphate, microcrystalline cellulose, sucrose, titanium dioxide (E171), povidone, carnauba wax, yellow ferric oxide (E172) and edible ink that contains shellac, propylene glycol, black iron oxide (E172) and potassium hydroxide.

The inks and dyes used to coat your tablets are approved for use as food colourings.

6.2 What Premique Low Dose looks like and contents of the pack

Your Premique Low Dose carton contains either one or three blister packs, each containing 28 tablets.

Not all pack sizes may be marketed.

The marketing authorisation holder is John Wyeth & Brother Ltd, trading as Wyeth Pharmaceuticals, Huntercombe Lane South, Taplow, Maidenhead, Berkshire SL6 0PH.

The manufacturer is Wyeth Medica Ireland, Little Connell, Newbridge, County Kildare, Republic of Ireland.

This leaflet applies to Premique Low Dose tablets only.

This leaflet was last approved in 04/2010.

*Trade mark

Wyeth®

PROPRANOLOL 10 mg, 40 mg, 80 mg AND 160 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

1 WHAT PROPRANOLOL IS AND WHAT IT IS USED FOR

- Propranolol is a type of drug called a beta-blocker.
- Propranolol is used for:
  - high blood pressure
  - angina pectoris (chest pain)
  - long term prevention of further heart attacks, if you have already had one
  - heart rhythm problems or a racing heartbeat
  - anxiety
  - migraine (as a preventative treatment)
  - involuntary muscle movements
  - an over-active thyroid gland.

2 BEFORE YOU TAKE PROPRANOLOL

DO NOT take Propranolol if you:
- are allergic (hypersensitive) to propranolol hydrochloride or any of the other ingredients of this medicine
- have a history of wheezing or asthma
- suffer from poor circulation
- suffer from Prinzmetal's angina (angina due to coronary artery spasm)
- have a slow heart rate
- suffer from other heart problems such as heart failure, cardiogenic shock, heart block or sick sinus syndrome
- suffer from uncontrolled heart failure
- have low blood pressure
- have an adrenal tumour (phaeochromocytoma) resulting in high blood pressure, flushing, and diarrhoea
- suffer from metabolic acidosis (an imbalance of the body's acid-base balance)
- undertake or have recently undertaken prolonged periods of fasting.

Take special care with Propranolol
Tell your doctor before you start to take this medicine if you:
- suffer from liver or kidney problems
- are undergoing treatment for diabetes
- have thyroid problems.

If you are to have surgery, propranolol should be withdrawn 24 hours before as it may interfere with response to stress.
Propranolol may increase reactions to a number of allergens.

Taking other medicines
Talk to your doctor if you are taking any of the following:
- sympathomimetic drugs such as adrenaline
- ergotamine (for migraine)
- prostaglandin synthetase inhibitors used to treat inflammatory conditions
- other drugs for other heart conditions such
- calcium channel blockers e.g. nifedipine, nisoldipine, nicardipine, isradipine or lacidipine
- drugs used to treat diabetes including insulin.

You should warn your doctor or dentist that you are using Propranolol if you are going to receive an anaesthetic. Some anaesthetics (e.g. ether, trichloroethylene) should not be used with Propranolol. Propranolol may also increase the effects of lidocaine.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Important information about some of the ingredients of Propranolol
- Patients who are intolerant to **lactose** should note that Propranolol tablets contain a small amount of lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Taking Propranolol with food and drink
- DO NOT take alcohol whilst taking these tablets, as it may interfere with the action of Propranolol.

Pregnancy and breast-feeding
- Propranolol is not recommended if you are pregnant, planning to become pregnant or are breast-feeding.
  Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
- Propranolol may cause drowsiness and dizziness. If affected, DO NOT drive or operate machinery.

3 HOW TO TAKE PROPRANOLOL

Always take Propranolol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed preferably with a glass of water. Propranolol can be taken with or without food. The usual dose is:

Adults including the Elderly
- **High Blood Pressure:**
  80 mg twice daily. This may subsequently be increased by your doctor to a maintenance dose of between 160 – 320 mg daily.
- **Angina Pectoris:**
  40 mg two or three times daily. This may then be adjusted by your doctor to a usual maintenance dose of between 120 – 240 mg per day.
- **Long term prevention of further Heart Attack:**
  Treatment should begin 5 – 21 days after the initial heart attack with 40 mg taken four times daily for two or three days.
  The dose should then be increased to 80 mg taken twice daily. In some cases, your doctor may adjust this dose according to your response to treatment.
- **Heart Rhythm Problems: Overactive Thyroid Gland:**
  The dose for adults is 10 – 40 mg three or four times daily.
- **Anxiety:**
  - 40 mg daily, for immediate relief of acute situational anxiety (fear triggered by a specific situation such as being in or on public transportation, tunnels, bridges, lifts, planes, cars, or enclosed spaces)
  - 40 mg two or three times per day, for longer term treatment of generalised anxiety disorder (also known as GAD, a condition characterised by persistent and excessive anxiety and worry that lasts for at least six months). Your doctor will review your dosage after 6 to 12 months.
- **Prevention of Migraine:**
  The dose for adults is 40 mg two or three times daily. This may then be increased by your doctor to between 80 – 160 mg per
- **Heart Rhythm Problems; Overactive Thyroid Gland**
  Your doctor will calculate the appropriate dose for your child based on the child's body weight. The dose should be taken three or four times daily.
- **Prevention of migraine**
  For children under 12 years old, 20 mg two or three times daily.
  Older children may be given the adult dose.

Patients with kidney problems
A reduced starting dose may be given.

If you take more Propranolol than you should
If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause low blood pressure, breathlessness, confusion, low blood sugar levels, slow pulse rate and heartbeat, unconsciousness. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Propranolol
If you forget to take a tablet, take one as soon as you remember, unless it is time to take the next one. DO NOT take a double dose to make up for a forgotten tablet dose.

If you stop taking Propranolol
DO NOT stop taking your medicine without talking to your doctor first, even if you feel better.
Your treatment with Propranolol must not be stopped suddenly. If it is necessary to stop treatment, your doctor should reduce your dose gradually.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 POSSIBLE SIDE EFFECTS

Like all medicines, Propranolol can cause side effects, although not everybody gets them.

Stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital, if the following happens:
- an allergic reaction causing swelling of the lips, face or neck leading to severe difficulty in breathing or severe skin rash or hives.

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor if you experience any of the following side effects:
- heart problems such as a very slow heart rate, heart failure getting worse (symptoms may include feeling breathless or swollen ankles) or heart block (symptoms may include slow or irregular heartbeat, shortness of breath, dizziness and fainting, pain or discomfort in your chest)
- low blood pressure, which may make you feel dizzy or light headed on standing
- breathlessness or wheezing (sometimes with a fatal outcome in patients with a history of asthma or hay fever)
- blood disorders (symptoms may include paleness of skin, fever, unusual bleeding or unexplained bruising)
- pain in the calf muscles, muscle weakness
- low levels of sugar in the blood (hypoglycaemia) may occur in children (symptoms may include weakness, headache, feeling hungry, double vision, and mood changes, aggressive or abnormal behaviour)
- being unable to distinguish between reality and your imagination, hallucinations (hearing, or seeing, things that are not there), or delusions (believing things that are untrue)
- skin troubles such as rashes or itching
- dry eyes.

Not all of these effects are serious, but your doctor may decide to stop your treatment with Propranolol.

The following side effects have also been
- confusion, mood changes
- pins-and-needles
- nightmares
- poor circulation, which makes the fingers and toes pale, cold and numb
- worsening of existing psoriasis (patches of thickened and sore skin)
- hair loss.

The following are minor side effects. If you get these, and they last for longer than a few days, tell your doctor:
- feeling or being sick, diarrhoea
- tiredness, and/or difficulty in sleeping.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 HOW TO STORE PROPRANOLOL

Keep out of the reach and sight of children.
Store in a dry place. Protect from light. Do not store above 25°C.
Do not use Propranolol after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION

What Propranolol tablets contain:
- The active ingredient is 10, 40, 80 or 160 mg of propranolol hydrochloride.
- The other ingredients are maize starch, lactose monohydrate, soluble starch, sodium starch glycolate, colloidal silicon dioxide (E551) and magnesium stearate (E572).
- The coating contains hypromellose (E464), macrogol, erythrosine (E127), brilliant blue (E133), titanium dioxide (E171) and iron oxide (E172).
- The tablets are polished with carnauba wax.

What Propranolol tablets look like and contents of the pack:
- Propranolol tablets are dark pink, biconvex, film coated tablets, engraved on one side with a breakline on the reverse. The engraving marks for each tablets strength are:
  10 mg: Berk 1Z1 or 1Z1
  40 mg: Berk 2Z1 or 2Z1
  80 mg: Berk 3Z1 or 3Z1
  160 mg: Berk 4Z1 or 4Z1
- All strengths are available in pack sizes of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160 and 168 tablets.
- Other pack sizes are available for each strength as follows:
  10 mg: 50, 500, 1000 and 40000 tablets
  40 mg: 50, 500, 1000 and 20000 tablets
  80 mg: 500 and 1000 tablets
  160 mg: 8000 tablets.

  Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN22 9AG.

This leaflet was last revised: September 2010

PL 00289/0168-0171

PIL211

PACKAGE LEAFLET: INFORMATION FOR USER

Ramipril 1.25mg Capsules/ Ramipril 2.5mg Capsules/ Ramipril 5mg Capsules/ Ramipril 10mg Capsules
Active Substance: Ramipril

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions or are unsure please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Ramipril Capsules are and what they are used for

Ramipril Capsules contain the active ingredient Ramipril. Ramipril belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors, which act on heart and blood vessels.

It works by:
- Decreasing your body's production of substances that could raise your blood pressure
- Making your blood vessels relax and widen
- Making it easier for your heart to pump blood around your body.

Ramipril Capsules can be used:
- To treat high blood pressure (hypertension)
- To reduce the risk of you having a heart attack or stroke
- To reduce the risk or delay the worsening of kidney problems (whether or not you have diabetes)
- To treat your heart when it cannot pump enough blood to the rest of your body (heart failure)
- As treatment following heart attack (myocardial infarction) complicated with heart failure.

