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

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

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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 lexicogrammar. 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 January 1999, 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, subheadings, 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
Chapter 1: Patient information leaflets (PILs)

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

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 colleagues (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.
Chapter 1: Patient information leaflets (PILs)

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).


“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;
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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.

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
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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.
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- 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.


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
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- 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 \textit{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.
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(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 MediLingua1 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

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1MediLingua 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 phrase “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.
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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 Ltd2 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).

2Luto 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.

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\(^3\)**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 website 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 website 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

<table>
<thead>
<tr>
<th>Prescription only medicine</th>
<th>POM</th>
<th>Requires a prescription from specified health professional/s</th>
<th>‘In the dispensary’</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy medicines</td>
<td>P</td>
<td>Must be sold by, or under the supervision of, a registered pharmacist</td>
<td>‘Behind-the-counter’</td>
</tr>
<tr>
<td>General sales list medicine</td>
<td>GSL</td>
<td>Available from any sales outlet, e.g. garage, newsagent</td>
<td>‘Off-the-shelf’</td>
</tr>
</tbody>
</table>

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). 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

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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](image)

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 subprocesses: 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 Gobbledygook) 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.
Chapter 2: Readability of PILs

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).
Chapter 2: Readability of PILs

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 (Schwanenflugel 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 metadiscourse; 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.”


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:

<table>
<thead>
<tr>
<th>Context of culture</th>
<th>Context of situation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genre</td>
<td>Register</td>
</tr>
<tr>
<td>Field (What is being talked about)</td>
<td>Tenor (Who is involved)</td>
</tr>
<tr>
<td>Use of medicine: side effects, etc.</td>
<td>Professional relationship: expert ‘informing’ lay person.</td>
</tr>
</tbody>
</table>

*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 \textbf{(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
Chapter 3: Hallidayan linguistics applied to PILs

- 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):
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:

<table>
<thead>
<tr>
<th>Name of medication</th>
<th>Treatment uses</th>
<th>Last revision of leaflet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenuric tablets</td>
<td>(gout)</td>
<td>Aug 2010</td>
</tr>
<tr>
<td>Advodart capsules</td>
<td>(prostate)</td>
<td>Mar 2010</td>
</tr>
<tr>
<td>Alendronic Acid</td>
<td>(osteoporosis)</td>
<td>Nov 2010</td>
</tr>
<tr>
<td>Amlodipine</td>
<td>(high pressure)</td>
<td>Sept 2010</td>
</tr>
<tr>
<td>Aspirin Enteric Tablets</td>
<td>(antiplatelet)</td>
<td>May 2009</td>
</tr>
<tr>
<td>Aspirin tablets</td>
<td>(anti-inflammatory)</td>
<td>Nov 2010</td>
</tr>
<tr>
<td>Atarax Tablets</td>
<td>(urticaria)</td>
<td>Sept. 2008</td>
</tr>
<tr>
<td>Azathioprine Tablets</td>
<td>(immunosuppressant)</td>
<td>July 2008</td>
</tr>
<tr>
<td>Benadryl Plus</td>
<td>(hay fever)</td>
<td>Sept. 2008</td>
</tr>
<tr>
<td>Benylin</td>
<td>(children’s chesty cough)</td>
<td>April 2008</td>
</tr>
<tr>
<td>Buscopan tablets</td>
<td>(antispasmodics)</td>
<td>Oct 2010</td>
</tr>
<tr>
<td>Butrans Trans. patches</td>
<td>(analgesics)</td>
<td>Jan. 2009</td>
</tr>
<tr>
<td>Cefalexin Capsules</td>
<td>(bacterial infections)</td>
<td>Oct. 2009</td>
</tr>
<tr>
<td>Celluvisc eye drops</td>
<td>(eye irritation)</td>
<td>Nov 2011</td>
</tr>
<tr>
<td>Citalopram</td>
<td>(anti-depressant)</td>
<td>July 2010</td>
</tr>
<tr>
<td>Clopidogrel Tablets</td>
<td>(thrombi)</td>
<td>July 2010</td>
</tr>
<tr>
<td>Coaprovel</td>
<td>(hypertension)</td>
<td>Jan. 2010</td>
</tr>
<tr>
<td>Co-codamol Tablets</td>
<td>(moderate pain)</td>
<td>Feb. 2011</td>
</tr>
<tr>
<td>Detrusitol</td>
<td>(anti-muscarinics)</td>
<td>Sept 2010</td>
</tr>
<tr>
<td><strong>Dulcolax tablets</strong></td>
<td>(laxative)</td>
<td>Feb 2011</td>
</tr>
<tr>
<td>----------------------</td>
<td>------------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Ezetrol tablets</strong></td>
<td>(high blood pressure)</td>
<td>Mar 2010</td>
</tr>
<tr>
<td><strong>Finasteride</strong></td>
<td>(prostate)</td>
<td>July 2010</td>
</tr>
<tr>
<td><strong>Flecainide Acetate tablets</strong></td>
<td>(fast heartbeats)</td>
<td>Jan 2011</td>
</tr>
<tr>
<td><strong>Flucloxacillin Capsules</strong></td>
<td>(penicillin antibiotic)</td>
<td>Jan. 2009</td>
</tr>
<tr>
<td><strong>Halfl Sinemet CR Tablets</strong></td>
<td>(Parkinson’s disease)</td>
<td>Nov. 2009</td>
</tr>
<tr>
<td><strong>Hydrocortisone ointment</strong></td>
<td>(skin inflammation)</td>
<td>Sept. 2009</td>
</tr>
<tr>
<td><strong>Istin</strong></td>
<td>(chest pain)</td>
<td>March 2010</td>
</tr>
<tr>
<td><strong>Lamictal tablets</strong></td>
<td>(epilepsy)</td>
<td>June 2011</td>
</tr>
<tr>
<td><strong>Lercanidipine Tablets</strong></td>
<td>(high blood pressure)</td>
<td>Feb. 2009</td>
</tr>
<tr>
<td><strong>Lipitor</strong></td>
<td>(cholesterol)</td>
<td>March 2011</td>
</tr>
<tr>
<td><strong>Liquifilm tears</strong></td>
<td>(dry eyes)</td>
<td>Feb. 2009</td>
</tr>
<tr>
<td><strong>Lisinopril tablets</strong></td>
<td>(high blood pressure)</td>
<td>Aug 2010</td>
</tr>
<tr>
<td><strong>Losartan Potassium</strong></td>
<td>(hypertension)</td>
<td>Jan 2010</td>
</tr>
<tr>
<td><strong>Macrodantin</strong></td>
<td>(infections)</td>
<td>Feb 2012</td>
</tr>
<tr>
<td><strong>Metoprolol Tartrate</strong></td>
<td>(high blood pressure)</td>
<td>Jan. 2009</td>
</tr>
<tr>
<td><strong>Multaq</strong></td>
<td>(anti-arrhythmics)</td>
<td>Dec. 2009</td>
</tr>
<tr>
<td><strong>Naproxen tablets</strong></td>
<td>(steroidal anti-inflammatory)</td>
<td>Feb 2010</td>
</tr>
<tr>
<td><strong>Neurpro transdermal patch</strong></td>
<td>(Parkinson’s disease)</td>
<td>Nov. 2010</td>
</tr>
<tr>
<td><strong>Nurofen for children</strong></td>
<td>(anti-inflammatory)</td>
<td>Mar 2010</td>
</tr>
<tr>
<td><strong>Nystatin Oral Suspension</strong></td>
<td>(anti-fungal)</td>
<td>Aug. 2008</td>
</tr>
<tr>
<td><strong>Omeprazole capsules</strong></td>
<td>(stomach acid reducer)</td>
<td>Nov 2010</td>
</tr>
<tr>
<td><strong>One-Alpha Capsules</strong></td>
<td>(osteodystrophy)</td>
<td>Feb. 2009</td>
</tr>
<tr>
<td><strong>Paracetamol caplets</strong></td>
<td>(anti-inflammatory)</td>
<td>Mar 2010</td>
</tr>
<tr>
<td><strong>Phenergan Tablets</strong></td>
<td>(allergic conditions)</td>
<td>March 2008</td>
</tr>
<tr>
<td><strong>Phorpain gel</strong></td>
<td>(anti-inflammatory)</td>
<td>July 2010</td>
</tr>
<tr>
<td><strong>Piriton tablets</strong></td>
<td>(allergy)</td>
<td>May 2010</td>
</tr>
<tr>
<td>--------------------------</td>
<td>------------------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Prednisolone tablets</strong></td>
<td>(cortisone for a variety of ailments)</td>
<td>July 2010</td>
</tr>
<tr>
<td><strong>Premique Tablets</strong></td>
<td>(hormone replacement)</td>
<td>April 2010</td>
</tr>
<tr>
<td><strong>Propranolol tablets</strong></td>
<td>(high pressure)</td>
<td>Sept 2010</td>
</tr>
<tr>
<td><strong>Ramipril capsules</strong></td>
<td>(heart failure)</td>
<td>Sept 2010</td>
</tr>
<tr>
<td><strong>Simvastin</strong></td>
<td>(cholesterol)</td>
<td>Nov 2011</td>
</tr>
<tr>
<td><strong>Temazepam Tablets</strong></td>
<td>(insomnia and anxiety)</td>
<td>April 2009</td>
</tr>
<tr>
<td><strong>Tritace Tablets</strong></td>
<td>(hypertension)</td>
<td>Feb. 2009</td>
</tr>
<tr>
<td><strong>Ventolin Evohaler</strong></td>
<td>(asthma symptoms)</td>
<td>June 2009</td>
</tr>
<tr>
<td><strong>Viscotears</strong></td>
<td>(ocular lubricator)</td>
<td>Dec. 2008</td>
</tr>
<tr>
<td><strong>Voltarol thermal patch</strong></td>
<td>(muscle relaxation)</td>
<td>July 2010</td>
</tr>
<tr>
<td><strong>Warfarin Tablets</strong></td>
<td>(anticoagulant)</td>
<td>April 2008</td>
</tr>
<tr>
<td><strong>Xalatan eye drops</strong></td>
<td>(ocular hypertension)</td>
<td>Nov 2010</td>
</tr>
<tr>
<td><strong>Zoton Fas Tab</strong></td>
<td>(stomach acid reducer)</td>
<td>July 2011</td>
</tr>
<tr>
<td><strong>Zovirax</strong></td>
<td>(cold sores)</td>
<td>Nov. 2008</td>
</tr>
</tbody>
</table>

*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:
Chapter 4: Presentation and discussion of results

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, alcohol, 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.
- This 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 leave the heat patch, even when in use, or apply strong pressure during use (e.g. under a belt/band).
- 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!

Voltarol® Thermal Patch PIL (front page and back page).
Chapter 4: Presentation and discussion of results

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

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

(Lercanidipine)

(Adenuric)
Chapter 4: Presentation and discussion of results

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](image)

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**

![Image of Lamictal leaflet]

In this leaflet

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

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)
Chapter 4: Presentation and discussion of results

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)*
Chapter 4: Presentation and discussion of results

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 prescription (including herbal medicines). This is because Ramipril Capsules can affect the way some other medicines work. Also some medicines can affect the way Ramipril Capsules work. Please tell your doctor if you are taking any of the following medicines. 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)
Section five

The purpose of section five is to describe, explain, and grade some of the undesirable side effects that may occur, and to instruct 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**

![Possible side effects](image)

(Lamictal)
Chapter 4: Presentation and discussion of results

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

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, rips, kidney problems, muscle pain (myalgia), pain in the joint (arthritis), 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):
- 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 disorders (including acute mastoiditis, mastoiditis and myelodysplastic syndrome)
- severe reaction 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 mastoiditis, mastoiditis and myelodysplastic syndrome)
- very serious allergic reaction.

(Azathioprine)

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

**Examples 4**

<table>
<thead>
<tr>
<th>4. Possible side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Common side-effects include: impotence (inability to maintain an erection); a reduced desire to have sex; producing a reduced amount of semen</td>
</tr>
<tr>
<td>Uncommon side-effects include: Swelling and/or tenderness of the breasts; problems with ejaculation; skin rashes</td>
</tr>
<tr>
<td>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</td>
</tr>
</tbody>
</table>

*(Finasteride)*

<table>
<thead>
<tr>
<th>Other side effects which may occur are:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncommon:</td>
</tr>
<tr>
<td>• headache</td>
</tr>
<tr>
<td>Rare:</td>
</tr>
<tr>
<td>• diarrhoea, wind or constipation. Tell your doctor if these last for more than a few days or become troublesome</td>
</tr>
<tr>
<td>Very rare:</td>
</tr>
<tr>
<td>• kidney problems may occur with ibuprofen</td>
</tr>
<tr>
<td>• stroke or heart problems may occur with ibuprofen. This is unlikely at the dose level given to children</td>
</tr>
<tr>
<td>• worsening of colitis and Crohn’s disease</td>
</tr>
<tr>
<td>• high blood pressure.</td>
</tr>
</tbody>
</table>

*(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

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 glycolate, 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 graoff white powder.
500mg Capsules are opaque caramel and grey printed with 'FXN 500' in black ink. The capsules contain a graoff 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.
Blisters 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.

(Flucloxacillin)
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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:

<table>
<thead>
<tr>
<th>Country</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria, Bulgaria, Czech Republic, Estonia, Germany, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia</td>
<td>Sortis</td>
</tr>
<tr>
<td>Belgium, Cyprus, Finland, Greece, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Sweden, UK</td>
<td>Lipitor</td>
</tr>
<tr>
<td>Denmark, Greece, Iceland, Portugal, Spain</td>
<td>Zarator</td>
</tr>
<tr>
<td>Finland</td>
<td>Orboeos</td>
</tr>
<tr>
<td>France</td>
<td>Tahor</td>
</tr>
<tr>
<td>Germany</td>
<td>Atorvastatin Pfizer, Liprimar</td>
</tr>
<tr>
<td>Greece</td>
<td>Edovin</td>
</tr>
<tr>
<td>Hungary</td>
<td>Obradon</td>
</tr>
<tr>
<td>Italy</td>
<td>Torvast, Totalip, Zarator</td>
</tr>
<tr>
<td>Portugal</td>
<td>Atorvastatina Parke-Davis, Tezzor</td>
</tr>
<tr>
<td>Spain</td>
<td>Cerdyl, Atorvastatina Norstrum, Atorvastatina Pharmacia, Prevencor</td>
</tr>
</tbody>
</table>

This leaflet was last approved in 03/2011.
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Two PILs, Multaq and CoAprovel, supplied the local representatives of the Marketing Authorisation 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.

**Belgie/Belgique/Belgien**
nano-fi-aventis Belgium
Tel/Tel: +32 (0)2 710 54 00

**България**
nano-fi-aventis Bulgaria ЕООД
Tel.: +359 (0)2 970 53 00

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

**Danmark**
nano-fi-aventis Denmark A/S
Tel: +45 45 16 70 00

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

**Eesti**
nano-fi-aventis Estonia OÜ
Tel: +372 627 34 88

**Ελλάδα**
nano-fi-aventis AEBE
Tel: +30 210 900 16 00

**España**
nano-fi-aventis, S.A.
Tel: +34 93 485 94 00

**France**
nano-fi-aventis France
Tel: 0 800 222 555
Fax: +33 1 57 63 23 23

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

**Ísland**
Vísir hf.
Sms: +354 535 7000

**Italia**
nano-fi-aventis S.p.A.
Tel: +39 02 393 91

**Кипр**
nano-fi-aventis Cyprus Ltd.
Tel: +357 22 871600

**Latvija**
nano-fi-aventis Latvia SIA
Tel: +371 67 33 24 51

**Lituva**
UAB nano-fi-aventis Lietuva
Tel: +370 5 2755224

**Luxembourg/Luxemburg**
nano-fi-aventis Belgium
Tel/Tel: +32 (0) 2 710 54 00

**Magyarország**
nano-fi-aventis zrt., Magyarország
Tel: +36 1 505 0650

**Malta**
nano-fi-aventis Malta Ltd.
Tel: +356 21493022

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

**Norge**
nano-fi-aventis Norge AS
Tel: +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 - Productos Farmacêuticos, S.A.
Tel: +351 21 35 89 400

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

**Сlovenija**
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/Finnland**
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

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*This leaflet was last approved in 12/2009*

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

(Multaq)
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.
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- 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.
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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 alfalcacidol 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)*
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)*
(Macrodantin)

If you stop taking Leicanidipine 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)
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**

If you have surgery or any blood tests, tell your doctor or hospital staff that you are taking this medicine.

*(Aspirin Enteric Tablets)*

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.

*(Lamictal)*

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

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.

*(Ezetrol)*

Talk to your doctor or pharmacist if any of the following apply to you:

*(Aspirin Gastro-Resistant)*
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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 Evoxaler, 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):

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)
- _topisetron_ (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.
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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 to 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. Ezetrol 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....

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
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black on light grey; 3, BuTrans, Coaprovél 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
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(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):

![Fig. 4.4 Portrait model of PIL](image-url)
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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**

*Celluvisc eye drops*
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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.
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:
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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).
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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.

(Ventolin Evohaler)

(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**

![Paracetamol](image)

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)

(Paracetamol)

![Zovirax](image)

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)

![Benylin](image)

Do not use this medicine.

Talk to your doctor or pharmacist...

(Benylin)

![Piriton](image)

2. **Check before you take Piriton Allergy Tablets**

Do not take Piriton Allergy Tablets:

(Piriton)

![Istin](image)

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**

![Taking Lipitor with food and drink](image)

*Taking Lipitor with food and drink*

> When taking Lipitor, do not drink more than one or two small glasses of grapefruit juice per day.

![Pregnancy](image)

*Pregnancy*

> Do not take Lipitor if you are pregnant or trying to become pregnant.

![Breast-feeding](image)

*Breast-feeding*

> Do not take Lipitor if you are breast-feeding.

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

![Taking other medicines](image)

*(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:
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!’

Example

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
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 Leeuwen, 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;
Chapter 5: Labels

- 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\textsuperscript{5} was released called: \textit{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).

\textsuperscript{5} BBC Radio 4 Today Programme: Interview with John Humphries, 3 March 2011
Chapter 5: Labels

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 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.
3. Warning. Avoid alcoholic drink
4. Do not take indigestion remedies at the same time of day as this medicine
5. Do not take milk, indigestion remedies, or medicines containing iron or zinc at the same time of day as this medicine
6. Do not stop taking this medicine except on your doctor’s advice
7. Take at regular intervals. Complete the prescribed course unless otherwise directed
8. Warning. Follow the printed instructions you have been given with this medicine
9. Avoid exposure of skin to direct sunlight or sun lamps
10. This medicine may colour the urine
11. Caution flammable: keep away from fire or flames
12. Allow to dissolve under the tongue. Do not transfer from this container. Keep tightly closed. Discard eight weeks after opening
Chapter 5: Labels

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

After: 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
Chapter 5: Labels

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 Leeds 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.
Chapter 5: Labels

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
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABPI</td>
<td>Association of the British Pharmaceutical Industry</td>
</tr>
<tr>
<td>AIFA</td>
<td>Agenzia Italian del Farmaco</td>
</tr>
<tr>
<td>APBI</td>
<td>Association of the British Pharmaceutical Industry</td>
</tr>
<tr>
<td>BNF</td>
<td>British National Formulary</td>
</tr>
<tr>
<td>BROMI</td>
<td>Better Regulation of Over-the-Counter Medicines Initiative</td>
</tr>
<tr>
<td>BSOC</td>
<td>Body System Order Class</td>
</tr>
<tr>
<td>CDH</td>
<td>Chronic daily headache</td>
</tr>
<tr>
<td>CRO</td>
<td>Contract Research Organisation</td>
</tr>
<tr>
<td>DH</td>
<td>Department of Health</td>
</tr>
<tr>
<td>EMEA</td>
<td>European Medicine Agency</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FKRGL</td>
<td>Flesch-Kincaid Reading Grade Level</td>
</tr>
<tr>
<td>FOG</td>
<td>Gunning Fog Index formula</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>GSL</td>
<td>General sales list medicines</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organisation for Standardisation</td>
</tr>
<tr>
<td>MA</td>
<td>Marketing Holder</td>
</tr>
<tr>
<td>MHA</td>
<td>Marketing Holder Authorization</td>
</tr>
<tr>
<td>MHLW</td>
<td>Ministry of Health, Labor, and Welfare</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines and Healthcare Regulatory Agency</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>OTC</td>
<td>Over-the-counter</td>
</tr>
<tr>
<td>P</td>
<td>Pharmacy medicines</td>
</tr>
<tr>
<td>Acronym</td>
<td>Full Form</td>
</tr>
<tr>
<td>---------</td>
<td>---------------------------------------</td>
</tr>
<tr>
<td>PIL</td>
<td>Patient information leaflet</td>
</tr>
<tr>
<td>PIQU</td>
<td>Patient Information Quality Unit</td>
</tr>
<tr>
<td>POM</td>
<td>Prescription only Medicine</td>
</tr>
<tr>
<td>QRD</td>
<td>Quality Review of Documents</td>
</tr>
<tr>
<td>RMS</td>
<td>Reference Member State</td>
</tr>
<tr>
<td>RNIB</td>
<td>Royal National Institute of the Blind</td>
</tr>
<tr>
<td>SFL</td>
<td>Systemic Functional Linguistics</td>
</tr>
<tr>
<td>SMOG</td>
<td>Simple Measure of Gobbledgegook</td>
</tr>
<tr>
<td>SPC</td>
<td>Summary of Product Characteristics</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
</tr>
</tbody>
</table>
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Web resources

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MHRA, Labels, patient information leaflets, and packaging for medicines, available at:
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http://www.luto.co.uk/news/1_04_05.pdf

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Web resources


QRD “Human” Product information template with explanatory notes (version 7.2 EMEA 10/2006), available at:

QRD Human Product Information Templates, adopted by the QRD Working Group, available at:
http://www.emea.europa.eu/index/indexh1.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
Appendix

Avodart

DOSAGE AND ADMINISTRATION

Avodart is used to treat men with an enlarged prostate (benign prostatic hypertrophy - BPH) - a non-cancerous growth of the prostate gland, caused by producing too much of a hormone called dihydrotestosterone. The active ingredient in Avodart 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 floor of the urethra to be shown and less able to function because of the pressure from the prostate. Avodart will not cure your enlarged prostate gland, but it will help to reduce the size of your prostate gland, which may help to improve your ability to move urine out of your body. Avodart may be used with another medicine called tamsulosin (used to treat the symptoms of an enlarged prostate).

1 What Avodart is and what it is used for

Avodart is used to treat men with an enlarged prostate (benign prostatic hypertrophy). It is used to help your symptoms get better and may help you to pass urine more easily. However, Avodart will not cure your enlarged prostate gland, but it will help to reduce the size of your prostate gland, which may help to improve your ability to move urine out of your body.

2 Before you take Avodart

Do not take Avodart

* If you are allergic (hypersensitive) to dutasteride or to any of the other ingredients of Avodart.
* If you have had any allergic reactions affecting your face, you may have some swelling of your face, neck, and arms.
* If you have had any allergic reactions affecting your throat, you may have some swelling of your throat.
* If you have had any allergic reactions affecting your eyes, you may have some swelling of your eyes.
* If you have had any allergic reactions affecting your mouth, you may have some swelling of your mouth.
* If you have had any allergic reactions affecting your ears, you may have some swelling of your ears.
* If you have had any allergic reactions affecting your skin, you may have some redness of your skin.

Avodart can affect a blood test for prostate-specific antigen (PSA), which is sometimes used to detect prostate cancer. Any doctor should be aware of this effect and will discuss it with you. If you are having a blood test for PSA, tell your doctor that you are taking Avodart.

Take Avodart with food

Avodart should be taken once daily with or without food. Take Avodart at the same time each day. Do not break or chew the capsule. Discard any medicine that you do not take as soon as possible. Do not share medicine with anyone else.

3 How to take Avodart

Always take Avodart exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

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 your doctor or pharmacist if you have too much or too little medicine.

Avodart is a long-term treatment. Some people find that it is easier to take the capsules if they are stored in a refrigerator. However, others may need to take Avodart for 6 months or more before it begins to have an effect.

Avoid 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.

4 Possible side effects

Like all medicines, Avodart can cause side effects, although not everybody gets them.

Very rare allergic reactions

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
- allergic reaction (anaphylaxis)
- convulsions or seizures (for high blood pressure)
- breathing difficulties (for high blood pressure)
- swelling of the face, lips, tongue or throat.

If you experience any of these symptoms, 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.

Pregnancy and breast-feeding

Women who are pregnant for any reason must not handle Avodart capsules. Avodart is not recommended for use in breast-feeding women because it can affect the normal development or a newborn baby. This is a particular risk in the first 16 weeks of pregnancy.

Use of condoms during sexual intercourse. Avodart has been studied in men who are taking Avodart. If you are using condoms, you must avoid using them 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 using condoms during sexual intercourse. Dutasteride has been shown to decrease sperm count, semen volume and sperm motility. This could reduce your fertility.

Driving and using machines

Avodart is unlikely to affect your ability to drive or operate machines.
Appendix

Alendronic Acid Tablets (Alendronate Acid)

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

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you have any questions.
- This medicine has been prescribed for you. Do not pass it on to others.
- Do not use it for other conditions or by other people.

In the leaflet:
1. What Alendronic Acid Tablets are and what they are used for
2. Before you take Alendronic Acid Tablets
3. How to take Alendronic Acid Tablets
4. Possible side effects
5. How to store Alendronic Acid Tablets
6. Further information

1. What Alendronic Acid Tablets are and what they are used for

Alendronic acid belongs to a group of non-steroidal medicines called bisphosphonates. Alendronic acid prevents the loss of bone that occurs in women after they have reached menopause, and in men with osteoporosis. Alendronic acid reduces the risk of a spinal or hip fracture in women who are postmenopausal.

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. This can occur in women after the menopause. As your bones become thinner, they become weaker and can break more easily.

Take Alendronic Acid Tablets when you should

1. Take the tablet before you eat or drink.
2. Do not take the tablet with food or drink.
3. Do not take Alendronic Acid tablets before or during your menstrual period.
4. If you experience difficulty or pain upon swallowing, take your tablet slowly.
5. Do not lie down for at least 30 minutes after swallowing the tablet.
6. If you experience difficulty or pain upon swallowing, take your tablet slowly.

If you take more Alendronic Acid Tablets than you should

1. If you take too much, contact your doctor immediately.
2. Do not make yourself vomit, and do not give any medicines.

If you forget to take Alendronic Acid Tablets

1. Take the missed tablet as soon as you remember it.
2. Do not take a double dose of the tablet.

If you stop taking Alendronic Acid Tablets

1. This medicine may cause side effects such as nausea, vomiting, diarrhea, or constipation.
2. If you experience any of these side effects, contact your doctor immediately.

2. Before you take Alendronic Acid Tablets

Do not take Alendronic Acid Tablets

1. If you have a history of allergy to alendronic acid or any of the other ingredients of this medicine.
2. If you have a history of heartburn or acid reflux.
3. If you have any of the following symptoms: diarrhea, nausea, vomiting, or constipation.

A denial examination should be considered before you start taking Alendronic Acid Tablets if you have any of the following conditions:

1. You have cancer.

Taking other medicines

Before you use this medicine, make sure you are not taking any other medicines that might interact with this medicine. Please check with your doctor or pharmacist before taking any other medicines.

1. Take Alendronic Acid Tablets only as directed.
2. Do not take more or less than the recommended dose.
3. Do not take this medicine for longer than recommended.

Do not take this medicine if you are allergic to any of the ingredients of this medicine.

Driving and using machines

Alendronic acid tablets do not affect your ability to drive or operate machines.