2. Before you take Ramipril Capsules

Do not take Ramipril Capsules if you:
- are allergic (hypersensitive) to ramipril, or other ACE inhibitor medicine or any of the other ingredients of ramipril (see section 6). Signs of an allergic reaction may include rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- have ever had a serious allergic reaction called "angioedema". The signs include itching, hives (urticaria), red marks on the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing
- are having dialysis or any other type of blood filtration. Depending on the machine/ membrane that is used, Ramipril may not be suitable for you.
- have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis)
- if your blood pressure is abnormally low or unstable, your doctor will need to make this assessment.
- are in the last **6 months of pregnancy** (see section below on "Pregnancy and breastfeeding")

Do not take Ramipril Capsules if any of the above apply to you. If you are not sure, talk to your doctor before taking Ramipril Capsules.

Take special care with this medicine:
Check with your doctor or pharmacist before taking your medicine:
- If you have heart, liver or kidney problems
- If you have lost a lot of body salts or fluids (through being sick (vomiting), having diarrhoea, sweating more than usual, being on a low salt diet, taking diuretics (water tablets) for a long time or having had dialysis)
- If you are going to have treatment to reduce your allergy to bee or wasp stings (desensitization)
- If you are going to receive an anesthestic. This may be given for an operation or any dental work. You may need to stop your Ramipril Capsules treatment one day beforehand; ask your doctor for advice
- If you have high amounts of potassium in your blood (shown in blood test results)
- If you have a collagen vascular disease such as scleroderma or systemic lupus erythematosus.
- You must tell your doctor if you think that you are (or might become) pregnant. Ramipril Capsules is not recommended in the first 3 months of pregnancy and may cause serious harm to your baby after 3 months of pregnancy, see section "Pregnancy and breast-feeding".

Children
Ramipril Capsules is not recommended for use in children and adolescents below 18 years of age because there is no information available in this population.
If any of the above apply to you (or you are not sure), talk to your doctor before taking Ramipril Capsules.

Ask your doctor or pharmacist if you have any doubt.

Taking Ramipril Capsules with other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any o medicines, including medicines obtained without a prescripon (including he medicines). This is because Ramipril Capsules can affect the way some o medicines work. Also some medicines can affect the way Ramipril Capsules wo Please tell your doctor if you are taking any of the following medicines. They can n Ramipril Capsules work less well:
- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflamm Drugs (NSAIDs) such as ibuprofen or indometacin and aspirin)
- Medicines used for the treatment of low blood pressure, shock, cardiac failure asthma or allergies such as ephedrine, noradrenaline or adrnaline.

Your doctor will need to check your blood pressure.
Please tell your doctor if you are taking any of the following medicines. They increase the chance of getting side effects if you take them wit Ramipril Capsu
- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflamm Drugs (NSAIDs) such as ibuprofen or indometacin and aspirin)
- Medicines for cancer (chemotherapy)
- Medicines to stop the rejection of organs after a transplant such as ciclosporir
- Diuretics (water tablets) such as furosemide
- Medicines which can increase the amount of potassium in your blood such a spironolactone, triamterene, amiloride, potassium salts and heparin (for thinnir blood)
- Steroid medicines for inflammation such as prednisolone
- Allopurinol (used to lower the uric acid in your blood)
- Procainamide (for heart rhythm problems).

Please tell your doctor if you are taking any of the following medicines. They ma affected by Ramipril Capsules:
- Medicines for diabetes such as oral glucose lowering medicines and insulin. Ra Capsules may lower your blood sugar amounts. Check your blood sugar amo closely while taking Ramipril Capsules
- Lithium (for mental health problems). Ramipril Capsules may increase the am of lithium in your blood. Your lithium amount will need to be closely checked by doctor.

If any of the above apply to you (or you are not sure), talk to your doctor before t Ramipril Capsules.

Pregnancy and breast feeding
You must tell your doctor if you think that you are (or might become) pregnant. You should not take Ramipril Capsules in the first 12 weeks of pregnancy, and must not take them at all after the 13th week as their use during pregnancy possibly be harmful to the baby.
If you become pregnant while on Ramipril Capsules, tell your doctor immediate switch to a suitable alternative treatment should be carried out in advance of a pla pregnancy.
You should not take Ramipril Capsules if you are breastfeeding.
Ask your doctor or pharmacist for advice before taking any medicine.

ll your doctor immediately if you experience:
Faster heart rate, uneven or forceful heartbeat (palpitations), chest pain, tightness in your chest or me serious problems including heart attack and stroke
Shortness of breath or a cough. These could be signs of lung problems
Bruising more easil bleeding for longer than normal, any sign of bleeding (e.g. bleeding from the gms), purple spots, blotching on the skin or getting infections more easily than usal, sore throat and fever, feeling tired, faint, dizzy or having pale skin. These can be signs of blood or bone marrow problems
Severe stomach pn which may reach through to your back. This could be a sign of pancreatitis inflammation of the pancreas).
Fever, chills, tiredness, loss of appetite, stomach pain, feeling sick, yellowing of your skin or eyes (aundice). These can be signs of liver problems such as hepatitis (inflammtion of the liver) or liver damage.

ther side effects nclude:
ease tell your doctr if any of the following gets serious or lasts longer than a few ays.

ommon (affects les than 1 in 10 people):
Headache or feeling tired
Feeling dizzy. Thi is more likely to happen when you start taking Ramipril Capsules or start aking a higher dose
Fainting, hypotension (abnormally low blood pressure), especially when you stand or sit up quickly
Dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis, shortness of breath
Stomach or gut pain, diarrhoea, indigestion, feeling or being sick
Skin rash with or without raised area
Chest pain
Cramps or pain in your muscles
Blood tests showing more potassium than usual in your blood.

ıcommon (affects less than 1 in 100 people):
Balance problems (vertigo)
Itching and unusual skin sensations such as numbness, tingling, pricking, burning or creeping on your skin (paraesthesia)
Loss or change in the way things taste
Sleep problems
Feeling depressed, anxious, more nervous than usual or restless
Blocked nose, difficulty breathing or worsening of asthma
A swelling in your gut called "intestinal angioedema" presenting with symptoms like abdominal pain, vomiting and diarrhoea
Heartburn, constipation or dry mouth
Passing more water (urine) than usual over the day
Sweating more than usual
Loss or decrease of appetite (anorexia)
Increased or irregular heart beats
Swollen arms and legs. This may be a sign of your body holding onto more water than usual
- Flushing
- Blurred vision
- Pain in your joints
- Fever
- Sexual inability in men, reduced sexual desire in men or women
- An increased number of certain white blood cells (eosinophilia) found during a blood test
- Blood tests showing changes in the way your liver, pancreas or kidneys are working.

Rare (affects less than 1 in 1,000 people)
- Feeling shaky or confused
- Red and swollen tongue
- Severe flaking or peeling skin, itchy, lumpy rash
- Nail problems (e.g. loosening or separation of a nail from its bed)
- Skin rash or bruising
- Blotches on your skin and cold extremities
- Red, itchy, swollen or watery eyes
- Disturbed hearing or ringing in your ears
- Feeling weak
- Blood tests showing a decrease in the number of red blood cells, white blood cells or platelets or in the amount of haemoglobin.

Very rare (affects less than 1 in 10,000 people)
- Being more sensitive to the sun than usual.

Other side effects reported:
Please tell your doctor if any of the following gets serious or lasts longer than a few days.
- Difficulty concentrating
- Swollen mouth
- Blood tests showing too few blood cells in your blood
- Blood tests showing less sodium than usual in your blood
- Fingers and toes changing colour when you are cold and then tingling or feeling painful when you warm up (Raynaud's phenomenon)
- Breast enlargement in men
- Slowed or impaired reactions
- Burning sensation
- Change in the way things smell
- Hair loss.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to Store Ramipril Capsule

- Keep out of the reach and sight of children.
- Do not use the capsules after the expiry date shown on the carton.
- Do not store above 25°C. Store in the original blister pack.

6. Further Information

What Ramipril Capsules contain
- The active substance in Ramipril Capsules is Ramipril.
- The other ingredient of the powder in Ramipril capsules is pregelatinised maize starch.
- The capsule shell for all strengths of Ramipril capsules contains gelatin, titanium dioxide (E171), sodium laurilsulfate, methyl parahydroxy benzoate and propyl parahydroxy benzoate
- In addition the capsule shell for
- Ramipril 1.25mg capsules contains the colours yellow ferric oxide (E172)
- Ramipril 2.5mg capsules contains colours sunset yellow (E110), ponceau 4R (E124) and carmoisine (E122)
- Ramipril 5mg capsules contains colours ponceau 4R (E124), brilliant blue (E13 and carmoisine (E122)
- Ramipril 10mg capsules contains colours brilliant blue (E133), erythrosine (E12 and carmoisine (E122)

What Ramipril capsules look like and content of the pack
Ramipril 1.25mg Capsules are yellow and white capsules.
Ramipril 2.5mg Capsules are orange and white capsules.
Ramipril 5mg Capsules are maroon and white capsules.
Ramipril 10mg Capsules are blue and white capsules.
Ramipril Capsules are available in packs containing 28 capsules.
In Poland this product is marketed as
- RAMVE 1.25mg
- RAMVE 2.5mg
- RAMVE 5mg
- RAMVE 10mg

Marketing Authorization Holder and Manufacturer:
Bristol Laboratories Limited,
Unit 3, Canalside, Northbridge Road,
Berkhamsted, Herts, HP4 1EG, United Kingdom

Date of last revision: September 2010

PIL211

Patient Information Leaflet

SIMVASTATIN 10mg TABLETS
SIMVASTATIN 20mg TABLETS
SIMVASTATIN 40mg TABLETS

Read all of the leaflet carefully before you start taking this medicine.
- *Keep this leaflet. You may need to read it again.*
- *If you have further questions, please ask your doctor pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours*
- *If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

In this leaflet:

1. What Simvastatin Tablets are and what they are used for

The name of your medicine is Simvastatin 10mg Tablets or Simvastatin 20mg Tablets or Simvastatin 40mg Tablets, but will be referred to as Simvastatin Tablets or simvastatin throughout this leaflet.
Simvastatin Tablets contain Simvastatin, which belongs to the group of medicines called HMG-CoA reductase inhibitors (a type of lipid-lowering medicine commonly known as "statins"). They work by lowering lipids (fats) such as cholesterol and triglycerides in your blood. In addition, Simvastatin raises levels of "good" cholesterol (HDL cholesterol). You should stay on a cholesterol-lowering diet while taking this medicine
Simvastatin Tablets are used along with diet if you have:
- a raised cholesterol level in your blood (primary hypercholesterolaemia) or elevated fat levels in your blood (mixed hyperlipidaemia)
- a hereditary illness (homozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood. You may also receive other treatments.
- coronary heart disease (CHD) or are at high risk of CHD (because you have sugar diabetes, history of stroke, or other blood vessel disease). Simvastatin Tablet may prolong your life by reducing the risk of heart disease problems, regardless of the amount of cholesterol in your blood.