Important information about some of the ingredients of Alendronic Acid Tablets

Nalidixic acid contains 25.77% of lactose. When taken according to the dosage recommendations in these tablets, you will be taking up to 27.2% of lactose. If you have been told by your doctor that you are lactose intolerant or allergic to any of the ingredients of this medicine, contact your doctor before taking this medicine.

Children and adolescents

Alendronic acid tablets should not be given to children and adolescents.

Pregnancy and breast-feeding

You should not breastfeed or breastfeed if you are pregnant or breast-feeding. Ask your doctor or pharmacist before taking any medicine.

Dosing and using machines

Alendronic acid tablets do not affect your ability to drive or operate machines.

Important information about some of the ingredients of Alendronic Acid Tablets

Nalidixic acid contains 5.77% of lactose. When taken according to the dosage recommendations in these tablets, you will be taking up to 27.2% of lactose. If you have been told by your doctor that you are lactose intolerant or allergic to any of the ingredients of this medicine, contact your doctor before taking this medicine.

Children and adolescents

Alendronic acid tablets should not be given to children and adolescents.

Pregnancy and breast-feeding

You should not breastfeed or breastfeed if you are pregnant or breast-feeding. Ask your doctor or pharmacist before taking any medicine.

Dosing and using machines

Alendronic acid tablets do not affect your ability to drive or operate machines.

Important information about some of the ingredients of Alendronic Acid Tablets

Nalidixic acid contains 5.77% of lactose. When taken according to the dosage recommendations in these tablets, you will be taking up to 27.2% of lactose. If you have been told by your doctor that you are lactose intolerant or allergic to any of the ingredients of this medicine, contact your doctor before taking this medicine.

Children and adolescents

Alendronic acid tablets should not be given to children and adolescents.

Pregnancy and breast-feeding

You should not breastfeed or breastfeed if you are pregnant or breast-feeding. Ask your doctor or pharmacist before taking any medicine.

Dosing and using machines

Alendronic acid tablets do not affect your ability to drive or operate machines.

Important information about some of the ingredients of Alendronic Acid Tablets

Nalidixic acid contains 5.77% of lactose. When taken according to the dosage recommendations in these tablets, you will be taking up to 27.2% of lactose. If you have been told by your doctor that you are lactose intolerant or allergic to any of the ingredients of this medicine, contact your doctor before taking this medicine.

Children and adolescents

Alendronic acid tablets should not be given to children and adolescents.

Pregnancy and breast-feeding

You should not breastfeed or breastfeed if you are pregnant or breast-feeding. Ask your doctor or pharmacist before taking any medicine.

Dosing and using machines

Alendronic acid tablets do not affect your ability to drive or operate machines.

Important information about some of the ingredients of Alendronic Acid Tablets

Nalidixic acid contains 5.77% of lactose. When taken according to the dosage recommendations in these tablets, you will be taking up to 27.2% of lactose. If you have been told by your doctor that you are lactose intolerant or allergic to any of the ingredients of this medicine, contact your doctor before taking this medicine.

Children and adolescents

Alendronic acid tablets should not be given to children and adolescents.

Pregnancy and breast-feeding

You should not breastfeed or breastfeed if you are pregnant or breast-feeding. Ask your doctor or pharmacist before taking any medicine.

Dosing and using machines

Alendronic acid tablets do not affect your ability to drive or operate machines.

Important information about some of the ingredients of Alendronic Acid Tablets

Nalidixic acid contains 5.77% of lactose. When taken according to the dosage recommendations in these tablets, you will be taking up to 27.2% of lactose. If you have been told by your doctor that you are lactose intolerant or allergic to any of the ingredients of this medicine, contact your doctor before taking this medicine.

Children and adolescents

Alendronic acid tablets should not be given to children and adolescents.

Pregnancy and breast-feeding

You should not breastfeed or breastfeed if you are pregnant or breast-feeding. Ask your doctor or pharmacist before taking any medicine.

Dosing and using machines

Alendronic acid tablets do not affect your ability to drive or operate machines.
Appendix
**Appendix**

### 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 result 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 heart 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.

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 so.
- 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 face, itching skin or nausea 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 or 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, you have been advised that 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:

- Diuretics or other blood thinners
- Medicines for depression
- Methotrexate for cancer, skin problems, rheumatoid arthritis, or Crohn’s disease
- Meprobamate for termination of pregnancy – do not take this medicine for 1-3 days after taking it.
- Other non-steroidal anti-inflammatory medicines, including aspirin and ibuprofen (e.g. naproxen, ibuprofen, and ketoprofen)
- Contraceptives (ask your doctor for other contraceptive methods)
- Phenylalanine and sodium valproate for epilepsy
- Tablets for diabetes (e.g. gliclazide), or insulin or insulin to take.
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**Patient Information Leaflet**

**Atarax® Tablets**

Hydroxyzine hydrochloride

- **Before you take Atarax®**
- **While you are taking Atarax®**
- **If you are pregnant or breast-feeding**
- **If you are allergic to hydroxyzine hydrochloride or any of the ingredients**
- **If you are taking other medicines**
- **Driving and using machines**
- **What to do if you take too much Atarax®**
- **What if you are taking Atarax® with other medicines**
- **Taking Atarax® with food and drink**
- **Taking Atarax® with alcohol**
- **Taking Atarax® with medicines which have already been prescribed for you**
- **Taking Atarax® with medicines which you have already bought from a pharmacy**

**Appendix**

**Atarax** (hydroxyzine hydrochloride) is a sedating antihistamine. It is used to treat allergies and is available as tablets, syrup, and cream.

1. **What is Atarax and how it is used for**
   - **Atarax belongs to a group of medicines called antihistamines**
   - **It is used to treat allergic reactions such as hives (urticaria) and angioedema (swelling)**

2. **Check before you take Atarax**
   - **Check with your doctor or pharmacist**
   - **Check with the manufacturer**

3. **What you should tell your doctor or pharmacist**
   - **If you have any of the following conditions**
   - **If you are pregnant or breast-feeding**
   - **If you are allergic to hydroxyzine hydrochloride or any of the ingredients**
   - **If you are taking other medicines**

4. **What to do if you take too much Atarax**
   - **If you take an extra dose**
   - **If you take an extra dose by accident**

5. **What if you are taking Atarax with other medicines**
   - **If you are taking other medicines**
   - **If you take an extra dose by accident**

6. **What to do if you take Atarax with alcohol**
   - **If you take an extra dose by accident**

7. **What to do if you take Atarax with other medicines**
   - **If you take an extra dose by accident**

8. **What to do if you take Atarax with medicines which have already been prescribed for you**
   - **If you take an extra dose by accident**

9. **What to do if you take Atarax with medicines which you have already bought from a pharmacy**
   - **If you take an extra dose by accident**

10. **How to store Atarax**
    - **If the tablet is already dispensed**
    - **If you have returned the tablet to the pharmacist**

11. **Appendix**
    - **If you have any questions or concerns**
    - **If you have any side effects**

12. **Further information**
    - **What is Atarax?**
    - **How it works in the body**
    - **How it is taken**
    - **Possible side effects**
    - **What should happen if you take too much Atarax?**
    - **What to do if you take Atarax with other medicines**
    - **What to do if you take Atarax with medicines which have already been prescribed for you**
    - **What to do if you take Atarax with medicines which you have already bought from a pharmacy**

13. **Marketing Authorisation Holder and Manufacturer**
    - **Atarax** is a trademark of Alliance Pharmaceuticals Limited.
Appendix

PACKAGE LEAFLET INFORMATION FOR THE USER

Azathioprine 50mg Tablets

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
2. BEFORE YOU TAKE AZATHIOPRINE 50MG TABLETS
3. HOW TO TAKE AZATHIOPRINE 50MG TABLETS
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE AZATHIOPRINE 50MG TABLETS
6. FURTHER INFORMATION
7. TAKING OTHER MEDICINES
8. TELL YOUR DOCTOR IF YOU ARE TAKING OR HAVE TAKEN ANY OF THE FOLLOWING MEDICINES AS THEY MAY INTERACT WITH YOUR AZATHIOPRINE TABLETS:
9. PRECAUTIONS AND BREAST-FEEDING
10. DRIVING AND USING MACHINES
11. HOW TO TAKE AZATHIOPRINE 50MG TABLETS

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 disease).

Azathioprine Tablets are used to:
- help your body accept a kidney, liver, heart, lung or pancreas transplant.
- [Azathioprine Tablets are also used together with other medicines in order to enhance their effect]
- treat severe dermatological or digestive disorders
- treat severe inflammatory diseases of the joint (such as rheumatoid arthritis)
- treat some diseases where your immune system is reacting against your own body (autoimmune disease) 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.
- you are allergic to any of the other ingredients in the tablet (see section 6 Further Information).
- you have a severe infection.
- you have severe liver or kidney problems.
- you have an infection or have been treated for an infection in the last 6 weeks.
- you have had a blood transfusion or have had to use many blood products.
- you are pregnant (see "Pregnancy and Breast-Feeding") or trying to conceive.
- 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:
- you or your child have had any liver or kidney problems.
- you have a condition where your body produces too little of a natural chemical called thymidine phosphorylase (TPAT).
- you have an infection which you have not yet received treatment for.
- you are pregnant or trying to conceive (see "Pregnancy and Breast-Feeding").
- you are going to have an operation (this is because medicines including thalidomide, penicillin V or sulphonamide may interact with your Azathioprine Tablets).
- if you have a rare genetic disorder called "Grave's Disease syndrome".

Consult your doctor if you are taking 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 you may be pregnant.

Do not take the tablet 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 or 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 the tablets during meals.

Your doctor will monitor how you respond to your medicine and may change your dose if required.

After organ transplant

A dose of 2mg 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 the medication.

Pregnancy with inactive ingredients

The usual dose is between 1 and 1.5mg per kilogram of your bodyweight per day.

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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 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 to 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 weight changes, 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)
• loss of appetite (anorexia).

**Common side effects** (probably affecting less than 1 in 10 patients):
• liver disease
• increased infections in patients with bowel inflammation
• reduced in blood platelets which increases risk of bleeding or bruising

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 difficulty in breathing, low blood pressure, fever, feeling cold, feeling severely sick and vomiting, diarrhoea, rash, rashes, kidney problems, muscle pain (myalgia), pain in the joints (arthritis), inflammation of blood vessels (vasculitis), high number of liver enzymes.

**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 (anhaeits anaemia)
• cough and fever caused by pneumonia or inflammation of the lungs.

**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, Mmribal, maize starch, Povidone K25, Croscarmellose sodium, Sodium stearyl fumarate.
- **Tablet coating:** 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, 60 and 100 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturers**

**Marketing Authorisation Holder:**

- **Arrow Genetics Limited,** Unit 2, Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom

**Manufacturer:**

- **Arrow Pharm (Malta) Limited,** 62, Hal Far Industrial Estate, Birkirkara BKR 06, Malta

This leaflet was last approved in 07/2008.

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Appendix

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 use this medicine:
  - if you are pregnant or breast feeding.
  - if you are allergic to pseudoephedrine or acrivastine.

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 medicine. See Section 2.
- Follow the dosage instructions carefully. See Section 3.

What the medicine is for
Benadryl PLUS Capsules are a medicine which is used to relieve the symptoms of hay fever and similar allergic conditions. This medicine contains pseudoephedrine hydrochloride, which is a decongestant that reduces nasal and sinus congestion and acrivastine which is an antihistamine that helps relieve allergy symptoms such as sneezing, runny nose and watery eyes.

How to take this medicine
Check the table below to see how much medicine to take.

1. Adults under 65 years old
   - Do not exceed 2 capsules in 24 hours.

2. Adult 65 years old or over
   - Do not exceed 1 capsule in 24 hours.

Possible side-effects
Benadryl PLUS Capsules can have side-effects. Like all medicines, although these do not affect everyone and are usually mild.

Other effects which may occur include:
- Tachycardia, having trouble getting to sleep or bad dreams.

Storing this medicine
Store below 25°C.

Further Information

What's in this medicine?
The active ingredients in Benadryl PLUS Capsules are: pseudoephedrine hydrochloride and 8 mg of acrivastine.

Other ingredients are: lactose, sodium starch glycolate, 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 3UC, UK.

Manufacturers:
Janssen-Cilag Ltd, Domaine de Maigremont, 27100 Val de Reuil, France.

This leaflet was revised September 2008.

Benadryl is a registered trade mark.
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.

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.

4 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.

4 Possible side-effects

Benylin Children's Chesty Coughs can cause side-effects, like all medicines, although these don't affect everyone and are usually mild.
- If you experience any side-effects or are not sure about anything, talk to your doctor or pharmacist.

5 Storing this medicine

Do not store the product above 25°C.

Store in the original package.

Keep this medicine out of the reach and sight of children.

Do not use after the end of the month shown on the expiry date on the packaging.

6 Further information

What's in this medicine?

The active ingredient is 9.5 ml of Benylin Children's Chesty Coughs 50 mg Guifenesin.

Other ingredients are: Glycerol, sorbitol liquid (E420), citric acid, sodium citrate, sodium benzoate, sodium benzoate (E211), citric acid monohydrate, strawberry flavour and water.

What the medicine looks like

Benylin Children's Chesty Coughs is a clear colourless syrup, available in 125 ml glass bottles.

Product Licence holder: Mead Johnson Products Ltd, Hungerfleet, Berkshire, SL6 9JU, UK.
Manufacturer: Mead Johnson Manufacturing, 5 avenue de Cormay, 62157 Lille, France.

This leaflet was revised April 2009. Benylin is a registered trade mark.
Appendix

Buscopan® Tablets
(hyoscine butylbromide)

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
2. Before you take BUSCOPAN Tablets
3. How to take BUSCOPAN Tablets
4. Possible side effects
5. How to store BUSCOPAN Tablets
6. Further Information

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)
• Malding 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, solubil 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, Brocknell, Berkshire, RG12 0YS, 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.
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(back page)
Appendix
Appendix

PACKAGE LEAFLET: INFORMATION FOR THE USER
Celluvinc® 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 Celluvinc 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 get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Celluvinc 0.5% w/v. Eye drops, solution, unit dose but will be referred to as Celluvinc throughout the remainder of the leaflet.