In most people, there are no immediate symptoms of high cholesterol. Your doctor can measure your cholesterol with a simple blood test. Visit your doctor regularly, keep track of your cholesterol, and discuss your goals with your doctor.

2. Before you take Simvastatin Tablets

Do not take Simvastatin Tablets if you are
- allergic to simvastatin or any other ingredients of Simvastatin Tablets listed in section 6.
  (An allergic reaction may include rash, itching, swelling of face, lips, or hands/feet, or breathing difficulties)
- pregnant or intend to become pregnant
- breast feeding
- currently having liver problems
- taking the following medicines:
  - itraconazole, ketoconazole, fluconazole, posaconazole (medicines for fungal infections)
  - protease inhibitors such as nelfinavir, indinavir, ritonavir, saquinavir (medicines for treatment of HIV infection)
  - Erythromycin, clarithromycin, telithromycin (antibiotics for treatment of infections)
  - Nefazodone (medicine for treating depression)

If you think any of these apply to you, do not take the tablets, talk to your doctor and follow the advice given.

Take special care with Simvastatin tablet
Tell your doctor if you
- have ever had or develop liver disease. Simvastatin Tablet may not be right for you.
- your doctor would do a blood test before you start taking Simvastatin tablet. This is to check how well your liver is working.
- are due to have an operation. You may need to stop taking Simvastatin Tablet for a short time.
- have severe lung disease.

Your doctor may also want you to have blood tests to check how well your liver is working after you start taking Simvastatin Tablet.
Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness.
This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.
Your doctor will decide to stop or continue the treatment

The risk of muscle breakdown is increased at higher doses of Simvastatin Tablet and is greater in certain patients.
Talk to your doctor if any of the following applies:
- You have problems with your kidney(s)
- You have an underactive thyroid gland (hypothyroidism)
- You are an elderly person (65 years of age or older)
- You have ever had muscle problems during treatment with cholesterol lowering medicines called "statins" (such as simvastatin, atorvastatin, pravastatin) or fibrates (such as gemfibrozil, bezafibrate)
- You have a family history of muscle problems (hereditary muscle disorder)
- You are female
- You drink large amount of alcohol

Using other medicines
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription.
Taking Simvastatin tablet with any of these drugs can increase the risk of muscle problems.
- *ciclosporin (a medicine used in organ transplant patients)*
- *danazol (a man-made hormone used to treat endometriosis)*
- *itraconazole, ketoconazole, fluconazole, posaconazole (medicines for fungal infections)*
- *gemfibrozil and bezafibrate (medicines for lowering cholesterol)*
- *erythromycin, clarithromycin, telithromycin, or fusidic acid (medicines for bacterial infections)*
- *protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (medicines for AIDS)*
- *nefazodone (a medicine for depression)*
- *amiodarone (a medicine for an irregular heartbeat)*
- *verapamil, diltiazem or amlodipine (medicines for high blood pressure, chest pain associated with heart disease, or other heart conditions)*
- *colchicine (a medicine used to treat gout).*

In particular, tell your doctor if you are taking any of the following:
- *medicines to prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol (anticoagulants)*
- *fenofibrate (another medicine for lowering cholesterol)*
- *niacin (another medicine for lowering cholesterol)*
- *rifamapicin (a medicine used to treat tuberculosis).*

Also tell your doctor if you are taking niacin (nicotinic acid) or a niacin-containing product and are Chinese.

Taking Simvastatin tablet with food and drink
Grapefruit juice contains one or more components that alter how the body uses some medicinal products, including Simvastatin Tablet. Consuming grapefruit juice [illegible]

starting dose is 10, 20 or, in some cases, 40 mg a day. Your doctor may increase or decrease your daily dose at intervals of at least 4 weeks.
The maximum recommended daily dose should not exceed 80 mg. The 80 mg dose is only recommended for adult patients with very high cholesterol levels and at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.
For children (10-17 years old), the recommended usual starting dose is 10 mg a day in the evening.
The maximum recommended dose is 40 mg a day.
Your doctor will determine the appropriate tablet strength for you, depending on your condition, your current treatment and your personal risk status.
Your doctor may prescribe lower doses, particularly if you are taking certain medicinal products listed above or have severe kidney disease.
Simvastatin Tablets may be used alone or in combination with other lipid lowering medicines including bile acid sequestrants (e.g. cholestyramine, colestipol). If you are also taking these medicines, you should take Simvastatin Tablets at least 2 hours before or 4 hours after taking bile acid sequestrants.
Your daily dose should not exceed 10 mg per day if you are taking other lipid lowering medicines including fibrates (e.g. gemfibrozil except fenofibrate), niacin, medicines to depress your immune system (e.g. ciclosporin), or if you have serious kidney problems. Your daily dose should not exceed 20 mg per day if you are taking medicines for heart problems (e.g. verapamil, amiodarone). Your daily dose should not exceed 40 mg per day if you are taking medicines for high blood pressure, chest pain associated with heart disease, or other heart conditions (e.g. diltiazem, amlodipine).

If you have taken more Simvastatin Tablets than you should, consult your doctor or go to the nearest hospital casualty department immediately. Take this leaflet or some tablets with you so that your doctor will know what you have taken.
If you forget to take Simvastatin Tablets at the right time, take them as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for missed doses.
If you stop taking Simvastatin Tablets, Take your tablets as directed and for as long as directed; do not stop them, even if you feel better, since your cholesterol may rise again.

4. Possible Side Effects

Like all medicines, simvastatin Tablets can cause side effects although not everybody gets them.
The frequency (likelihood of occurring) of side effects is classified as follows:
Very common: Affects more than 1 user in 10
Common: Affects 1 to 10 users in 100
Uncommon: Affects 1 to 10 users in 1,000
Rare: Affects 1 to 10 users in 10,000
Very rare: Affects less than 1 user in 10,000
Not known (cannot be estimated from the available data)

The following side effects have been reported rarely
If any of the following happen, stop taking simvastatin and tell your doctor immediately or go to the casualty department at your nearest hospital:
- hypersensitivity (allergic) reactions including:
- swelling of the face, tongue and throat which may cause difficulty in breathing
- severe muscle pain usually in the shoulders and hips
- rash with weakness of limbs and neck muscles
- pain or inflammation of the joints
- inflammation of the blood vessels often with skin rash
- unusual bruising, skin eruptions and swelling, hives, skin sensitivity to the sun, fever, flushing
- shortness of breath and feeling unwell
- lupus-like disease picture (including rash, joint disorders, and effects on blood cells).

These are very serious side effects. If you have them you may have had a serious allergic reaction to simvastatin. You may need urgent medical attention or hospitalization.
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following rare serious side effects:
- Unexplained/ persistent muscle aches and weakness, or cramps, with or without passage of pink coloured urine. On rare occasions, muscle damage can be serious (see section 'Before you take Simvastatin Tablets')
- Unusual bleeding or increased tendency to bleed, persistent sore throat and frequent infections, and/or anaemia (tiredness, headaches, being short of breath when exercising, dizziness and looking pale)
- Sudden onset of severe abdominal pain with nausea and vomiting (pancreatitis)
- Yellowing of skin and whites of eyes with decreased appetite, abdominal pain, dark coloured urine or pale-coloured stool (hepatitis/jaundice), liver failure (very rare)

Inform your doctor if you notice any of the following
Rare effects
- Hair loss, rash, itching
- Headache, dizziness
- Weakness
- Nausea (feeling sick), vomiting (being sick), diarrhoea (loose stools) or constipation, indigestion, wind, abdominal pain
- Pins and needles, tingling and numbness in the hands/legs
- Increased sensitivity to sunlight

Very rare side effects
- Trouble sleeping (insomnia)
- Poor memory

Possible side effects reported with some statins (medicines of the same type as Simvastatin).
- Sleep disturbances, including trouble sleeping and nightmares
- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever.

There may also be changes in the results of certain laboratory tests. The following have been reported rarely
- Abnormal liver function tests
- Increased levels of muscle enzymes [Creatine Phosphokinase (CPK)] in blood
- Abnormal blood counts (increased ESR, increased eosinophils, decreased red blood cells)

Other side effects not listed above may also occur in some patients. If you notice any other effects, please inform your doctor or pharmacist.

5. Storing Simvastatin Tablets

Keep Simvastatin Tablets out of the reach and sight of children. Do not take after the expiry date on the labelling.
Do not store above 25°C. Store in the original package.

6. Further information

These tablets are available in strengths of 10 mg, 20 mg and 40 mg.
Simvastatin 10 mg tablets are peach coloured, film coated, oval shaped tablets. Each tablet contains 10 mg of simvastatin.
Simvastatin 20 mg tablets are tan coloured, film coated, oval shaped tablets. Each tablet contains 20 mg of simvastatin.
Simvastatin 40 mg tablets are brick-red coloured, film coated, oval shaped tablets. Each tablet contains 40 mg of simvastatin.
Simvastatin Tablets are available as blister strips of 6, 10, 12, 20, 28, 49, 84 and 98 tablets.
Not all pack sizes may be marketed.
The active substance is simvastatin.
Your tablets contain the following inactive ingredients: lactose monohydrate, pregelatinised maize starch, ascorbic acid (E300), citric acid monohydrate (E330), microcrystalline cellulose (E460 (i)), butylhydroxyanisole (E320), croscarmellose sodium, magnesium stearate (E572). The film coating materials contain hydroxypropylcellulose (E463), hypromellose 15cp (E464), titanium dioxide (E171), talc (E553(b)), iron oxide yellow (E172), iron oxide red (E172) and iron oxide black (E172).

Marketing Authorisation Holder:
Ranbaxy (UK) Limited, Building 4, Chiswick Park, 566 Chiswick High Road, London, W4 5YE, United Kingdom
Manufacturers:
Ranbaxy Ireland Ltd, Spafield, Cork Road, Cashel, Co Tipperary, Ireland
Terapia SA, Str. Fabricii nr. 124, Cluj-Napoca, Romania

This leaflet was last approved in July 2011.

PACKAGE LEAFLET: INFORMATION FOR THE USER

TEMAZEPAM 10 mg AND 20 mg TABLETS

(Temazepam)

Read all of this leaflet carefully before you start taking this medicine • Keep this leaflet. You may need to read it again • If you have further questions, ask your doctor or pharmacist • This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours • If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT TEMAZEPAM IS AND WHAT IT IS USED FOR

Temazepam belongs to a group of medicines called benzodiazepines or hypnotics. Benzodiazepines are used to make you feel less anxious, they can also be used to make you feel sleepy, relax your muscles and stop or prevent fits. Temazepam can be used for the following:

- difficulty sleeping (insomnia), when your lack of sleep is causing you a lot of distress
- given before minor surgery and other similar procedures (pre-medication) to make you feel more relaxed (or less anxious).