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

1. What Celluvinc is and what it is used for
Celluvinc is a tear substitute and contains a lubricant called carmellose sodium. It is used for the treatment of the symptoms of dry eyes (such as涩涩iness, burning, irritation or dryness) caused by your eyes not producing enough tears to keep the eye wet.

2. Before you use Celluvinc
Do not use Celluvinc
- if you are allergic to any ingredients in carmellose sodium or any of the other ingredients of Celluvinc. These are listed at the end of this leaflet in section 6 "Further information".

Take special care with Celluvinc:
- if you have a history of sensitivity to carmellose sodium or any of the other ingredients of Celluvinc. These are listed at the end of this leaflet in section 6 "Further information".

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 the application times of Celluvinc and the other eye drops.

Pregnancy and breast-feeding
Celluvinc can be used during pregnancy and breast-feeding.

Drug interactions
Celluvinc is not expected to cause blurred vision. If you do experience temporary blurring, do not drive or use machinery 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 Celluvinc
Follow these instructions unless the pharmacist or your doctor gave you different advice.
The usual dose is 1-2 drops of Celluvinc in the affected eye(s) each affected eye, 4 times a day or as needed.
You do not need to remove contact lenses before using Celluvinc. Make sure that the single-dose container is intact before use. The solution must 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 open 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 Celluvinc 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 Celluvinc, 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, Celluvinc can cause side effects, although not everybody gets them.

Common side effects (occurring in between 1 and 10 patients in every 1000 use):
- redness of the eye, blurred vision, eye watering and redness of the eyelids.

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 Celluvinc
Keep out of the reach and sight of children.
Do not store above 25°C.
Do not use Celluvinc after the expiry date on the pack. If the expiry date has passed, do not use the medicine.
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.

Nestle’s 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 Celluvinc contains
Each 1 ml contains 5 mg carmellose sodium
The other ingredients are sodium hydroxide, sodium citrate, potassium chloride, sodium citrate, magnesium chloride and purified water.

The ingredients in Celluvinc were designed to match the natural tear composition.

What Celluvinc looks like and the contents of the pack
Celluvinc is a clear, colourless, tear replacement solution in a small, plastic and see-through glasside tube (known as a single-dose container).
The single-dose container has a twist of cap. Each single-dose container contains 0.5 ml of eye drops solution.
Each pack contains 20 or 50 single-dose containers.

PL 2077/1150 Celluvinc 0.5% w/v, Eye drops, solution, unit dose
P

Manufactured by Allergan Pharmaceuticals Ireland, Castledermot Road, Westport, Co. Mayo, Ireland. Produced from within the EU. Product Licence Holder: Quintiles Pharmaceuticals Llc, Lusk Road, Lusk, Dublin, D18 B4A. Repackaged by Maestro Ltd, Bethlen, BL6 4SA.

Leaflet Revision date: 1st July 2011
Celluvinc is a registered trademark of Allergan Inc.
PP11109/MV
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, diarrhea, 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 10,000 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 4.4). The syndrome of inappropriate antidiuretic hormone secretion (SIADH). Symptoms: 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.

## 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.

## 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 (E403), colloidal silica (E744), 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, Barnstable, EX32 9NS, UK

Date of revision: July 2010

## Citalopram 10mg, 20mg and 40mg tablets

- are taking, or have taken within the last two weeks, any monoamine oxidase inhibitors (MAO inhibitors). These are medicines used to depression or Parkinson’s disease (e.g. selegiline or moclobemide)
- are taking pimecrolim (an antipsychotic medicine) or linezolid (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)
- 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-cardioversion or therapy (ECI).
- 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), almotriptan or topothan (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:

## Index

1. What Citalopram tablets are and what they are used for
2. Before you take
3. How to take
4. Possible side effects
5. How to store
6. Further information

## 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.

## 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).
CLOPIDOGREL 75 mg FILM-COATED 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 take it if you are not prescribed.

It may harm them, even if their symptoms are the same as yours.

If any of the side effects persist or become severe, 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
2. Before you take CLOPIDOGREL Tablets
3. How to take CLOPIDOGREL Tablets
4. Possible side effects
5. How to store CLOPIDOGREL Tablets
6. Further information

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 the clumping, antiplatelet medicinal products reduce the chance of blood clots forming at places called arterial or venous arteries.

CLOPIDOGREL Tablets are taken to prevent blood clots (thrombosis) forming in hardened blood vessels (arteries), a process known as atherosclerosis, 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 seven events because:

- You have a history of hardening of the 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 (see section 3.4).
- 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 history of any of the following medical conditions:
  - a medical condition that puts you at risk of internal bleeding (such as a stomach ulcer) or
  - a medical condition that prevents you from being able to bleed internally (bleeding outside the body).
- If you have a recent surgery (including dental).
- If you have a recent surgery (including dental) in the next seven days if you have had a clot in an artery of your brain (encephalitic 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 you are taking any other medicine (including dental) which has a long-term effect on the blood.
- You should tell your doctor if you are taking any other medicine (including dental) which has a long-term effect on the heart or if you are taking any other medicine which is known to affect blood clotting.
- You should tell your doctor if you are taking any other medicine which is known to affect blood clotting.
- You should tell your doctor if you are taking any other medicine which is known to affect blood clotting.

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 1.5 mg tablet per day to be taken once a day with milk, fruit juice, or other food, but in the same time each day.

If you take more CLOPIDOGREL Tablets than you should:

Contact your doctor or the Poisons Information Centre for advice on what to do if you or anyone else has taken too much CLOPIDOGREL Tablets with your first bite.

If you are unsure or you have a doubt about how much CLOPIDOGREL Tablets to take or how much to take, ask your pharmacist and they will explain it to you.

4. POSSIBLE SIDE EFFECTS

Like many medicines, CLOPIDOGREL Tablets can cause side effects, although not everybody gets them.

Contact your doctor immediately if you experience:
- severe, sudden onset of chest pain or breathlessness.
- signs of serious bleeding such as bleeding from the mouth or the nose, coughing, vomiting, or bleeding from the skin, bruising, internal bleeding, or taking longer than usual to recover from an injury or surgery.
- signs of major blood clots such as severe chest pain or severe pain in the leg.
- signs of serious bleeding such as bleeding from the skin, bruising, internal bleeding, or taking longer than usual to recover from an injury or surgery.
- signs of major blood clots such as severe chest pain or severe pain in the leg.
- signs of serious bleeding such as bleeding from the skin, bruising, internal bleeding, or taking longer than usual to recover from an injury or surgery.
- signs of serious bleeding such as bleeding from the skin, bruising, internal bleeding, or taking longer than usual to recover from an injury or surgery.

If you experience prolonged bleeding when taking CLOPIDOGREL Tablets:
- If you are in any doubt about how much CLOPIDOGREL Tablets to take or how much to take, ask your pharmacist and they will explain it to you.

If you need to stop taking CLOPIDOGREL Tablets:
- Do not stop taking CLOPIDOGREL Tablets without consulting your doctor first.

5. HOW TO STORE CLOPIDOGREL TABLETS

Keep out of reach of children.

Do not dispose of medicines. If your doctor or pharmacist tells you that you have taken too much CLOPIDOGREL Tablets, follow the advice which is on the container and/or the leaflet which is before or after the IDP. The medical product decision must not require any special storage conditions.

Do not use CLOPIDOGREL Tablets after the expiry date which is on the container and/or the leaflet which is before or after the IDP. The medical product decision must not require any special storage conditions.

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

6. FURTHER INFORMATION

What CLOPIDOGREL Tablets contain
The active ingredient is clopidogrel. Each film-coated tablet contains 75 mg of clopidogrel (as besilate).

- The other ingredients are:
  - Carbomer 980, calcium sulphate dihydrate, lactose monohydrate (E421), magnesium stearate, sodium starch glycolate (E472f), talc, titanium dioxide (E171).

CLOPIDOGREL Tablets look like contents of the pack CLOPIDOGREL Tablets are pink in colour and oval in shape.

This leaflet is approved by PREGIONAL Ltd. Lithuanian in LFPJU AUKSJU Tabletų produkcijos centras contains 14, 36, 56, 84, 96, 108 or 109 film-coated tablets. Not all packs sizes may be marketed.

Benzing Authorization Holder and Manufacturer:

This leaflet was last updated on July 2013.
Appendix
Appendix

PATIENT INFORMATION LEAFLET
Codemed Pharmaceuticals Limited

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

If you have any questions, a doctor, pharmacist or other health professional.

The name of the medicine is Codemed Pharmaceuticals Limited. It is supplied in the form of tablets for oral administration and comes in packs containing 15 tablets in blisters of 4.

1. Before you take co-codamol

Important things you should know about co-codamol

Be sure to talk to your doctor before taking it.

Taking co-codamol for long-term may lead to tolerance and dependence. Do not increase the dose or add another drug without discussing this with your doctor.

2. 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.

3. POSSIBLE SIDE EFFECTS

As with all medicines, co-codamol can cause side effects, although not everybody gets them. The following side effects may occur with this medicine.

Taking co-codamol with food and drink

You should not drink alcohol while you are taking this medicine. This is because taking co-codamol can change the way you feel.

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:

Talk to your doctor or pharmacist before taking these tablets.

Usually it is safe to take Co-Codamol with breast feeding if the levels of codeine in breast milk are low enough to cause your baby any problems. However, some women who are on treatment with immediately taking the dose of aspirin or codeine in breast milk are low enough to cause your baby any problems. However, some women who are on treatment with.

Taking co-codamol with food and drink

You should not drink alcohol while you are taking this medicine. This is because taking co-codamol can change the way you feel.

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:

Talk to your doctor or pharmacist before taking these tablets.

Usually it is safe to take Co-Codamol with breast feeding if the levels of codeine in breast milk are low enough to cause your baby any problems. However, some women who are on treatment with immediately taking the dose of aspirin or codeine in breast milk are low enough to cause your baby any problems. However, some women who are on treatment with.
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: This medicine 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 other medicine called dopaminergic, which will not affect the effectiveness of your medicine. You may experience more side effects if you also take dopaminergic.

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 Finasteride 5mg Tablets than you should
If you take more than the recommended number of tablets, contact your doctor or pharmacist for advice. Sleepwalking, inability to maintain erections and sleepwalking as these may be signs of a serious condition, such as heart 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 breast, problems with ejaculation, also rare.

Rare side-effects include: Allergic reactions including itching, rashes or swelling of the face and lips, pain, headache, loss of sexual desire 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.

4. Possible side effects

Use 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 heart area such as lump, pain, swelling of the breast tissue or nipple discharge as these may be signs of a serious condition, such as heart cancer.

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, colloidal silicon dioxide (E460), starch pregelatinised, potassium chlorate (E516), magnesium stearate (E462). The coating of these tablets contains hypromellose (E464), titanium dioxide (E171), magnesium and magnesium stearate (E172). The weight of each tablet is 6.48 g.

What Finasteride 5mg Tablets looks like and 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 packaged in blister packs containing 28, 30, 60 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 Iverhouse Road, Boreham, Chelmsford, Essex CM3 6JL
UK
Tel: +44 (0) 1245 887042

This leaflet was last amended on 14th May 2019.

Presented by: Finasteride 5mg Apar Group companies licenced by EUP.
Appendix

• Feeling 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 dizzy, 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 flecaainide 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 to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What flecaainide tablets contain
Each tablet contains 50mg or 100mg of flecaainide acetate as the active substance.

The other ingredients are microcrystalline cellulose, maize starch, pregelatinised maize starch, croscarmellose sodium and magnesium stearate.

What flecaainide 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 “CF” above the line and “F1” below, the reverse side embossed with a breakline.

The tablets are available in blister packs of 60 tablets.

Marketing Authorisation Holder and Manufacturer
Centlivra, One Oatley Street, Guildford, Surrey, GU1 4YS, UK
Manufacturer:
Centlivra, One Oatley 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

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60000081

PATIENT INFORMATION LEAFLET

FLECAINIDE ACETATE 50MG AND 100MG TABLETS

Flecaainide 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 flecaainide is and what it is used for
2. Before you take flecaainide
3. How to take flecaainide
4. Possible side effects
5. How to store flecaainide
6. Further information

1. WHAT FLECAINIDE IS AND WHAT IT IS USED FOR

What flecaainide is
The name of your medicine is Flecaainide Acetate 50mg or 100mg Tablets (called flecaainide 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.

Flecaainide 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 flecaainide or any of the other ingredients of this medicine (listed in Section 6 below)
• Signs of an allergic reaction include: a rash, swelling 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 ‘sinus-atral’ 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 flecaainide.
IN THIS LEAFLET
1. What your medicine is and what it is used for
2. How to take your medicine
3. Possible side effects of your medicine
4. How to store your medicine
5. Further information

1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

The name of your medicine is Flucloxacillin. 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). If you react to a penicillin antibiotic, you may also react to other penicillin antibiotics.
- You have ever had an allergic reaction to any of the 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 25mg, 500mg per tablet. 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 this medicine could cause them in women
- 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)
- Metronidazole (used to treat bacterium, ulcers, and some skin diseases)
- 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.

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
- Up to 1g daily, in divided doses six to eight hours
- Surrounded by:
- 1 to 2g every 24 hours as one hour before or up to 48 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 lower doses.

When to take your medicine:
- Take your medicine on an empty stomach, at least thirty minutes before some hours. 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 until your doctor tells you to. If you stop taking the medicine, your infection may become more serious. If you are still unwell after taking all the medicine, go and see your doctor.

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 need serious. However, some may be serious and need medical attention.

Read common side effects

Allergic reactions especially skin rash. Other reactions include nausea, fever, joint pain, rash, swelling of the face, tongue, mouth, tongue in throat, tarry stools, abdominal pain, and yellowing of the skin and eyes. Discontinue medicine immediately and contact your doctor.

Occasional side effects:
- Some mouth
- Rare side effects:
- Dizziness, heart attacks, and feeling sick
- Should be mild and wear off after a few days. If severe or lasting longer, tell your doctor.

5. HOW TO STORE YOUR MEDICINE

Do not use this medicine after the expiry date shown on this label. Keep this medicine in a safe place where children cannot see or reach it.

6. FURTHER INFORMATION

What Flucloxacillin Capsules BP contain:
Active ingredient: Flucloxacillin sodium.
Other ingredients: Sodium starch glycolate, magnesium stearate, red iron oxide (E172), yellow iron oxide (E172), and magnesium stearate (E475), and gelatin.
Please see further information on side-effects in section 2.

What Flucloxacillin Capsules BP look like:
250mg capsules are opaque, clear-grey, and printed with "NTM 25" in black ink. The capsules contain a plastic bag.
500mg capsules are opaque, clear-grey, and printed with "NTM 500" in black ink. The capsules contain a plastic bag.
Both strengths are available in the following pack sizes:
Pack sizes are available in packs sizes of 10, 15, 20, 30, 50, 100, 250 & 500 capsules.
Blister packs are available in packs sizes of 10, 15, 20, 31, 30, 40, 50, 100, 250 & 500 capsules.
No all pack sizes may be marketed.

The licence holder and manufacturer is:
Aphex Laboratories Limited, Balanor, Co. Roscommon, Ireland.
PLS43360015
PLS43360016

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 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 Half Sinemet CR Tablets and what is it used for?
2. Before you take Half Sinemet CR Tablets
3. How to take Half Sinemet CR Tablets
4. Possible side effects
5. More about Half Sinemet CR Tablets
6. Further information

1. WHAT IS HALF SINEMET CR TABLETS AND WHAT IS IT USED FOR?

Half Sinemet CR Tablets improve the signs of Parkinson's disease. Parkinson's disease is a long-term illness where you have difficulty moving. This makes it more difficult for you to do daily activities. Parkinson's disease may develop more completely in people who have been diagnosed with Parkinson's disease. Parkinson's disease may affect the way you move and think. This leaflet will help to improve the signs of Parkinson's disease by controlling the symptoms.

2. BEFORE YOU TAKE HALF SINEMET CR TABLETS

Do not take Half Sinemet CR Tablets if:
- you are allergic (hypersensitive) to carbamazepine or any of the other ingredients of Half Sinemet CR Tablets (listed in Section 6).
- you have ever had skin cancer or you have rare familial disease which have not been examined by your doctor.
- you are taking certain medicines called MAO inhibitors (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 "malignant glaucoma" that is likely to build up pressure in the eye.
- you have a serious mental disorder.
- you are pregnant, make pregnant or breastfeed. There is no evidence to show that Half Sinemet CR Tablets affect the medicine.

3. HOW TO TAKE HALF SINEMET CR TABLETS

Are there any instructions you should follow while taking Half Sinemet CR Tablets?

4. POSSIBLE SIDE EFFECTS

If you do not have levodopa before the treatment starts in the Half Sinemet CR Tablets is one tablet a day.

5. HOW TO STOP TAKING HALF SINEMET CR TABLETS

If you have taken more than the recommended amount of Half Sinemet CR Tablets, or if you think you may have taken too much Half Sinemet CR Tablets:
- contact your doctor or pharmacist as soon as possible.

6. FURTHER INFORMATION

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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 have been, 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. How to use Hydrocortisone Ointment
3. Before you use Hydrocortisone Ointment
4. Possible side effects
5. Further information
6. Patient Information

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

Hydrocortisone Ointment is a smooth 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 dermatological skin conditions, including eczema and dermatitis of all types, such as:
- atopic dermatitis
- nummular dermatitis
- lichen simplex chronicus
- annular dermatitis caused by irritants or allergies
- lichen planus
- lichen nitidus
- lichen amyloidosis
- scalp, face, and other dermatomic conditions
- irritant or eczematous lesions

Before you use Hydrocortisone Ointment
Do not use Hydrocortisone Ointment if you:
- have an allergy to hydrocortisone or any of the other ingredients in Hydrocortisone Ointment (see Section 6 and end of Section 4).
- have a bacterial infection (e.g. impetigo), viral infection (e.g. herpes simplex) or fungal infection (e.g. tinea, also called ringworm)

Take special care with Hydrocortisone Ointment
Hydrocortisone Ointment is sold suitable for use on the face in the following cases:
- Allergic skin reactions including erythema and urticaria.
- Conditions involving the dermatitis (e.g. atopic dermatitis, nummular dermatitis).

Take care to avoid contact with the eyes and mouth.

Your doctor may advise the use of a mild topical treatment at the same time as Hydrocortisone Ointment and 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 breastfeeding
Tell your doctor if you are pregnant or may be pregnant. Ask your doctor for advice before taking any medicine during pregnancy. There is a very small risk of malformation in the unborn child if this product is used during pregnancy.

If you are breastfeeding, do not apply the product to your breast area.

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

2. BEFORE YOU USE HYDROCORTISONE OINTMENT

3. HOW TO USE HYDROCORTISONE OINTMENT

Always use Hydrocortisone Ointment exactly as your doctor has told you. Your doctor will tell you how much to apply and how often.

Do not exceed the stated dose.

Before application to the skin:
1. Wash your hands thoroughly before use.
2. Apply the ointment sparingly to the affected area.
3. Once applied, do not cover the area with any dressing or plaster.

Increase the interval 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 pack with you to help identification.

If you forget to use Hydrocortisone Ointment
If you forget 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.

- dizziness, drowsiness, or feeling light-headed in some patients.

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 30 °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 container. Medicines should not be disposed of via wastewater or unauthorized 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 in Hydrocortisone Ointment contains 10 mg in every 1g (1%)"
- "The other ingredients are: water, isopropyl myristate, propylene glycol, and parabens (see end of Section 6 for further information)."

What Hydrocortisone Ointment looks like and contains of the pack
The product is a smooth white ointment and is available in aluminium tubes containing 5g, 10g, 20g, 30g or 50g. No other pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Perrigo Limited, Dungannon, County Tyrone, Ireland.
PL 059123456

This leaflet was last updated in 202000
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
2. Before you take ISTIN
3. Possible side effects
4. How to store ISTIN
5. Further information
6. Further information

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 can pass 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 Amiodarone, or any of the other ingredients of this 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 heart valve (aortic stenosis), unstable angina or congestive 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:
- Renal 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 medicine obtained without a prescription.

Taking ISTIN with food and drink
Your medicine can be taken before or after food. Grapefruit juice and grapefruits should not be consumed by people who are taking ISTIN. It is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amiodarone, which can cause an unpredictable increase in the blood pressure lowering effect of ISTIN.

3. 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 serious:
- Fainting, unconsciousness, 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 causes you problems or if they last for more than one week, you should contact your doctor.

Common side-effects:
- Headache, dizziness, sleepiness
- Hypertension (awareness of your heart beat), flushing
- Abdominal pain, feeling sick (vomiting)
- 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:
- Headache, dizziness
- Trembling, loss of balance, feeling of warmth
- Nausea, vomiting
- Loss of appetite
- Visual disturbances, ringing in the ear
- Lower blood pressure
- Shortness of breath, worsening of heart failure

4. FURTHER INFORMATION

What ISTIN contains
- The active substance is Amiodarone (as amiodarone hydrochloride).
- The other ingredients are: dibasic calcium phosphate, magnesium stearate, hydroxypropyl cellulose and microcrystalline cellulose.

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 oval marked AP-5 on one side and the Pfizer logo on the other. They contain 5mg amiodarone hydrochloride. The 10mg tablets are white; emerald shaped oval marked AP-10 on one side and the Pfizer logo on the other. They contain 10mg amiodarone hydrochloride. ISTIN comes in packs of 28 tablets.

Marketing Authorisation Holder
Pfizer Limited
Ramsey Road
Sandwich
Kent CT13 9NR
United Kingdom

Manufacturer
Pfizer Manufacturing Deutschland GmbH
Hannover Park Hill 2
30727 Hanover
Germany

This leaflet was approved in March 2019

Ref Code: IS14_3 UK

Appendix

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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 side reactions, which may develop into more serious problems if they are not treated.

These symptoms are more likely to happen during the first few months after starting Lamictal, especially if you have been treated with other medicines in the past. Follow the instructions below to help prevent these symptoms.

If you notice any of these symptoms:

- Consult a doctor immediately. Your doctor may decide to stop taking Lamictal.

Very common side effects

These may affect more than 1 in 10 people:

- abdominal pain
- headache
- feeling dizzy
- feeling sleepy or drowsy
- weakness and lack of coordination (incoordination)
- dizziness of blurred vision
- feeling or being sick (nausea)
- loss of appetite.

Common side effects

These may affect up to 1 in 10 people:

- appetite or interest
- unusual eye movements (difficulty)
- shaking or trembling
- difficulty in sleeping
- dizziness.

Rare side effects

These may affect up to 1 in 100 people:

- tiredness
- loss of appetite
- nightmares and anxiety
- feeling or being sick (nausea)
- unusual behavior.

According to the information at the beginning of Section 4.

Very rare side effects

These may affect up to 1 in 10 000 people:

- hallucinations
- abnormal thinking or behavior.

According to the information at the beginning of Section 6.

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

Each tablet contains 25 mg, 50 mg, 100 mg or 200 mg lamotrigine. The active substance is lamotrigine. Each tablet also contains:

- lactose monohydrate, maize starch, 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.

Marketing Authorisation holder

Marketing Authorisation holder: GlaxoSmithKline UK Limited. 

GNU/Linux Foundation

If you have any further questions about the content of this leaflet or want to know where to get medical advice, please contact your doctor or pharmacist.

Leaflet date: June 2011

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Appendix
Appendix
Take special care with LIQUIFILM TEARS:

- Stop using LIQUIFILM TEARS and consult 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 in 3 days after having started treatment with LIQUIFILM TEARS.

Using other medicines

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 breastfeeding

You can use LIQUIFILM TEARS if you are pregnant and when you are breastfeeding.

Driving and using machines

Your sight may become blurred for a short time after using LIQUIFILM TEARS. Do not drive or use machinery 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, 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".

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.

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 anything else. Put the screw-cap back on to close the bottle. Store 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: 1.4% w/v eye drops, solution Polyvinyl alcohol
Appendix

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 LISISONPRIL 2.5mg tablets / LISISONPRIL 5mg tablets
LISISONPRIL 10mg tablets / LISISONPRIL 20mg tablets

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 “S” and a breakline on one side and “BL” on the reverse.

The 5mg 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, 120, 280, 500 or 1000 tablets who will then provide you with the required number of tablets as prescribed by your doctor.

DO NOT TAKE THIS MEDICINE IF:

You are allergic to lisinopril, other ACE inhibitors (e.g. enalapril) or any of the other ingredients in the tablets which are listed above. (An allergic reaction may be one 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 arteries to one or both kidneys.

You are suffering from cardiogenic shock (blood 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 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 have 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-sparing diuretics 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 metaproterenol such as calcium channel blockers and meperidine or other diuretics (water tablets) such as hydrochlorothiazide.

- Insulin or antidiabetic medicines taken by mouth.

- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, diclofenac or aspirin.

- The drug Warfin (used to treat depression) as your doctor will want you to have regular blood tests when this is taken in conjunction with lisinopril.

- Atropine (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, or have connective tissue disorders eg systemic lupus erythematosus and scleroderma, have low immunity 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
Swallow the tablets whole with a glass of water. You should take the tablets as a single dose at approximately the same time each day.

The dosage of Lisinopril tablets required depends on the condition being treated and varies according to the needs of each individual patient. Take the tablets exactly as directed by your doctor, which will be written on the pharmacist’s label. If you do not understand the directions, ask your pharmacist or doctor to explain them to you.

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 is 20 mg once daily, with a maximum daily dose of 40 mg. For patients suffering from heart failure, the usual effective dose is 8 to 20 mg per day.

If you are also taking a diuretic medicine, your doctor will probably have already changed your diuretic medicine or reduced your dosage for 2 to 3 days before starting your treatment with Lisinopril Tablets. The dose may be reduced later if this is considered necessary by your doctor.

For unstable angina, the initial dose is 5 mg daily for 2 days, increased to 10 mg daily thereafter for 2 weeks. Patients with very high 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 nondialysis days the dose given will depend on the patient’s 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 2.5 mg and 5 mg once daily, which can be increased to a maximum of 50 mg to 100 mg once daily. Patients with hypotensive 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 take your next dose at its regular time. 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 breastfeeding:
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 breastfeeding or about to start breastfeeding. Lisinopril is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

Possible Side-Effects
As with all medicines there is a possibility of unwanted effects while taking this medicine.

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, shakiness of breath, inflamed red or itching skin, These are signs of a severe allergic reaction, which can occur rarely.
- Blisters of the skin, rash, eyes or genitals
- If you notice any of the following, tell your doctor straight away:
- Sweating or severe chest pain (signs of angina or a possible heart attack), sudden 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 common side-effects include:
- Appetite and other blood cell disorders which may result in bulging (haemorrhage) under the skin or signs of infection such as sore throat or fever, high blood levels of potassium which can cause abnormal heart rhythms, low blood levels of sodium which can cause weakness and confusion, muscle twitching, fits 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, taking or peeling of the skin.
- Impotence, fever, sensitivity to light, joint pain or swelling, muscle pain, inflammation or blood vessels.
- Increased levels of waste products in the blood (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 tablet**

Keep out of reach of children.

Blister: 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 use all tablets that you no longer need. Give them back to the pharmacist.

This leaflet was last revised in August 2010.

(back page)
Metoprolol Tartrate 50mg and 100mg tablets

- Pregnancy and breast feeding
- Metoprolol Tartrate tablets are not recommended during pregnancy or breast feeding. Ask your doctor or pharmacist for further advice before taking any medicine.