2. BEFORE YOU TAKE TEMAZEPAM

Do not take Temazepam if you:

- are allergic (hypersensitive) to temazepam or any other benzodiazepine or any of the other ingredients in this medicine
- suffer from long term fatigue and muscle weakness (myasthenia gravis)
- suffer from irregular breathing whilst asleep (sleep apnoea syndrome)
- have severe lung or liver problems
- are under 18 years old.

Take special care with Temazepam - You should tell your doctor before taking this medicine if you:

- have a history of alcohol or drug abuse
- have liver or kidney problems
- are suffering from depression or anxiety associated with depression
- have a personality disorder such as schizophrenia.

Taking other medicines - Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, or the following:

- any other medicine to treat nervousness or feeling anxious
- any medicine to treat severe mental conditions
- Disulfiram used in the treatment of alcohol dependence
- strong pain killers eg. Morphine
- antihistamines that cause drowsiness, used to treat allergies
- any medicine to treat Parkinson's disease
- medicine to treat convulsions or fits (epilepsy)
- any other medicine that can make you feel drowsy or less alert as Temazepam may increase this effect.

If you are going to have an operation or need an anaesthetic, tell the doctor or dentist that you are taking Temazepam. If you take Temazepam before a minor operation or procedure it is important that you have someone to accompany you home.

Taking Temazepam with food and drink - Do not drink alcohol while you are taking Temazepam as it will change the way this medicine works.

Pregnancy and breast-feeding - Do not take Temazepam if you are pregnant, might become pregnant or are breast-feeding. If your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby might have a low body temperature, floppiness, and breathing and feeding difficulties. If this medicine is taken regularly in late pregnancy, your baby may develop withdrawal symptoms.

Driving and using machines - Temazepam may make you sleepy or affect your concentration. This may affect your ability to drive or operate machinery.

Important information about some of the ingredients of Temazepam - This medicine contains **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. HOW TO TAKE TEMAZEPAM

Always take Temazepam exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will usually give you Temazepam for a maximum of 4 weeks, this will include a period of time when your dose is reduced. Reducing your dose slowly will help to reduce the risk of side effects from withdrawal of the product. If you take Temazepam for sleeping difficulties it is important that you are able to have 7-8 hours of uninterrupted sleep after taking your tablet. If you are late getting to bed or your sleep is interrupted you may suffer from unwanted side effects such as memory loss or feeling drowsy. You may also behave strangely or differently to how you would normally behave. At high doses taken for a long period of time, it is possible that you may become dependent on your medicine. If this happens to you, you must speak to you doctor.

Adults: Insomnia - The usual dose is 10 mg or 20 mg half an hour before going to bed. In certain cases your doctor may increase the dose to 30 mg or 40 mg.

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Pre-medication - The usual dose is 20-40 mg, half to one hour before your procedure.

Elderly: Elderly patients usually require smaller doses of 10 mg at night, but in certain cases the dose may be increased to 20 mg at night. As this medicine is a muscle relaxant, elderly patients who have taken Temazepam and get up during the night are at risk of falling and fracturing their hip.

Pre-medication - The usual dose is 10-20 mg, half to one hour before your procedure.

Children - Temazepam is **not** recommended for use in children or adolescents younger than 18 years of age.

People with breathing difficulties or liver problems - If you have a long-term problem with your breathing or problems with your liver you are likely to be given a lower dose.

If you take more Temazepam than you should - Contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you. Symptoms of overdose include drowsiness and confusion. In more serious cases of overdose, symptoms include uncontrollable movements, floppiness, shallow breathing, unconsciousness, dizziness, light-headedness or fainting on standing up.

If you forget to take Temazepam - If you are still likely to have uninterrupted sleep of 7-8 hours, then take it as soon as you remember. Otherwise, if you miss a dose **do not** take a double dose to make up for a forgotten dose. Take your normal dose the following night.

If you stop taking Temazepam - You should only stop taking this medicine when your doctor tells you. **Do not** suddenly stop. If this happens you may suffer from side effects such as feeling nervous, depressed, irritable, suffer from sleep problems, sweating, diarrhoea, confusion, psychosis, fits or shaking.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Temazepam can cause side effects, although not everybody gets them.

In some patients, particularly young people and the elderly, Temazepam can cause unusual reactions. If any of the following happen, tell your doctor or pharmacist. You may need to stop taking Temazepam or lower your dose:

- restlessness
- agitation
- irritability
- aggressiveness
- delusions
- rage
- nightmares
- hallucinations (feeling, hearing or seeing things which are not there).

Other side effects are:

- drowsiness, tiredness or less alert during the next day, reduced alertness, sleep disturbances
- numbed emotions, depression
- reduced alertness, confusion, memory loss, accompanied by odd behavior
- headaches, dizziness, double vision
- low blood pressure, which will make you feel dizzy or faint when you stand up
- muscle weakness or lack of co-ordination
- lack of sex drive
- stomach pain or diarrhoea
- skin rashes, yellowing of the skin or whites of the eyes caused by blood disorders or liver problems (jaundice).

If any side effect gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TEMAZEPAM

Keep out of the reach and sight of children. Do not use Temazepam after the expiry date, which is stated on the bottle, container, blister or carton after 'EXP'. The expiry date refers to the last day of that month. Store below 25°C. Keep your medicine in the original package.
Plastic Containers and Amber Glass Bottles: Store in the original container. Replace the cap immediately after use.
Blisters: Store in the original package.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Temazepam contains - each tablet contains 10 mg or 20 mg of temazepam as the active substance. The other ingredients are lactose monohydrate, maize starch, gelatin, talc and magnesium stearate.

What Temazepam looks like and contents of the pack - Your medicine comes as a white or pale yellow round tablet in either two strengths of 10 mg or 20 mg. The tablets are marked 'T/10' for the 10 mg and 'T/20' for the 20 mg on one side and 'G' on the other. Temazepam is available in amber glass bottles, plastic containers or blisters of 7, 10, 14, 28, 30, 56, 60, 84, 90, 100, 250 and 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Generics [UK] Ltd., Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturer: McDermott Laboratories T/A Gerard Laboratories, Baldoyle Industrial Estate, Dublin 13, Ireland.

This leaflet was last approved in: April 2009 LT1486AC 10002733

④

PACKAGE LEAFLET:
INFORMATION FOR THE USER

Tritace® 1.25mg - 2.5mg 5mg - 10mg Tablets Tritace® Tablet Titration Pack

Ramipril

sanofi aventis

Is this leaflet hard to see or read?
Phone 01483 505515 for help

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Tritace is and what it is used for

Tritace contains a medicine called ramipril. This belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme inhibitors).

Tritace works by:
- Decreasing your body's production of substances that could raise your blood pressure
- Making your blood vessels relax and widen
- Making it easier for your heart to pump blood around your body.

Tritace can be used:
- To treat high blood pressure (hypertension)
- To reduce the risk of you having a heart attack or stroke
- To reduce the risk or delay the worsening of kidney problems (whether or not you have diabetes)
- To treat your heart when it cannot pump enough blood to the rest of your body (heart failure)
- As treatment following heart attack (myocardial infarction) complicated with heart failure.

2. Before you take Tritace

Do not take Tritace:
× If you are allergic (hypersensitive) to ramipril, any other ACE inhibitor medicine or any of the other ingredients of Tritace (see Section 6) Signs of an allergic reaction may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
× If you have ever had a serious allergic reaction called "angioedema". The signs include itching, hives (urticaria), red marks on the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing
× If you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Tritace may not be suitable for you
× If you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis)
× During the last **6 months of pregnancy** (see section below on "Pregnancy and breast-feeding)
× If your blood pressure is abnormally low or unstable. Your doctor will need to make this assessment.

Do not take Tritace if any of the above apply to you. If you are not sure, talk to your doctor before taking Tritace.

Take special care with Tritace
Check with your doctor or pharmacist before taking your medicine:
▲ If you have heart, liver or kidney problems
▲ If you have lost a lot of body salts or fluids (through being sick (vomiting), having diarrhoea, sweating more than usual, being on a low salt diet, taking diuretics (water tablets) for a long time or having had dialysis)
▲ If you are going to have treatment to reduce your allergy to bee or wasp stings (desensitization)
▲ If you are going to receive an anesthetic. This may be given for an operation or any dental work. You may need to stop your Tritace treatment one day beforehand; ask your doctor for advice
▲ If you have high amounts of potassium in your blood (shown in blood test results)
▲ If you have a collagen vascular disease such as scleroderma or systemic lupus erythematosus.
▲ You must tell your doctor if you think that you are (or might become) pregnant. Tritace is not recommended in the first 3 months of pregnancy and may cause serious harm to your baby after 3 months of pregnancy, see section "Pregnancy and breast-feeding".

Children
Tritace is not recommended for use in children and adolescents below 18 years of age because there is no information available in this population.
If any of the above apply to you (or you are not sure), talk to your doctor before taking Tritace.

Turn Over

Very rare (affects less than 1 on 10,000 people)
- Being more sensitive to the sun than usual.

Other side effects reported:
Please tell your doctor if any of the following gets serious or lasts longer than a few days.
- Difficulty concentrating
- Swollen mouth
- Blood tests showing too few blood cells in your blood
- Blood tests showing less sodium than usual in your blood
- Fingers and toes changing colour when you are cold and then tingling or feeling painful when you warm up (Raynaud's phenomenon)
- Breast enlargement in men
- Slowed or impaired reactions
- Burning sensation
- Change in the way things smell
- Hair loss.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Tritace

- Keep out of the reach and sight of children.
- Do not use Tritace after the expiry date which is stated on the carton and blister pack. The expiry date refers to the last day of that month.
- Store below 25°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Tritace Tablets contain.
- The active substance is ramipril.
- The other ingredients are methylhydroxypropylcellulose, pregelatinised starch, microcrystalline cellulose, sodium stearyl fumarate.
- The 2.5mg tablets also contain yellow ferric oxide (E172).
- The 5mg tablets also contain red ferric oxide (E172).

What Tritace Tablets look like and contents of the pack
- Tritace® 1.25mg Tablets are white to almost white oblong tablets with score-line. The upper face is marked with 1.25 and a logo (Ⓢ) and the lower face is marked with HMN and 1.25.
- Tritace® 2.5mg Tablets are yellowish to yellow oblong tablets with a score-line. The upper face is marked with 2.5 and a logo (Ⓢ) and the lower face is marked with HMR and 2.5.
- Tritace® 5mg Tablets are pale red oblong tablets with a score-line. The upper face is marked with 5 and a logo (Ⓢ) and the lower face is marked with HMP and 5.
- Tritace® 10mg Tablets are white to almost white oblong tablets with a score-line. The upper face is marked with HMO/HMO and the lower face is unmarked.

All strengths are supplied in PVC aluminium blisters in packs of 28 tablets.

Your Tritace Tablets Titration Pack contains 3 different strengths of Tritace Tablets in 3 different cartons.
- 7 x 2.5mg ramipril (yellowish to yellow white oblong tablets with a score-line. The upper face is marked with 2.5 and a logo (Ⓢ) and the lower face is marked with HMR and 2.5
- 21 x 5mg ramipril (pale red oblong tablets with a score-line. The upper face is marked with 5 and a logo (Ⓢ) and the lower face is marked with HMP and 5
- 7 x 10mg ramipril (white to almost white oblong tablets with a score-line. The upper face is marked with HMO/HMO and the lower face is unmarked

Your Titration Pack is available in packs containing a total of 35 tablets.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Sanofi-aventis, One Onslow Street, Guildford, Surrey, GU1 4YS, UK
Tel: 01483 505515
Fax: 01483 535432
email: uk-medicalinformation@sanofi-aventis.com

Manufacturer
Sanofi-aventis S.p.A.
SS 17 Km 22, Scoppito (AQ), Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Tritace, Triatec, Delix, Ramace, Cardace, Loavel, Pramace, Ramipril, Acovil, Unipril, Vesdil, Hypren, Quark, Ramiwin, Zenra, Ramipril Winthrop, Ramipril Medgenerics, Ramipril Protect, Ramipril Prevent, Traiteckit, Ramikit.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in 02/2009

ALLEN & HANBURYS

Package Leaflet: Information for the User

Ventolin™ Evohaler™

100 micrograms

salbutamol sulphate

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet:

1 What Ventolin Evohaler is and what it is used for

Ventolin Evohaler contains a medicine called salbutamol. This belongs to a group of medicines called bronchodilators.
- Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out.
- They help to relieve chest tightness, wheezing and cough.

Ventolin Evohaler is used to treat breathing problems in people with asthma and similar conditions. This includes relieving and preventing asthma brought on by exercise or other "triggers". These are things, which bring on asthma symptoms in some people. Common triggers include house dust, pollen, cats, dogs and cigarette smoke.

Ventolin Evohaler contains a propellant called HFA 134a. This is less harmful to the environment than older inhalers. Older inhalers may taste differently to Ventolin Evohaler. This will make no difference to how your medicine works.

2 Before you use Ventolin Evohaler

Do not use Ventolin Evohaler if:
- you are allergic (hypersensitive) to salbutamol sulphate or the other ingredient HFA 134a.

Take special care with Ventolin Evohaler

Check with your doctor, nurse or pharmacist before taking your medicine if:
- you have high blood pressure
- you have an overactive thyroid gland
- you have a history of heart problems such as an irregular or fast heartbeat or angina.

Taking other medicines

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go to hospital.

In particular tell your doctor, nurse or pharmacist if you are taking:
- medicines for an irregular or fast heartbeat
- other medicines for your asthma.

Taking Ventolin Evohaler with food and drink

You can take Ventolin Evohaler at any time of day, with or without food.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding.

Driving and using machines

Ventolin is not likely to affect you being able to drive or use any tools or machines.

3 How to use Ventolin Evohaler

Always use your Ventolin Evohaler exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.

Adults and Children
- to relieve asthma - One or two puffs.
- to prevent asthma - Two puffs 10-15 minutes before exercise or exposure to a "trigger".
- the maximum dose is 8 puffs in a 24 hour period.
- for regular treatment - Two puffs up to 4 times a day.

Instructions for use
- To help identify that the inhaler is Ventolin, there is an embossed letter V on the plastic case. There is also a special ridged 'touch pad' area to distinguish the 'reliever' inhalers from 'preventer' or 'protector' inhalers which have different touch pads.
- Ventolin Evohaler produces a fine mist which you inhale through your mouth into your lungs. Your doctor, nurse or pharmacist should show you how to use your inhaler. If you are not sure ask your doctor, nurse or pharmacist.
- Each Evohaler canister provides 200 puffs.

Do not use your inhaler more often than the doctor told you to. Tell your doctor if your medicine does not seem to be working as well as usual, as your chest problem may be getting worse and you may need a different medicine.

Your doctor may have told you to take more than this as an emergency treatment if your wheezing or breathing gets very bad. It is very important that you keep to your doctor's instructions as to how many puffs to take and how often to use your inhaler.

Testing your inhaler

1 When using the inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.

2 To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release a puff into the air. If you have not used the inhaler for a week or more, release two puffs of medicine into the air.

Using your inhaler

It is important to start to breathe as slowly as possible just before using your inhaler.

1 Stand or sit upright when using your inhaler.

2 Remove the mouthpiece cover (as shown in the first picture). Check inside and outside to make sure that the mouthpiece is clean and free of objects.

3 Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.

4 Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable. Do not breathe in again yet.

5 Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.

6 Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply.

Asthma Control Test™

The Asthma Control Test is one way to quickly assess your asthma control, giving you a simple score out of 25.
Your healthcare professional may ask you additional questions during a consultation.

Are you in control of your asthma? Or is your asthma in control of you? Here's how to find out

Step 1: Read each question carefully, circle your score and write it in the box.

Step 2: Add up each of your five scores to get your total Asthma Control Test ™ score.

Step 3: Use the score guide to learn how well you are controlling your asthma.

Q1 During the **past 4 weeks**, how often did your asthma prevent you from getting as much done at work, school or home? — Score:
All of the time 1 | Most of the time 2 | Some of the time 3 | A little of the time 4 | None of the time 5

Q2 During the **past 4 weeks**, how often have you had shortness of breath? — Score:
More than once a day 1 | Once a day 2 | 3-6 times a week 3 | 1-2 times a week 4 | Not at all 5

Q3 During the **past 4 weeks**, how often did your asthma symptoms (wheezing, coughing, chest tightness, shortness of breath) wake you up at night or earlier than usual in the morning? — Score:
4 or more times a week 1 | 2-3 nights a week 2 | Once a week 3 | Once or twice 4 | Not at all 5

Turn over for Questions 4 and 5.

7 Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable.

8 If your doctor has told you to take two puffs, wait about half a minute before you take another puff by repeating steps 3 to 7.

9 After use always replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position. Practise in front of a mirror for the first few times. If you see a 'mist' coming from the top of your inhaler or the sides of your mouth you should start again.

Young children may need help and their parents may need to operate the inhaler for them. Encourage the child to breathe out and operate the inhaler just after the child starts to breathe in. Practise the technique together. You may find the Volumatic™ spacer device, with a face mask, or the Babyhaler™ device useful if you have to give Ventolin Evohaler to a baby or a child under 5 - speak to your doctor if you think you might need one of these.

Older children or people with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece. If this does not help, a special device called a Haleraid™ may make it easier. Your doctor, nurse or pharmacist will be able to advise you.

Cleaning your inhaler

To stop your inhaler blocking, it is important to clean it at least once a week.

To clean your inhaler:
- Remove the mouthpiece cover.
- Do not remove the metal canister from the plastic casing at any time.
- Wipe the inside and outside of the mouthpiece and the plastic casing with a dry cloth or tissue.
- Replace the mouthpiece cover.

Do not put the metal canister in water.

If you take more Ventolin Evohaler than you should

If you take more than you should, talk to a doctor as soon as possible. The following effects may happen:
- your heart beating faster than usual
- you feel shaky.

These effects usually wear off in a few hours.

If you forget to take Ventolin Evohaler
- If you forget a dose, take it as soon as you remember it.
- However, if it is time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Ventolin Evohaler

Do not stop taking Ventolin Evohaler without talking to your doctor.

If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

4 Possible side effects

If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.

Like all medicines, Ventolin Evohaler can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic Reactions (affects less than 1 in 10,000 people)
If you have an allergic reaction, stop taking Ventolin Evohaler and see a doctor straight away. Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and collapse.

Talk to your doctor as soon as possible if:
- you feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while
- you may feel your heartbeat is uneven or it gives an extra beat
- these affect less than 1 in 10 people.

If any of these happen to you, talk to your doctor as soon as possible. **Do not stop using this medicine unless told to do so.**

Tell your doctor if you have any of the following side effects which may also happen with this medicine:

Common (affects less than 1 in 10 people)
- feeling shaky
- headache.

Uncommon (affects less than 1 in 100 people)
- mouth and throat irritation
- muscle cramps.

Rare (affects less than 1 in 1,000 people)
- a low level of potassium in your blood
- increased blood flow to your extremities (peripheral dilatation).

Very rare (affects less than 1 in 10,000 people)
- changes in sleep patterns and changes in behaviour, such as restlessness and excitability.

The following side effects can also happen but the frequency of these are not known:
- chest pain, due to heart problems such as angina. Tell your doctor, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

If you think this medicine is not working well enough for you

If your medicine does not seem to be working as well as usual, talk to your doctor as soon as possible. Your chest problem may be getting worse and you may need a different medicine. Do not take extra doses of Ventolin Evohaler unless your doctor tells you to.

5 How to store Ventolin Evohaler

- Keep out of the reach and sight of children.
- Do not store above 30°C. Protect from frost and direct sunlight.
- If the inhaler gets very cold, take the metal canister out of the plastic case and warm it in your hands for a few minutes before use. Never use anything else to warm it up.
- The metal canister is pressurised. Do not puncture, break or burn it even when apparently empty.
- Do not use Ventolin Evohaler after the expiry date, which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Ventolin Evohaler contains
- The active substance is salbutamol sulphate.
- The other ingredient is HFA 134a.

What Ventolin Evohaler looks like and contents of the pack

Ventolin Evohaler comprises an aluminium alloy can sealed with a metering valve, actuator and dust cap.
Each canister contains 200 doses of 100 micrograms of salbutamol (as salbutamol sulphate).