- Blood pressure
- Metoprolol Tartrate tablets may make you feel tired and sleepy. Make sure you know how you react to this medicine before driving a car or operating machines, particularly after changing to another medicine or taking alcohol with Metoprolol Tartrate tablets.

- Anaesthetic and surgery
- If you are going to have an operation or an anaesthetic, ask your doctor or dentist if you are taking Metoprolol Tartrate tablets, as your heart rate might slow down too much.

- How to take
- Always take your medicine exactly as your doctor or pharmacist has told you. If you are unsure, check with your doctor or pharmacist.

Usual dose
- High blood pressure: initially 100mg metoprolol tartrate daily. The dose may be increased to 200mg daily in one or divided doses.
- Angina: 50-100mg metoprolol tartrate two or three times daily.

- Irregular heart beats (arrhythmia)
- Stopping metoprolol tartrate three or four times daily. The dose may be increased to 100mg daily in divided doses.

- Heart failure
- Stopping metoprolol tartrate every six hours. The usual maintenance dosage is 150-225mg a day in divided doses.

- Other (types of conditions)
- Stopping metoprolol tartrate three or four times daily.

- Prevention of migraine
- Take metoprolol tartrate daily in divided doses in the morning and evening.
- Children
- Under 12 years.

- Patients with impaired kidney or liver function
- In such cases the dose should be reduced. 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 tel your doctor pharmacist at once. Do not stop taking your medicine. Even if you feel better, keep taking it.
- Children
- Under 12 years.

- Patients with impaired kidney or liver function
- In such cases the dose should be reduced. Always follow your doctor’s advice.

4. Possible side effects
- Like all medicines, Metoprolol Tartrate tablets can cause side effects, although not everybody gets them.
- Stop treatment and contact a doctor at once if you have the following 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 any other effects not listed below.
- Nasal disorders (nasal congestion, rhinitis, sneezing)
- Skin disorders (itchy skin, rash, itching)
- Heart disorders (irregular heart beats, palpitations)
- Other (types of conditions)
- Make sure you know how you react to this medicine before driving a car or operating machines, particularly after changing to another medicine or taking alcohol with Metoprolol Tartrate tablets.

- Anaesthetic and surgery
- If you are going to have an operation or an anaesthetic, ask your doctor or dentist if you are taking Metoprolol Tartrate tablets, as your heart rate might slow down too much.

- How to take
- Always take your medicine exactly as your doctor or pharmacist has told you. If you are unsure, check with your doctor or pharmacist.

Usual dose
- High blood pressure: initially 100mg metoprolol tartrate daily. The dose may be increased to 200mg daily in one or divided doses.
- Angina: 50-100mg metoprolol tartrate two or three times daily.

- Irregular heart beats (arrhythmia)
- Stopping metoprolol tartrate three or four times daily. The dose may be increased to 100mg daily in divided doses.

- Heart failure
- Stopping metoprolol tartrate every six hours. The usual maintenance dosage is 150-225mg a day in divided doses.

- Other (types of conditions)
- Stopping metoprolol tartrate three or four times daily.

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- Take metoprolol tartrate daily in divided doses in the morning and evening.
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- Under 12 years.

- Patients with impaired kidney or liver function
- In such cases the dose should be reduced. 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 tel your doctor pharmacist at once. Do not stop taking your medicine. Even if you feel better, keep taking it.
- Children
- Under 12 years.

- Patients with impaired kidney or liver function
- In such cases the dose should be reduced. Always follow your doctor’s advice.

4. Possible side effects
- Like all medicines, Metoprolol Tartrate tablets can cause side effects, although not everybody gets them.
- Stop treatment and contact a doctor at once if you have the following 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 any other effects not listed below.
- Nasal disorders (nasal congestion, rhinitis, sneezing)
- Skin disorders (itchy skin, rash, itching)
- Heart disorders (irregular heart beats, palpitations)
- Other (types of conditions)
Appendix
Appendix

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
2. Before you take Naproxen Tablets
3. How to take Naproxen Tablets
4. Possible side effects
5. How to store Naproxen Tablets
6. Further information

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, osteoarthritis, 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)

If you go into hospital or to see a doctor or dietitian tell them:

- You have Systemic Lupus Erythematosus (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, sulfonamides such as sulphanmethoxazole, 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 prescription
- Phenytoin used to treat epilepsy
- Gliclazide or glibenclamide (sulphonylureas) used to treat diabetes
- Probendazol 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 always be taken with food.

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.

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Appendix

For rheumatoid arthritis, osteoarthritis and ankylosing spondylitis:
250-500mg taken 12 hour intervals.

Acute musculoskeletal disorder: 500mg to start with, followed by 250mg every 8-6 hours. Do not take more than 1250mg (i.e. five 250mg tablets) in any 24 hour period.

Acute gout: 75mg 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 at the lowest possible dose for the shortest possible duration. Your doctor should monitor your condition regularly.

Children over 6 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 6 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 accidentally take too many Naproxen tablets, tell your doctor at once. If you are not at this hospital, get 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 most people do not notice 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 stools (diarrhoea)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds
- STOP THE MEDICATION AND SEE YOUR DOCTOR IF YOU EXPERIENCE: Indigestion or heartburn, abdominal pain (spills in your stomach) or other abnormal stomach symptoms

Medicines such as Naproxen 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 eyes, lips, face or hands, rash, itching, or hives, 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 (Stevens Johnson Syndrome)
- Haemorrhage
- 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, feelingness, looking pale)
- Swollen feet or ankles
- High blood pressure
- Headache

The following side effects have also been reported, if they become troublesome contact your doctor:

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 35° 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 contain:

The active substance(s) is:
Naproxen

The other ingredients are:
Lactose Monohydrate
Mannitol
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 250mg: Pale yellow film coated tablet with a breakline on one side and plain on the reverse.
Naproxen tablets 500mg: Pale yellow Colouring tablet with a breakline on one side and pale on the reverse.

Contents of pack:
Naproxen tablets 250mg: Pack of 28, 56 or 250 tablets
Naproxen tablets 500mg: Pack of 28, 56, 100 or 250 tablets

Marketing Authorisation Holder and Manufacturer:

Goes-Pharma Limited
Unit 14, Market Centre,
Yelverton Lane, Watford,
Herts.
UK WD18 9JS
Tel: 01923 330300
Fax: 01923 330301

This leaflet was last amended: February 2010.
Neupro 4 mg/24 h
transdermal patch

1. What is Neupro and what is it used for?
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
If you are allergic (hypersensitive) to nicotine or any of the other ingredients of Neupro (see Section 6: "Further information").
If you have to use magnetic resonance imaging (MRI) to visualize internal organs and tissues of the body or xeroradiography (treatment of abnormal heart rhythms). You must take your Neupro patch off before such procedures. You can put on 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 lung problems, your doctor may have to adjust the dose. If during treatment your lung problems get worse, you should contact your doctor as soon as possible.
- If you feel very drowsy or find that you full asleep suddenly, please contact your doctor (see also below in this section, under Driving and using machines).

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
- hip
- side (your side, your ribs, your rump)

Help to avoid skin irritations
- 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 swollen.
- 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 or by right clothing.
- Do not use creams, oils, lotions, powders, or other skin products on the areas of skin where you are 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 you put 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, 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 this 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. Pull apart the foil and open the sachet.

Further information
- The leaflet was last approved in: 01/09
- Detailed information on this medicine is available on the European Medicines Agency website:
  https://www.ema.europa.eu
Appendix

# NUROFEN for Children

## 3 months to 9 years

### 100mg / 5ml Oral Suspension

**Contains Ibuprofen**

Read 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, ask your doctor or pharmacist.

- The medicine is designed to help bring down a high temperature (fever) and relieve pain for headaches, sore throats, ear aches and pains, toothache and backache.

- The medicine is available to most people over 3 months of age. Children and adults.

- Follow the dose instructions carefully. Section 3 shows the different amounts that children need.

- Speak to your doctor or pharmacist if:
  - your child has been taking these medicines for a long time.
  - you are at risk of heart disease.

- If your child is taking more than one medicine:
  - Ibuprofen with paracetamol.

- Make sure you read this leaflet before giving to children.

**Tell your doctor or pharmacist if:**

- your child has high blood pressure, heart problems or a stroke.

- your child has a history of taking other ibuprofen-based medicines.

- your child has asthma or any allergic reaction to ibuprofen.

- your child is allergic to aspirin, ibuprofen or paracetamol.

- your child has high blood pressure, kidney or bowel problems.

- your child has had diabetes, kidney, heart or bowel problems.

- your child has SLE (Systemic Lupus). Encephalitis, a condition of the immune system or any similar disease.

- your child has a recent history of inflammatory bowel disease such as Colitis, 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.
  - medicines for high blood pressure (eg, captopril, enalapril, losartan).
  - medicines for mental illness (eg, risperidone, olanzapine).
  - antibiotics (eg, trimethoprim, doxycyclines, or ciprofloxacin).
  - antiplatelet drugs (eg, aspirin, clopidogrel).
  - anticoagulants (eg, warfarin).
  - medicines for other conditions (eg, medicines for cancer).

- Seek the advice of a doctor or pharmacist before giving this medicine to a pregnant or breastfeeding woman.

- If you are unsure about any of these medicines:
  - your doctor or pharmacist.

- If you are unsure about any of the above medicines:
  - your doctor or pharmacist.

### 1. What Nuromen for Children 3 months to 9 years

1.1 What is Nurofen for Children?

1.2 How to use Nurofen for Children 3 months to 9 years

1.3 Possible side effects

1.4 How to store Nurofen for Children 3 months to 9 years

1.5 Further information

- If you are unsure about any of the above medicines:
  - your doctor or pharmacist.

### 2. How to use Nurofen for Children 3 months to 9 years

2.1 Store Nurofen for Children 3 months to 9 years

2.2 Possible side effects

2.3 How to store Nurofen for Children 3 months to 9 years

2.4 Further information

### 3. Important Information

- Please read this leaflet carefully before you use this medicine.

- Keep this leaflet. You might need it again.

- If you have any further questions, ask your doctor or pharmacist.

- The medicine is designed to help bring down a high temperature (fever) and relieve pain for headaches, sore throats, ear aches and pains, toothache and backache.

- The medicine is available to most people over 3 months of age. Children and adults.

- Follow the dose instructions carefully. Section 3 shows the different amounts that children need.

- Speak to your doctor or pharmacist if:
  - your child has been taking these medicines for a long time.
  - you are at risk of heart disease.

- If your child is taking more than one medicine:
  - Ibuprofen with paracetamol.

- Make sure you read this leaflet before giving to children.

**Tell your doctor or pharmacist if:**

- your child has high blood pressure, heart problems or a stroke.

- your child has a history of taking other ibuprofen-based medicines.

- your child has asthma or any allergic reaction to ibuprofen.

- your child has a recent history of inflammatory bowel disease such as Colitis, 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.
  - medicines for high blood pressure (eg, captopril, enalapril, losartan).
  - medicines for mental illness (eg, risperidone, olanzapine).
  - antibiotics (eg, trimethoprim, doxycyclines, or ciprofloxacin).
  - antiplatelet drugs (eg, aspirin, clopidogrel).
  - anticoagulants (eg, warfarin).
  - medicines for other conditions (eg, medicines for cancer).

- Seek the advice of a doctor or pharmacist before giving this medicine to a pregnant or breastfeeding woman.

- If you are unsure about any of these medicines:
  - your doctor or pharmacist.

- If you are unsure about any of the above medicines:
  - your doctor or pharmacist.

### 4. Important Information

- Please read this leaflet carefully before you use this medicine.

- Keep this leaflet. You might need it again.

- If you have any further questions, ask your doctor or pharmacist.

- The medicine is designed to help bring down a high temperature (fever) and relieve pain for headaches, sore throats, ear aches and pains, toothache and backache.

- The medicine is available to most people over 3 months of age. Children and adults.

- Follow the dose instructions carefully. Section 3 shows the different amounts that children need.

- Speak to your doctor or pharmacist if:
  - your child has been taking these medicines for a long time.
  - you are at risk of heart disease.

- If your child is taking more than one medicine:
  - Ibuprofen with paracetamol.

- Make sure you read this leaflet before giving to children.

**Tell your doctor or pharmacist if:**

- your child has high blood pressure, heart problems or a stroke.

- your child has a history of taking other ibuprofen-based medicines.

- your child has asthma or any allergic reaction to ibuprofen.

- your child has a recent history of inflammatory bowel disease such as Colitis, 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.
  - medicines for high blood pressure (eg, captopril, enalapril, losartan).
  - medicines for mental illness (eg, risperidone, olanzapine).
  - antibiotics (eg, trimethoprim, doxycyclines, or ciprofloxacin).
  - antiplatelet drugs (eg, aspirin, clopidogrel).
  - anticoagulants (eg, warfarin).
  - medicines for other conditions (eg, medicines for cancer).

- Seek the advice of a doctor or pharmacist before giving this medicine to a pregnant or breastfeeding woman.

- If you are unsure about any of these medicines:
  - your doctor or pharmacist.

- If you are unsure about any of the above medicines:
  - your doctor or pharmacist.

### 5. How to store Nurofen for Children 3 months to 9 years

- Store Nurofen for Children 3 months to 9 years

- Possible side effects

- How to store Nurofen for Children 3 months to 9 years

- Further information

- If you are unsure about any of these medicines:
  - your doctor or pharmacist.

- If you are unsure about any of the above medicines:
  - your doctor or pharmacist.
Appendix

Package leaflet: Information for the user

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:
1. What Nystatin Oral Suspension is and what it is used for
2. Before you take Nystatin Oral Suspension
3. How to take Nystatin Oral Suspension
4. Possible side effects
5. How to store Nystatin Oral Suspension
6. Further information

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).