Marketing Authorisation holder
Glaxo Wellcome UK
Limited trading as:
Allen & Hanburys
Stockley Park West
Uxbridge
Middlesex UB11 1BT

Manufacturer
Glaxo Wellcome
Aranda de Duero
Burgos
Spain

Other formats:

To listen to or request a copy of this leaflet in Braille, large print please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:
Product name Ventolin Evohaler
Reference number 10949/0274

This is a service provided by the Royal National Institute of Blin

Leaflet date: June 2009

ALLEN & HANBURYS

Q4 During the **past 4 weeks**, how often have you used your reliever inhaler (usually blue)? — Score:
3 or more times a day 1 | 1-2 times a day 2 | 2-3 times a week 3 | Once a week or less 4 | Not at all 5

Q5 How would you rate your **asthma control** during the **past 4 weeks**? — Score:
Not controlled 1 | Poorly controlled 2 | Somewhat controlled 3 | Well controlled 4 | Completely controlled 5

Total Score

What does your score mean?

Score: 25 - WELL DONE
- Your asthma appears to have been UNDER CONTROL over the last 4 weeks.
- However, if you are experiencing any problems with your asthma, you should see your doctor, nurse or pharmacist.

Score: 20 to 24 - ON TARGET
- Your asthma appears to have been REASONABLY WELL CONTROLLED during the past 4 weeks.
- However, if you are experiencing symptoms your doctor, nurse or pharmacist may be able to help you.

Score: less than 20 - OFF TARGET
- Your asthma may NOT HAVE BEEN CONTROLLED during the past 4 weeks.
- Your doctor, nurse or pharmacist can recommend an asthma action plan to help improve your asthma control.

P8589

VISCOTEARS® LIQUID GEL
CARBOMER 2MG/G LIQUID GEL
(carbomer)

Patient Information Leaflet

Your eye drops are available using the names Viscotears Liquid Gel / Carbomer 2mg/g Liquid Gel, but will be referred to as Viscotears throughout this leaflet.

Please read this leaflet carefully before you start to use Viscotears. It contains important information. Keep the leaflet in a safe place because you may want to read it again.
Do not share these eye drops with anyone else just in case you have an eye infection which you could pass on.
If you have any other questions, or if there is something you don't understand, please ask your pharmacist.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Viscotears is and what it's used for

Viscotears contains the active ingredient, carbomer (polyacrylic acid). Viscotears is used to make your eyes more comfortable when they feel dry. It is one of a group of eye drops called 'artificial tears'.

2. Things to consider before you start to use Viscotears

DO NOT use Viscotears if:
- you think you may be allergic to any of the ingredients. (These are listed at the end of the leaflet.)

You should also ask yourself these questions before starting to use Viscotears:
- Do you wear contact lenses? Take your lenses out before you put the drops in your eyes. Don't put the lenses back in for at least 30 minutes.
- Do you have problems with your eyes apart from sore or dry eyes? Talk to your doctor before your start to use Viscotears.
- Are you using any other eye drops? If you need to use more than one kind of eye drops wait 5 minutes between treatments. Viscotears should always be the last of the eye drops used.
- Are you pregnant or breast-feeding? Discuss whether you should use Viscotears with your doctor.

Will there be any problems with driving or using machinery.
Some people may find that their vision is blurred immediately after using Viscotears. If affected, wait until your vision clears before you drive or use machinery.

3. How to use Viscotears

If your doctor has prescribed Viscotears he/she will tell you how and when to use it and the dose will be on the pharmacist's label.

The usual dosage is:
Adults (including the elderly): One drop in each affected eye, three or four times a day.
Children: Viscotears should only be used if prescribed by a doctor

If you are not sure ask your doctor or pharmacist.

How to use your eye drop
1. Wash your hands.
2. If you wear contact lenses, remove them before using the drops and do not replace for at least 30 minutes.
3. Hold the tube **vertically** (see figure 1).
4. Tilt your head backwards (see figure 2).
5. Rest one hand on your cheek and gently pull down your lower eye lid.
6. Look upwards.
7. Insert one drop by squeezing the tube gently (see figure 3).
8. Blink a few times to spread the liquid gel evenly over your eye.
9. Wipe away any excess gel from around the eyelids.
10. Repeat for your other eye if required.

NOTE: Do not touch your eye or the surrounding area with the tip of the dropper. Follow the instructions carefully. If there is anything you don't understand, ask your pharmacist or doctor.

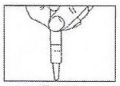


Figure 1


Figure 2


Figure 3

4. Possible side effects

Viscotears is suitable for most people, but like all medicines, it can sometimes cause side effects.

Some people notice that the drops make their eyes burn or sting slightly. This usually quickly passes.
Viscotears can make your eyelids feel sticky.
Sometimes your vision may be blurred for a short time. This will gradually clear (but do not drive or operate machinery while affected).

These effects are often mild. If they are severe, or if you notice anything else not mentioned here, please go and see your doctor.

Some patients have reported that their eyes or eyelids have become red, swollen, itchy or painful during use with Viscotears.

5. How to store Viscotears

Do not store above 25°C.
Discard 4 weeks after first opening.
Keep out of the reach and sight of children.
Do not use the eye drops after the expiry date shown on the tube (EXP).
Take any unused Viscotears back to your pharmacist to be destroyed. Do not throw it away with your normal household waste or water. This will help to protect the environment.

6. Further Information

The name of your eye drops is Viscotears Liquid Gel. Each gram of eye gel contains 2mg of Carbomer (polyacrylic acid).
Viscotears Liquid Gel also includes: cetrimide, sorbitol, sodium hydroxide and water for injection.

The tube contains 10g of liquid gel. This is one of a group of medicines called artificial tears.

Each pack contains either 1 x 10g tube, or 3 x 10g tubes.

Tamper-evident sealed carton containing one or three white/blue plastic tubes with a nozzle applicator head and a white plastic screw cap. The tube contains a clear, colourless, odourless gel.

Your medicine is manufactured by: Dr Winzer Pharma GmbH, Berlin, Germany.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

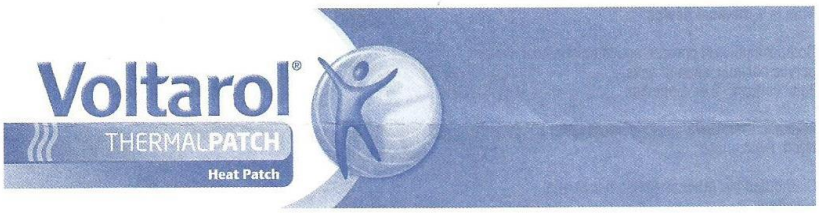
Product Licence holder: BR Lewis Pharmaceuticals Ltd., Kirk Sandall, Doncaster, DN3 1QR.

P PL No: 08929/0390

Leaflet revision and issue date: 05.12.08

Viscotears® is a registered trademark of Novartis AG.

P8589



Voltarol® Themal patch effectively and naturally provides pain relief and deep muscle relaxation for muscle pain, back, neck and shoulder pain.

Voltarol® Thermal patch is applied directly to the skin, on the site of your muscular pain. You feel the heat and relief instantly. The patch provides **10 hours** of penetrating heat that works to unwind tight, aching muscles and increases circulation to help soothe pain away. Thin, discrete and designed to work on your body where it hurts, the patch helps you to get active again soon and take your mind away from pain.

Using the heat patch
- Make sure your skin is clean, dry and non-greasy.
- Carefully tear open the sachet (start tearing by notch).
- Remove the patch from the sachet only at the time of use.
- Immediately take the protective film off the adhesive part of the patch, and apply the heat patch onto your skin at the site of your muscular pain.
- The patch will gradually warm up to a comfortable, soothing level (approximately 40°C).
- For optimum results, leave the patch to act for 10 hours. However, do not apply for longer than this time on the same area. However, if needed you can apply another patch on the same area 24 hours later.
- The patch stays in place and is easily removable.
- The patch can be used alone or with other pain relief medicines,except for medicated products applied on the skin and on injection sites (see Precautions)
- If you sweat excessively, remove the patch.
- The patch is for **external** and **single use only.**

Precautions
Do not use the Voltarol® Thermal patch:
- on irritated, cracked or damaged skin.
- on children under the age of 12.
- on people who are unable to remove the patch themselves (e.g. the elderly, handicapped or disabled), unless supervised by a responsible adult.
- if the wearer is unable to remove the patch or to feel the heat of the patch: for example if you have areas on your body you cannot feel.
- if your perception may be impaired by e.g. sedative medicines, alcoholic drinks.
- on an injection site.
- straight after an injury – heat may make swelling or bruising worse.
- over medicated products applied to the skin, or with any other sources of heat (such as infrared light).
- while bathing or showering.

Talk to your pharmacist or doctor before using the patch if you:
- have poor circulation, diabetes or arthritis or any other serious medical condition.
- have skin conditions like eczema or psoriasis, or have very sensitive skin.
- are pregnant.

For your safety
- Do not cut, tear or damage the patch. Do not use the patch if it is torn or damaged.
- The patch contains iron powder, which could be harmful if ingested. Consult a doctor straight away if this happens.
- If the skin or eyes come into contact with the powder, immediately rinse the affected area well and consult a doctor.
- Do not lie on the heat patch, even when in bed, or apply strong pressure during use (e.g. under a waistband).
- As with any heat product, this product has the potential to cause skin irritation or burns. If the patch feels too hot or your skin becomes irritated (swelling, eruption or prolonged redness), remove the heat patch straight away.
- Remove patch before medical scans
- If the pain does not improve, contact your doctor.
- Keep out of the reach of children and pets, both before and after use.
- Do not microwave or reheat the patch after use.
- Dispose of the patch in a waste bin.
- Avoid exposure to direct sunlight.
- Store the patch in a cool dry place. Do not store it in the freezer.

Keep the leaflet until all the patches contained in the box have been used !

This is a medical device

Composition: Iron powder, activated charcoal, water, acrylic polymer, sodium salts.
Total content: 2 or 4 patches

Manufacturer: Novartis Consumer Health S.A., Nyon, Switzerland

Distributed by: *Novartis Consumer Health*
Horsham
RH12 5AB, UK.

Text revised on: 15.7.10

CE 0459

PIL210

PACKAGE LEAFLET: INFORMATION FOR THE USER

WARFARIN 1MG, 3MG OR 5MG TABLETS

Read all of this leaflet carefully before you start taking this medicine. Even if you have used this medicine or a similar product before, you should read this leaflet carefully as the information may have changed.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Warfarin Tablets are and what they are used for

Warfarin belongs to a group of medicines called 'anticoagulants' which work by affecting your body's blood clotting mechanism. They extend the normal time it takes for blood to clot.
This medicine is sometimes also referred to as 'blood thinners'. Warfarin is used to prevent heart attacks, strokes, and blood clots in veins and arteries.

2. Before you take Warfarin Tablets

Do not take these tablets if you:

- have ever been told you are allergic to Warfarin or any of the other ingredients (these are listed in Section 6, Further Information)
- have kidney or liver problems
- have been diagnosed as having an infection of the heart
- suffer from high blood pressure
- have any conditions which cause bleeding or you bruise easily
- are about to undergo surgery or within 24 hours after surgery
- have or have ever had a stomach ulcer

Take special care with this medicine if:

- you drink large amounts of alcohol
- your weight changes rapidly. Keep your diet and level of activity as close to normal as possible, even when on any extended trips such as holidays
- you are elderly
- you are suffering from diarrhoea or vomiting
- you take part in sports activities which have a high risk of injury
- you change to another type of anticoagulant medication
- you have to go to another doctor, hospital, or to the dentist tell them that you are being treated with an anticoagulant and ask them to contact your own doctor.

Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed, for example, herbal remedies and health supplements from a pharmacy, supermarket or health food shop, as they may interact with this medicine.
Some of the medicines used for the following conditions may interfere with Warfarin tablets:

- pain e.g. Aspirin, Paracetamol,Dextropropoxyphene
- heart problems e.g. Amiodarone, Propafenone, Quinidine
- problems with platelet aggregation (blood cells sticking together) e.g. Dipyridamole
- depression e.g. Amitriptyline or Nortriptyline
- pain and inflammation e.g. Azapropazone, Diflunisal
- high levels of lipids (fats) in the blood e.g. Bezafibrate, Gemfibrozil and Clofibrate, cholestyramine
- infection e.g. Azetreonam, Chloramphenicol, Ciprofloxacin, Co-trimoxazole, Erythromycin, Fluconazole, Griseofulvin, Ketoconazole, Latamoxef, Metronidazole, Miconazole, Nalidixic acid, Neomycin, Norfloxacin, Rifampicin and Sulphonamides
- stomach ulcers or excessive production of stomach acid e.g. Cimetidine, Omeprazole, Sucralfate
- endometriosis, menstrual problems e.g. Danazol
- diabetes e.g. Tolbutamide and Glucagon
- gout and rheumatic diseases e.g. Allopurinol, Flurbiprofen, Indomethacin, Mefenamic Acid, Piroxicam, Sulindac
- cancer e.g. Tamoxifen
- insomnia e.g. Chloral hydrate
- hyperactivity e.g. Methylphenidate
- thyroid problems
- treatment of chronic alcohol dependence (under specialist supervision) e.g. Disulfiram
- insomnia e.g. barbiturates
- epilepsy e.g. Carbamazepine, Primidone, Phenytoin
- oral contraceptives
- oral ulceration and inflammation e.g. steroids
- herbal remedy St. John's Wort

Taking these tablets with food and drink

- Avoid sudden changes in your diet. Changing your diet can suddenly affect your Warfarin levels, especially if you begin to eat more vegetables and salad or if you change the amount of fatty foods you have been eating. You should not begin a weight reducing diet without discussing it with your doctor first.

If you stop taking these tablets
Do not stop taking these tablets without talking to your doctor. Treatment should continue for as long as your doctor feels it is needed. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, these tablets can cause side effects, although not everybody gets them.

Tell your doctor immediately if you get any of the following:

- allergic reaction (symptoms of which are skin rash, swelling, pain and difficulty breathing)
- unusual bruising
- bleeding from the nose without any apparent cause
- changes in the amount or colour of urine or blood in the urine
- blackened stools
- loss of hair
- fever
- nausea, vomiting or diarrhoea
- jaundice (yellowing of the skin or the eyes)
- purple discolouration to any other part of your skin e.g. toes

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Warfarin Tablets

- Keep all medicines in a safe place where children cannot see or reach it.
- Bulk containers and Blister Carton: Do not store above 25°C. Store in the original container and keep the container tightly closed in order to protect the tablets from light and moisture.
- Do not use the tablets after the expiry date shown on the carton or label.
- If you have any left over tablets then take them back to your pharmacist for safe disposal.

6. Further Information

What Warfarin Tablets Contain

- Warfarin Tablets come in three strengths. Each tablet contains 1 mg, 3mg or 5mg of the active ingredient Warfarin Sodium which is equivalent to 1mg, 3mg or 5mg of Warfarin respectively.
- The other ingredients in Warfarin 1mg, 3mg & 5mg tablets are: lactose monohydrate, maize starch, sucrose, pregelatinised starch, magnesium stearate
- Warfarin 1mg Tablets also contains: colour pigment blend brown (which contains black iron oxide (E172), red iron oxide (E172) and yellow iron oxide (E172))
- Warfarin 3mg Tablets also contains: indigo carmine aluminium lake (E132)
- Warfarin 5mg Tablets also contains: erythrosine aluminium lake (E127)

What Warfarin Tablets look like and contents of the pack
Warfarin Tablets are available in three different strengths.
Each strength has a separate colour to distinguish it from the others. Be sure you are taking the right tablet by checking the colour and strength.

Each strength appears as follows:

- The 1mg tablet is brown coloured, circular and uncoated tablet with '1' embossing on one side and 'BL' embossing on the other.
- The 3mg tablet is blue coloured, circular and uncoated tablet with '3' embossing on one side and 'BL' embossing on the other.
- The 5mg tablet is pink coloured, circular and uncoated tablet with '5' embossing on one side and 'BL' embossing on the other.
- The tablets are packaged in blister packs of 28, 56 or 112 tablets or in bulk containers of 100 or 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder/Manufacturer

Name and address: Bristol Laboratories Limited,
Unit 3, Canalside, Northbridge Road,
Berkhamsted, Hertfordshire,
HP4 1EG, United Kingdom
Telephone: 0044 (0)1442 200922
Fax: 0044 (0)1442 873717
Email: info@bristol-labs.co.uk

Warfarin 1mg Tablets; PL 17907/0103
Warfarin 3mg Tablets; PL 17907/0104
Warfarin 5mg Tablets; PL 17907/0105

This leaflet was last approved in April 2008

To request a copy of this leaflet in Braille, large print or audio format, please contact the licence holder at the address (or telephone, fax email) above.

PIL210

XALATAN®

0.005% Eye Drops, Solution

LATANOPROST

8R125
49

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine. Even if you have already used Xalatan or a similar medicine before, we advise you to read this text carefully. The information may have been changed.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What is Xalatan and what is it used for

Xalatan belongs to a group of medicines known as prostaglandin analogues. It works by increasing the natural outflow of fluid from inside the eye into the bloodstream.

Xalatan is used to treat conditions known as **open angle glaucoma** and **ocular hypertension**. Both of these conditions are linked with an increase in the pressure within your eye, eventually affecting your eye sight.

2. Before you use Xalatan

Xalatan can be used in adult men and women (including the elderly) but is not recommended for use if you are less than 18 years of age.

Do not use Xalatan if you are

- Allergic (hypersensitive) to latanoprost or any of the other ingredients of Xalatan (see section 6 for the list of ingredients in your medicine)
- Pregnant or trying to become pregnant
- Breast feeding

Take special care with Xalatan

Talk to your doctor or pharmacist before you take Xalatan if you think any of the following apply to you:

- If you are about to have or have had eye surgery (including cataract surgery)
- If you suffer from eye problems (such as eye pain, irritation or inflammation, blurred vision)
- If you know that you suffer from dry eyes
- If you have severe asthma or your asthma is not well controlled
- If you wear contact lenses. You can still use Xalatan, but follow the instructions for contact lens wearers in Section 3.

Taking other medicines

Xalatan may interact with other medicines. Please tell your doctor or pharmacist if you are taking or have taken any other medicines including those medicines (or eye drops) obtained without a prescription.

Pregnancy

Do not use Xalatan when you are pregnant. Tell your doctor immediately if you are pregnant, think you are pregnant, or are planning to become pregnant.

Breast-feeding

Do not use Xalatan when you are breast-feeding.

Driving and using machines

When you use Xalatan you might have blurred vision, for a short time. If this happens to you, **do not drive** or use any tools or machines until your vision becomes clear again.

Important information about some of the ingredients of Xalatan

Xalatan contains a preservative called benzalkonium chloride. This preservative may cause eye irritation or disruption to the surface of the eye. Benzalkonium chloride can be absorbed by contact lenses and is known to discolour soft contact lenses. Therefore, avoid contact with soft contact

swelling of the retina (macular oedema), symptoms of swelling or scratching/damage to the surface of the eye, swelling around the eye (periorbital oedema) misdirected eyelashes or an extra row of eyelashes
- Skin reactions on the eyelids, darkening of the skin of the eyelids.
- Asthma, worsening of asthma and shortness of breath (dyspnoea).

Very rare effects (likely to affect less than 1 in 10,000 people):

- Worsening of angina in patients who also have heart disease. Chest pain.

Patients have also reported the following side-effects: fluid filled area within the coloured part of the eye (iris cyst), headache, dizziness, palpitations, muscle pain, joint pain and developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Side effects seen more often in children compared to adults are: runny itchy nose and fever.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please contact your doctor or pharmacist.

5. How to store Xalatan

Keep out of the reach and sight of children.

Do not use Xalatan after the expiry date which is stated on the carton and bottle. The expiry date refers to the last day of that month.

Store the unopened bottle in a refrigerator (between 2°C and 8°C), protected from light.

After opening the bottle it is not necessary to store the bottle in a refrigerator but do not store it above 25°C. Use within 4 weeks of opening. When you are not using Xalatan, keep the bottle in the outer carton, in order to protect it from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Xalatan contains

The active substance is 0.005% (50 micrograms/ml) latanoprost.

The other ingredients are: benzalkonium chloride, sodium chloride, sodium dihydrogen phosphate monohydrate (E339a) and anhydrous disodium phosphate (E339b) dissolved in water for injections.

What Xalatan looks and contents of the pack

Xalatan Eye Drops, Solution is a clear, colourless liquid.

Xalatan is available in pack sizes of 1, 3 and 6 cartons. Not all pack sizes may be marketed.
Each carton contains one bottle of Xalatan. Each bottle contains 2.5 ml of Xalatan Eye Drops, Solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom.

Manufacturer: Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium.

This leaflet was last updated in November 2010.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zoton FasTab* 15 mg oro-dispersible tablets
Zoton FasTab* 30 mg oro-dispersible tablets

lansoprazole

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Zoton FasTab is and what it is used for
2. Before you take Zoton FasTab
3. How to take Zoton FasTab
4. Possible side effects
5. How to store Zoton FasTab
6. Further information

1. WHAT ZOTON FasTab IS AND WHAT IT IS USED FOR

The active ingredient in Zoton FasTab is lansoprazole, which is a proton pump inhibitor. Proton pump inhibitors reduce the amount of acid that your stomach makes.