The usual doses are as follows:

**Adults and the elderly**
- Denture and mouth infections caused by Candida albicans: 1 ml, 4 times a day.
- Oral infections: 1 ml, 4 times a day.
- Prevent candidal infection (in growth): If you are also taking other antibiotics, a total daily dosage of 10 ml will probably be sufficient.

**Children**
- Intestinal and mouth infections caused by Candida albicans in infants and children: 1 ml, 4 times a day.
- Protection against infection in newborn babies: 1 ml, 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.

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.

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).
- Headache and dizziness.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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.

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:
- Succrose - 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.
- Propyl-p-hydroxybenzoate (E216) and methyl-p-hydroxybenzoate (E218) - may cause allergic reactions such as rashes 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.

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 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 1 ml of suspension contains 100,000 International Units (IU) of nystatin.

The other ingredients are: sodium carbomethylcellulose, methyl-p-hydroxybenzoate, propyl-p-hydroxybenzoate, sodium metabisulphite, sucrose, saccharin sodium, sodium citrate, anhydrous 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 50ml 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 0GQ.

This leaflet was last approved in 08/2008
Appendix

Omeprazole 10 mg, 20 mg and 40 mg Capsules

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 they seem the same as you.

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
2. Before you take Omeprazole
3. How to take Omeprazole
4. Possible side effects
5. How to store Omeprazole
6. Further information

1. What Omeprazole is and what it is used for

Omeprazole contains the antacid 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:
- Gastric-oesophageal reflux disease (GERD), where the acid from your stomach is sucked up into the tube (the tube which connects your throat to your stomach) and causes heartburn and indigestion.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer). Omeprazole can be used to stop ulcers forming if you are taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) or Aspirin. Omeprazole can also be used to stop ulcers from forming if you are taking Helicobacter pylori.
- 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.
- Gastric-oesophageal reflux disease (GERD). This is where acid from the stomach escapes up into the tube (the tube which connects your throat to your stomach) and causes heartburn and indigestion.

In children, the symptoms of the condition can include the return of symptoms into the mouth (regurgitation), being sick (vomiting) and losing weight.

2. Before you take Omeprazole

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 well you are. The usual doses are given below.

Adults:
- For treatments of GERD such as heartburn and acid regurgitation.
- If your doctor has told you 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 4–8 weeks for severe reflux of food from the stomach.

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 well you are. The usual doses are given below.

Adults:
- For treatments of GERD such as heartburn and acid regurgitation.
- If your doctor has told you 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 4–8 weeks for severe reflux of food from the stomach.

4. Possible side effects

Medicines that are used to thin your blood, such as warfarin or other vitamin K. If your doctor may need to monitor you when you start or stop taking omeprazole.
- Rifampicin (used to treat tuberculosis) and St John’s wort (Hypericum perforatum) are also likely to interact with omeprazole.
- Taking omeprazole (used to treat heartburn and acid reflux) and antacids (used to prevent heartburn) at the same time may reduce the effect of omeprazole.
- If you are taking antibiotics (oral) or if you have had surgery on your oesophagus, stomach or duodenum.
- If you are taking other medicines that you have not told your doctor or pharmacist about.
- 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.
- Driving and using machines. Omeprazole is not likely to affect your ability to drive or use any tool or machine. Side effects such as dizziness and visual disturbances may occur (see side effects list). If affected, you should not drive or operate machinery.

Important information about some of the ingredients of Omeprazole capsules:
- Some capsules contain lactose, so these capsules are not suitable for some people, including those who follow a strict vegan diet.

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 well you are. The usual doses are given below.

Adults:
- For treatments of GERD such as heartburn and acid regurgitation.
- If your doctor has told you 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 4–8 weeks for severe reflux of food from the stomach.

Common side effects:
- Headache.
- Effects on your stomach or gut.
- Bloating, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).

Uncommon side effects:
- Severe heartburn.
- Disturbed sleep (insomnia).
- Constipation, feeling tired, dizziness, tingling feelings such as pins and needles, feeling sick or dizzy.
- Changes in your blood tests that show how your liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.

Rare side effects:
- Abnormal problems such as a reduced number of white cells or platelet. This can cause weakness, bruising or more infections more likely.
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing.
- Significant changes in the way your stomach works. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Tape changes.
- Eye problems such as blurred vision.
- Sudden feeling sickness or short of breath (bronchospasm).
- Dry mouth.
- An infection in 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 (arthritis) or muscle pains (myalgia).
- Severe liver problems (jaundice).
- Increased sweating.

Very rare side effects:
- Changes in blood count including agranulocytosis (lack of white blood cells).
- Asthenia.
- Severe or lasting breathing or hearing problems.
- Serositis.
- Rare 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 pain.
Appendix

One-Alpha Capsules 0.25 microgram
One-Alpha Capsules 1 microgram

Please read all of this leaflet carefully before you start taking this medicine.

• Do not take this medicine if you are allergic to any ingredients contained in this medicine.

• You may have some side effects. If any of these side effects become serious, or if any side effects continue, tell your doctor or pharmacist immediately.

• This leaflet on One-Alpha capsules will be called One-Alpha.

1. WHAT IS ONE-ALPHA AND WHAT IS IT USED FOR

One-Alpha Capsules is a progestogen tablet. This medicine is used to:

• Prevent withdrawal bleeding
• Treat menopausal symptoms
• Treat acne

2. BEFORE YOU TAKE ONE-ALPHA

• Do not take One-Alpha if you:
  - Are allergic to any of the ingredients or the packaging of One-Alpha Capsules
  - Have had a blood clot
  - Have a history of thrombosis or embolism

• If you have any side effects, you should tell your doctor or pharmacist immediately.

3. HOW TO TAKE ONE-ALPHA

• Take One-Alpha exactly as your doctor has prescribed.
• Take One-Alpha at the same time each day.
• Do not forget to take One-Alpha at the right time each day.
• If you miss a dose, take it as soon as you remember. Do not take a double dose.

4. POSSIBLE SIDE EFFECTS

One-Alpha may cause side effects. It is important to be aware of these side effects.

• If you experience any of these side effects, tell your doctor or pharmacist immediately.

5. FURTHER INFORMATION

This leaflet has been provided for you by Merck Sharp & Dohme. If you have any questions, you should contact your doctor or pharmacist.

### Additional Information

- **Precautions:**
- **Contraindications:**
- **warnings:**
- **Side Effects:**
- **Interactions:**
- **Overdosage:**

### Notes

- This leaflet is designed to provide information to help you understand your treatment.
- If you have any concerns or questions, please consult your healthcare provider.

### Contact Information

Merck Sharp & Dohme

For more information, visit www.merck.com or call 1-800-633-9717.

***End of Medication Information***
Appendix

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 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 pains, 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
- 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 dependence
- 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)
- Micronidnemine (used to control anxiety)
- Metoclopramide and domperidone (prevent nausea and sickness)
- Chlorpromazine (an antihistamine)
- Blood thinning medicines such as warfarin
- Anti-inflammatory medicines (NSAIDs), e.g. ibuprofen or aspirin
- Any other medicines that affect the liver

3. How to Take the Caplets

Daily: Take one to two caplets every 4 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, nose or mouth ulcers or bleeding gums accompanied by sickness 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
- Feel in the lower back and groin
- Restlessness and excitement
- Blood disorders
- Nausea
- 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. Storage Conditions
Keep this 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 marked on the packaging.

6. Other Ingredients
The active ingredients in Paracetamol Extra Caplets are Paracetamol Sulphate and Caffeine.

Hydroxypropyl Methylcellulose. They are tablets with an embossed 'AP' and 'X' on one face or either side of a break line. The other ingredients are starch, povidone K-30, talc, starch paste and magnesium stearate.

The product licence holder and manufacturer is Aspex Pharmaceuticals Ltd, Capel Way, Cippenham, London MK4 0EO.
PIL 08977/0925
Paracetamol Extra Caplets are sold in blister packs of 8 and 16.
Appendix
PATIENT INFORMATION LEAFLET
PHORPAIN® GEL MAXIMUM STRENGTH
(Ibuprofen)

START OF MEDICINE

Always use Phorpaingel 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: Swallow 50 to 150mg (2 to 5mL) of gel from the tube on affected area. Massage until absorbed. The dose should not be repeated more frequently than every four hours and no more than four times a day in any 24-hour period.

Phorpaingel Maximum Strength should only be used on healthy, unbroken skin. Do not use on or near cuts or grazes or under dressings such as plaster.

Do not let any gel come in contact with your eyes. If it does, rinse your eyes with cool water and consult your doctor. Hands should be washed after applying Phorpaingel 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: Phorpaingel Maximum Strength is not recommended for use in children under 14 years.

If you use more than you should:

If you accidentally swallow any Phorpaingel Maximum Strength, contact your doctor, or nearest hospital, as soon as possible.

If you forget to use your Phorpaingel 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 Phorpaingel 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 swelling of the skin
• Abdominal pain (pain in your stomach) or other abnormal stomach symptoms
• A burning feeling
• Stomatitis or peeling.

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 PHORPAIN® GEL MAXIMUM STRENGTH

Keep out of reach of children.

Do not use Phorpaingel 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 wastewaste 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.

What Phorpaingel Maximum Strength looks like and contents of the pack:

Phorpaingel Maximum Strength is supplied in 4 ml 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:
Farmaesca Manufacturing B.V., Caniles De Iruin KM 26, 2000 BR0, SAN Sebastian De Los Reyes, Madrid, Spain.

This leaflet was last revised in July 2010.
Appendix

Piriton Allergy Tablets
Chlorphenamine Maleate

Please read 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
2. Check before you take Piriton Allergy Tablets
3. How to take Piriton Allergy Tablets
4. Possible side effects
5. How to store Piriton Allergy Tablets
6. Further information

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 itching, redness, swelling, tenderness and irritation that can be caused by:
- Hayfever and other allergies e.g. pets, house dust mite and mould spores, allergies
- Nettle rash and hives

- skin allergies and dermatitis
- pricky heat and 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

X 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 (MAOI) 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, a previous 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 dizzy.
- 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 tarry 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 sputum.

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.

Pack of Piriton Allergy Tablets contain 30 or 50 tablets.
The marketing authorisation holder is GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9DH, U.K. All enquiries should be sent to this address.
The manufacturer is Haupt Pharma Würzburg GmbH, Betheliner Landstrasse 16, D-31308 Gruenau, 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
Appendix

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.

Keep away from children. This medicine is for oral use only.

If you have any side effects not listed in this leaflet, please tell your doctor or pharmacist.

PRECAUTIONS - 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 rounded face (see section 4 for more information).

If you take it for more than 3 weeks, you will get a blue ‘steroid card’ to keep with you and show to any doctor or nurse treating you.

You may need to use people who have taken PREDNISOLONE and may also have long-term effects on various health conditions such as diabetes.

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 2015.

WHAT PREDNISOLONE IS AND WHAT IT IS USED FOR

PREDNISOLONE is a corticosteroid. Its name is cortisone. Its full name is corticosteroids. These corticosteroids occur naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroids (such as PREDNISOLONE) is an effective way to treat various illnesses involving inflammation in

- abnormal feeling of well-being, feeling of dependency on treatment
- depression, including difficulty sleeping
- diziness
- weakness of the skin
- pressure on the nerve to the eye (e.g. caused by inflammation of the optic disc)
- abnormalities in blood circulation
- swelling of the optic disc
- warping of the lens (cataracts)
- thinning of the eye tissue (neuroretinitis)
- exacerbation of retinitis and uveitis
- worsening of epilepsy
- fatigue and general feeling of being unwell

Withdrawal: Symptoms: anxiety, mood swings, insomnia, vomiting, headaches, fever, joint pain, swelling of skin, muscle pain, fatigue, unusual bleeding or bruising, skin nodules, loss of weight and/or hyperglycemia.

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.

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 this medicine 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 crushed or chewed. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

FURTHER INFORMATION

What PREDNISOLONE tablets contain:

- The active ingredient is prednisolone 1 mg or 5 mg.

- The other ingredients are lactose monohydrate, crospovidone, sodium starch and sodium chloride (E570).

What PREDNISOLONE tablets looks like and contents of the pack:

- Prednisolone 1 mg are white bevelled tablets, marked "AP" on one side and "1.0" on the reverse, or marked "APS 1.0" on one side and plain on the reverse.

- Prednisolone 5 mg are white bevelled tablets, marked "AP" on one side and "5.0" on the reverse, or marked "APS 5.0" on one side and plain on the reverse.

- The 1 mg tablets are available in packs of 28, 30, 60, 90, 180, 300, and 500.

- The 5 mg tablets are available in packs of 28, 30, 60, 100 and 150.

- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder and company responsible for manufacture: TEVR UK Limited, Eastbourne, BN22 9AB.

This leaflet was last revised: July 2015.
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

3. Do not take Premique Low Dose if:
   • you 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.

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE PREMIQUE LOW DOSE

6. FURTHER INFORMATION

7. What Premique Low Dose contains

The active substances are conjugated estrogens (an estrogen) and medroxysterone acetate (a progestogen). Each tablet contains 0.3mg of conjugated estrogens and 1.5mg of medroxysterone 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, glycerin, microcrystalline cellulose, sorbitol, titanium dioxide (E171), povidone, cornstarch, yellow ferric oxide (E172) and edible ink that contains shellac, propylene glycol, black iron oxide (E172) and potassium hydroxide.

8. What Premique Low Dose looks like and contents of the pack

Your Premique Low Dose tablet 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 8PZ. The manufacturer is Wyeth Medica Ireland, Little Cornell, Newbridge, County Kildare, Republic of Ireland.

This leaflet applies to Premique Low Dose tablets only. This leaflet was last approved in 04/2013. "Trade mark Wyeth"
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PRECAUTIONS

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:
- To help you sleep if you are not able to get to sleep or keep sleeping because you worry too much.
- To help you get to sleep if you wake up too early and cannot get back to sleep.
- To help reduce the number of attacks if you have a condition called epilepsy.

2. How to take Temazepam

Take Temazepam as directed by your doctor. Follow all directions carefully.