Your doctor may prescribe Zoton FasTab for the following indications:

- Treatment of duodenal and stomach ulcer
- Treatment of inflammation in your oesophagus (reflux oesophagitis)
- Prevention of reflux oesophagitis
- Treatment of heartburn and acid regurgitation
- Treatment of infections caused by the bacteria *Helicobacter pylori* when given in combination with antibiotic therapy
- Treatment or prevention of duodenal or stomach ulcer in patients requiring continued NSAID treatment (NSAID treatment is used against pain or inflammation)
- Treatment of Zollinger-Ellison syndrome.

Your doctor may have prescribed Zoton FasTab for another indication or with a dose different from that which is written in this information leaflet. Please follow your doctor's instructions for taking your medicine.

2. BEFORE YOU TAKE ZOTON FasTab

Do not take Zoton FasTab:

- if you are allergic (hypersensitive) to lansoprazole or any of the other ingredients of Zoton FasTab
- if you are taking a medicine containing the active substance atazanavir (used in the treatment of HIV).

Take special care with Zoton FasTab

Please tell your doctor if you have serious liver disease. The doctor may have to adjust your dosage ...

undesirable effects, one of the factors that can reduce your ability to do these things safely is your use of medicines.

Descriptions of these effects can be found in other sections.

Read all the information in this leaflet for guidance.

Discuss with your doctor, nurse or pharmacist if you are unsure about anything.

Important information about some of the ingredients of Zoton FasTab

Zoton FasTab contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Zoton FasTab contains aspartame. Aspartame is a source of phenylalanine, which may be harmful for people with phenylketonuria.

3. HOW TO TAKE ZOTON FasTab

Place the tablet on your tongue and suck gently. The tablet rapidly dissolves in the mouth, releasing microgranules which you should swallow without chewing. You can also swallow the tablet whole with a glass of water.

Your doctor might instruct you to take the tablet with an oral syringe, in case you have serious difficulties with swallowing.

The following instructions should be followed if administered via oral syringe:

It is important that the appropriateness of the selected oral syringe is carefully tested.

- Remove the plunger of the syringe (at least 5 ml syringe for the 15 mg tablet and 10 ml syringe for the 30 mg tablet)
- Put the tablet into the barrel
- Put the plunger back onto the syringe
- For the 15 mg tablet: draw 4 ml tap water into the syringe ...

...

Prevention of duodenal or stomach ulcer in patients requiring continued NSAID treatment: one 15 mg oro-dispersible tablet every day, your doctor may adjust your dose to one 30 mg oro-dispersible tablet every day.

Zollinger-Ellison syndrome: The usual dose is two 30 mg oro-dispersible tablets every day to start with, then depending on how you respond to Zoton FasTab the dose that your doctor decides is best for you.

Use in children:

Zoton FasTab should not be given to children.

Take your medicine exactly as your doctor has told you. You should check with your doctor if you are not sure how to take your medicine.

If you take more Zoton FasTab than prescribed

If you take more Zoton FasTab than you have been told to, seek medical advice quickly.

If you forget to take Zoton FasTab

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. If this happens skip the missed dose and take the remaining oro-dispersible tablets as normal. Do not take a double dose to make up for a forgotten oro-dispersible tablet.

If you stop taking Zoton FasTab

Do not stop treatment early because your symptoms have got better. Your condition may not have been fully healed and may reoccur if you do not finish your course of treatment.

If you have any further questions on the use of this product, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zoton FasTab can cause side effects, although not everybody gets them.

The following side effects are common (occur in more than 1 in 100 patients):

- headache, dizziness
- diarrhoea, constipation, stomach pains, feeling or being sick, wind, dry or sore mouth or throat
- skin rash, itching
- changes in liver function test values
- tiredness.

The following side effects are uncommon (occur in less than 1 in 100 patients):

- depression
- joint or muscle pain
- fluid retention or swelling
- changes in blood cell counts.

The following side effects are rare (occur in less than 1 in 1000 patients):

- fever
- restlessness, drowsiness, confusion, hallucinations, insomnia, visual disturbances, vertigo
- a change in the way things taste, loss of appetite, inflammation of your tongue (glossitis)

6. FURTHER INFORMATION

What Zoton FasTab contains

- The active substance is lansoprazole
- The other ingredients are lactose monohydrate, microcrystalline cellulose, magnesium carbonate, low-substituted hydroxypropyl cellulose, hydroxypropyl cellulose, hypromellose, titanium dioxide, talc, mannitol, methacrylic acid – ethyl acrylate copolymer, polyacrylate dispersion, macrogol 8000, glyceryl monostearate, polysorbate 80, triethyl citrate, citric acid anhydrous, crospovidone, magnesium stearate, aspartame, strawberry flavour and iron oxide red and yellow (E172).

What Zoton FasTab looks like and contents of the pack

Zoton FasTab 15 mg and 30 mg are white to yellowish white oro-dispersible tablets speckled with orange to dark brown gastro-resistant microgranules. Zoton FasTab 15 mg have "15" imprinted on one side of the tablets and Zoton FasTab 30 mg have "30" imprinted on one side of the tablets. Each Zoton FasTab oro-dispersible tablet is strawberry flavoured.

Zoton FasTab 15 mg and 30 mg are available in packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is:
Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ
United Kingdom.

The manufacturer is:
Pfizer Ireland Pharmaceuticals
Little Connell
Newbridge
County Kildare
Ireland

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This leaflet can be made available in large print, audio or Braille on request.

Contact 0800 198 5000 to request this, quoting one of the following numbers: 00057/1296 or 00057/1297.

ZOVIRAX®
COLD SORE CREAM
aciclovir

Please read right through this leaflet before you start using this medicine. This medicine is available without prescription, but you still need to use Zovirax Cold Sore Cream carefully to get the best results from it.
- Keep this leaflet, you may need to read it again.
- If you have any further questions, ask your pharmacist.

In this leaflet:

1. What Zovirax does

Zovirax is used for the treatment of cold sores. The active ingredient is aciclovir, an antiviral agent. **Apply at the first signs of a cold sore** (such as tingling and itching). It can also be used to speed up healing if one has already appeared.

2. Check before you use Zovirax

Do not use Zovirax:

- **if you have ever had an allergic reaction** to aciclovir, valaciclovir, propylene glycol or any of the other ingredients (listed in Section 6)
- **inside your mouth**
- to treat **mouth ulcers**
- in the **eyes** or **genital area.**

Take special care with Zovirax

- **Always wash your hands** before and after applying Zovirax.
- **Do not touch your eyes** until you have washed your hands after application.
- **If you accidentally get cream in your eye,** wash out thoroughly with warm water. Consult your doctor if you are concerned.
- **Do not swallow** the cream. If you accidentally swallow any cream, it is unlikely to cause any ill effects but consult your doctor if you are concerned.
- **Avoid touching a cold sore** to prevent transferring the infection or making it worse.
- If you have been told by your doctor that you have a **weakened immune system,** contact your doctor before treating any type of infection.
- **If you are in any doubt if you have a cold sore,** contact your doctor.
- **If your cold sore gets very severe,** contact your doctor.

Pregnancy and breast feeding

Talk to your doctor or pharmacist before using Zovirax if you are **pregnant, trying to become pregnant or are breast feeding.**

3. How to use Zovirax

Suitable for all ages:
- Apply at the first signs of a cold sore (such as tingling and itching).
- Apply liberally to the affected area 5 times a day.
- Continue treatment for 4 days. If your cold sore hasn't healed after this time, you can use the cream for up to 10 days in total.
- Treat your cold sore for 4 full days to ensure rapid healing.
- If you forget a dose, apply when you remember and continue as before.

- If your cold sore hasn't healed fully after 10 days, or if it gets worse at any time, contact your doctor.
- Never give your Zovirax to others, even if their symptoms are the same as yours.
- The amount of cream inside this pack is enough for one cold sore attack. For any future attacks, start treatment at the first signs of a cold sore developing (such as tingling or itching). It can also be started during the blister stage.
- Do not use more than the recommended dose.

continued ove

4. Possible side effects

Like all medicines, Zovirax can have side effects, but not everybody gets them.

Stop using the medicine and **tell your doctor** if you experience:
- Allergy-like reactions, for example swelling of the lips, face and eyelids.

The following side effects could also occur:
- Mild burning or stinging after application. This will quickly go away.
- Redness, itching or a mild drying or flaking of the skin, skin rashes or weals.

If you do get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

5. How to store Zovirax

Keep out of the reach and sight of children.
Do not use this medicine after 'EXP' date shown on the pack.
Do not store above 25°C but do not keep it in a refrigerator.

6. Further information

Active ingredient 5% w/w Aciclovir.
Other ingredients Dimeticone, propylene glycol, poloxamer 407, cetostearyl alcohol, sodium laurilsulfate, white soft paraffin, liquid paraffin, arlacel 165 (glycerol monostearate, macrogol stearate 100) and purified water.

Propylene glycol may cause skin irritation.

Zovirax is available in a 2g tube or pump.

More about cold sores

A cold sore is an infection which is caused by the herpes simplex virus (HSV), which lies dormant in nerve cells supplying your lips and the surrounding skin.

When does the first infection occur?

The first infection usually occurs in early childhood, probably after being kissed by a person with the infection. The virus passes through the skin, travels up a nerve and stays in a nerve junction indefinitely.

What can trigger the virus?

Various things, including colds, 'flu, menstruation, fatigue, emotional upset, stress, physical injury, bright sunlight and simply when you are feeling 'run down'. Once triggered, the virus travels back down the nerve to the skin on and around the lips where it causes the cold sore to develop.

Remember – cold sores are infectious

The virus is capable of infecting other parts of the body. To reduce the risk of passing the infection on, do not allow others to touch your cold sore, or to share your towel, etc. You should avoid kissing and oral sex if you or your partner has an active cold sore. Always wash your hands before and after touching cold sores.
- Avoid touching your eyes. HSV infection of the eye can lead to ulcers on the window of the eye (cornea).
- Avoid kissing – especially children – when you have a cold sore.
- Don't break the blisters or pick the scabs. Not only could you infect your cold sore with other germs, you may infect your fingers with the virus.
- Don't share your eating and drinking utensils.

The marketing authorisation holder is GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K. and all enquiries should be sent to this address.

The manufacturer is Glaxo Wellcome Operations, Greenford, Middlesex, UB6 0NN.

This leaflet was last revised in November 2008.

gsk GlaxoSmithKline

ZOVIRAX®
COLD SORE CREAM
aciclovir

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