3. Possible side effects

Some common side effects of Temazepam are:
- Drowsiness
- Feeling dazed or confused
- Decreased ability to perform tasks
- Feeling restless or agitated
- Tiredness or drowsiness
- Headache
- Nausea
- Diarrhea
- Constipation
- Dry mouth
- Blurred vision
- Difficulty concentrating

If any of these effects persist or become severe, tell your doctor or pharmacist immediately.

4. Other side effects

Some side effects are:
- Dizziness, weakness or loss of balance.
- Drowsiness, fatigue, lack of energy.
- Tiredness, drowsiness, or confusion.
- Headache, dizziness, or dizziness.
- Low blood pressure, which may make you feel faint or dizzy.
- Constipation.

If any of these effects persist or become severe, tell your doctor or pharmacist immediately.

5. How to store Temazepam

Keep out of reach of children.

6. Further information

Temazepam should not be used by anyone who has had an allergic reaction to Temazepam or any other medicines containing benzodiazepines.

[Additional text about the use of Temazepam, side effects, and precautions is provided.]
2. Before you take Tritec

Do not take Tritec:
- If you are allergic to any of the ingredients or any of the other substances or substances in this medication.
- If you have a family history of allergies to any of the ingredients or any of the other substances in this medication.
- If you are taking any other medications or any other substances that may interact with Tritec.
- If you are taking any other medications or any other substances that may interfere with the effectiveness of Tritec.
- If you are taking any other medications or any other substances that may cause liver damage.
- If you are taking any other medications or any other substances that may cause kidney damage.
- If you are taking any other medications or any other substances that may cause blood problems.
- If you are taking any other medications or any other substances that may cause blood pressure problems.
- If you are taking any other medications or any other substances that may cause respiratory problems.
- If you are taking any other medications or any other substances that may cause heart problems.
- If you are taking any other medications or any other substances that may cause gastrointestinal problems.
- If you are taking any other medications or any other substances that may cause metabolic problems.
- If you are taking any other medications or any other substances that may cause neurological problems.
- If you are taking any other medications or any other substances that may cause hepatic problems.
- If you are taking any other medications or any other substances that may cause endocrine problems.
- If you are taking any other medications or any other substances that may cause renal problems.
- If you are taking any other medications or any other substances that may cause hematological problems.
- If you are taking any other medications or any other substances that may cause genitourinary problems.
- If you are taking any other medications or any other substances that may cause musculoskeletal problems.
- If you are taking any other medications or any other substances that may cause dermatological problems.
- If you are taking any other medications or any other substances that may cause ophthalmological problems.
- If you are taking any other medications or any other substances that may cause otological problems.
- If you are taking any other medications or any other substances that may cause neurological problems.
- If you are taking any other medications or any other substances that may cause psychiatric problems.
- If you are taking any other medications or any other substances that may cause gastrointestinal problems.
- If you are taking any other medications or any other substances that may cause genitourinary problems.
- If you are taking any other medications or any other substances that may cause hematological problems.
- If you are taking any other medications or any other substances that may cause endocrinological problems.
- If you are taking any other medications or any other substances that may cause hepatic problems.
- If you are taking any other medications or any other substances that may cause renal problems.
- If you are taking any other medications or any other substances that may cause dermatological problems.
- If you are taking any other medications or any other substances that may cause ophthalmological problems.
- If you are taking any other medications or any other substances that may cause otological problems.
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- If you are taking any other medications or any other substances that may cause otological problems.
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- If you are taking any other medications or any other substances that may cause psychiatric problems.
- If you are taking any other medications or any other substances that may cause gastrointestinal problems.
- If you are taking any other medications or any other substances that may cause genitourinary problems.
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- If you are taking any other medications or any other substances that may cause endocrinological problems.
- If you are taking any other medications or any other substances that may cause hepatic problems.
- If you are taking any other medications or any other substances that may cause renal problems.
- If you are taking any other medications or any other substances that may cause dermatological problems.
- If you are taking any other medications or any other substances that may cause ophthalmological problems.
- If you are taking any other medications or any other substances that may cause otological problems.
- If you are taking any other medications or any other substances that may cause neurological problems.
- If you are taking any other medications or any other substances that may cause psychiatric problems.
- If you are taking any other medications or any other substances that may cause gastrointestinal problems.
- If you are taking any other medications or any other substances that may cause genitourinary problems.
- If you are taking any other medications or any other substances that may cause hematological problems.
- If you are taking any other medications or any other substances that may cause endocrinological problems.
- If you are taking any other medications or any other substances that may cause hepatic problems.
- If you are taking any other medications or any other substances that may cause renal problems.
- If you are taking any other medications or any other substances that may cause dermatological problems.
- If you are taking any other medications or any other substances that may cause ophthalmological problems.
- If you are taking any other medications or any other substances that may cause otological problems.
- If you are taking any other medications or any other substances that may cause neurological problems.
- If you are taking any other medications or any other substances that may cause psychiatric problems.
- If you are taking any other medications or any other substances that may cause gastrointestinal problems.
Appendix

# Package leaflet: Information for the Patient

**Ventolin® Evihaer®**

**Salbutamol sulphate**

Note: this leaflet cannot be taken with this medicine. See the Patient Information Booklet enclosed with this medicine if you have any questions about this medicine or any other medicines you are taking.

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## 1. What Ventolin Evihaer is and what it is used for

Ventolin Evihaer is a beta2 agonist bronchodilator. This is a group of medicines called bronchodilators. They work by relaxing the muscles in the wall of the bronchi, which are the small tubes that carry air to and from the lungs. This makes it easier for you to breathe.

## 2. How much is Ventolin Evihaer used for?

Ventolin Evihaer is used to:

- Relieve the symptoms of asthma
- Relieve the symptoms of chronic obstructive pulmonary disease (COPD)
- Relieve the symptoms of chronic bronchitis

## 3. Possible side effects

Ventolin Evihaer can cause side effects, although most people do not experience any. The following side effects may happen in any number of people:

- Headache
- Dizziness
- Tiredness
- Fast heartbeat
- Nervousness
- Tremors
- Nausea
- Vomiting
- Diarrhea
- Constipation
- Confusion
- Irritability

## 4. How to use Ventolin Evihaer

Always read the patient information leaflet before you start using this medicine. You should not stop using Ventolin Evihaer without talking to your doctor.

## 5. Further information

This leaflet has been compiled by the medicines regulator to provide useful information about medicines. It is not a substitute for professional medical advice.

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**Questions 1 & 2**

**1.** What is the difference between a bronchodilator and a beta agonist?

**2.** What are the possible side effects of using Ventolin Evihaer?

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**Questions 3 & 4**

**3.** Why is it important to use Ventolin Evihaer regularly?

**4.** How do I know if I have asthma?

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**Questions 5 & 6**

**5.** What should I do if I miss a dose of Ventolin Evihaer?

**6.** What should I do if I overdose on Ventolin Evihaer?

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**Questions 7 & 8**

**7.** What are the common side effects of using Ventolin Evihaer?

**8.** What should I do if I experience these side effects?

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**Questions 9 & 10**

**9.** What are the precautions for using Ventolin Evihaer?

**10.** How long will it take for Ventolin Evihaer to work?

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**Questions 11 & 12**

**11.** What are the possible interactions with other medicines?

**12.** How do I store Ventolin Evihaer?

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**Questions 13 & 14**

**13.** What should I do if I have an asthma attack while using Ventolin Evihaer?

**14.** What should I do if I am allergic to salbutamol sulphate?

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**Questions 15 & 16**

**15.** What are the important warnings and precautions for using Ventolin Evihaer?

**16.** What should I do if I am pregnant or breastfeeding while using Ventolin Evihaer?

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**Questions 17 & 18**

**17.** What are the legal and regulatory requirements for using Ventolin Evihaer?

**18.** How do I report any side effects of using Ventolin Evihaer?

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**Questions 19 & 20**

**19.** What are the indications for using Ventolin Evihaer?

**20.** What should I do if I am allergic to the ingredients of Ventolin Evihaer?

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**Questions 21 & 22**

**21.** What are the differences between the strengths of Ventolin Evihaer?

**22.** What are the indications for using Ventolin Evihaer in children?

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**Questions 23 & 24**

**23.** What are the precautions for using Ventolin Evihaer in children?

**24.** What should I do if I am allergic to the excipients of Ventolin Evihaer?

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**Questions 25 & 26**

**25.** What are the important warnings and precautions for using Ventolin Evihaer in children?

**26.** What should I do if I am pregnant or breastfeeding while using Ventolin Evihaer in children?

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**Questions 27 & 28**

**27.** What are the legal and regulatory requirements for using Ventolin Evihaer in children?

**28.** How do I report any side effects of using Ventolin Evihaer in children?

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**Questions 29 & 30**

**29.** What are the indications for using Ventolin Evihaer in children under 6 years of age?

**30.** What should I do if I am allergic to the ingredients of Ventolin Evihaer in children under 6 years of age?
3. How to use Viscotears

If your doctor has prescribed Viscotears you/the patient 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 bottle vertically (see Figure 1).
4. Tip your head back slightly and gently pull down your lower lid by.
5. Keep your eye open.
6. Press the dropper firmly against your cheek and gently pull down your lower lid (see Figure 3).
7. Gently look up.
8. Gently close your eyes.
9. While away any excess gel from around the eyes.
10. Repeal 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.

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.

Appendix

Patient Information Leaflet

Your eye drops are available under the names Viscotears Liquid Gel / Carbomer 2mg/g Liquid Gel (carbomer) and 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 this leaflet in a safe place because you may need to read it again.

Do not share these eye drops with anyone else just because 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 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 Viscotears is and what it's used for
2. Things to consider before you start to use Viscotears
3. How to use Viscotears
4. Possible side effects
5. How to store Viscotears
6. Further Information

1. What Viscotears is and what it's used for

Viscotears contains the active ingredient, carbomer (polyacrylate salt). Viscotears is used to make your eyes more comfortable when they feel dry. It is a 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 three questions before starting to use Viscotears:
- Do you have a temperature? Take your temperature before you put the drops in your eyes. Don't.
- Do you have any infections in your eyes? Please ask your pharmacist or doctor if you don't.
- Are you going to use Viscotears for dry eyes? If you are, you must be used to one kind of eye drops well. It is possible that you may have to change your routine.

If you are not sure ask your doctor or pharmacist.

3. How to use Viscotears

If your doctor has prescribed Viscotears you/the patient 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 drops:
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 bottle vertically (see Figure 1).
4. Tip your head back slightly and gently pull down your lower lid by.
5. Keep your eye open.
6. Press the dropper firmly against your cheek and gently pull down your lower lid (see Figure 3).
7. Gently look up.
8. Gently close your eyes.
9. While away any excess gel from around the eyes.
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.

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.

Appendix
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Voltarol® Thermal 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. 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).
- whilst 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 or press the 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, erosion or prolonged redness), remove the heat patch straight away.
- Remove patch before medical scans.
- If you do 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

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2. Before you take Varifarm Tablets

Do not take these tablets if you:
- have not been told by your doctor or pharmacist
- have any other tablets that you take.
- have any other medicines that contain any of the ingredients in Varifarm (see Section 4, Further Information).

- have just been diagnosed as having an infection of the heart
- have just been diagnosed as having multiple sclerosis
- have any other medicines which cause bleeding or if your doctor is aware of any
- are at risk of surgery or being operated on within 24 hours after surgery
- have had any recent history of bleeding
- have any other medicines that you are taking that may interact with this medicine.

Take special care with this medicine if:
- you have high blood pressure
- you have had a recent history of bleeding
- you have any other medicines that you are taking that may interact with this medicine.

Taking other medicines

Please inform your doctor or pharmacist if you are taking or have been recently taken any other medicines, even those not prescribed, or enzymes, nutritional supplements, or herbal medicine. Make sure your doctor or pharmacist are aware of any other medicines you are taking, including other medicines, herbal medicine, and supplements.

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 bleeding
- difficulty breathing, including any unusual pain
- pain in the arm or leg while walking
- severe pain in the arm or leg while walking
- loss of vision
- loss of smell
- loss of taste
- muscle weakness or dizziness
- pale skin (whether in the face or the eyes)
- puffy skin (on the body or the face)
- purplish discharge from the eyes or mouth
- skin rash
- swelling of the legs or arms
- urinary problems
- visual loss
- weight gain
- yellowing of the skin or the eyes.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Varifarm Tablets

Keep all medicines out of the reach of children and pets. Store the tablets in a cool, dry place.

6. Further Information

Any further questions about the use of this product should be directed to your doctor or pharmacist.

Marketing Authorisation Holder/Manufacturer

K. S. Pharmaceuticals Limited, Unit 3, Castlebay Court, North Shields, NE13 9DN, United Kingdom.

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Website: www.ksp.com

This leaflet was last updated in April 2018.
Appendix

**XALATAN® 0.005% Eye Drops, Solution**

**LATANOPROST**

**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 Xalatan is and what it is used for
2. Before you use Xalatan
3. How to use Xalatan
4. Possible side effects
5. How to store Xalatan
6. Further information

**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 adults 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

**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 lenses.

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 skin reactions: 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 microgrammes/ml) latanoprost.

The other ingredients are: benzalkonium chloride, sodium chloride, sodium dihydrogen phosphate monohydrate (E338a) and anhydrous disodium hydrogen phosphate (E336b) dissolved in water for injection.

**What Xalatan looks and contains 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 1 bottle of Xalatan. Each bottle contains 2.5 ml of Xalatan Eye Drops, Solution.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder:** Pfizer Limited, Frimleygate Road, Sandwich, Kent. CT13 9NJ, United Kingdom.

**Manufacturer:** Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium.

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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, your doctor, or your cold sore gets very severe, consult 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 has not 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 to 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 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 sign 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.

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 the expiry 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: Dibencosine, propylene glycol, polysorbat 40, oleasteryl alcohol, sodium laurylsulphate, white soft paraffin, liquid paraffin, water 163 (glycerol monoestearate, macrogol estraate 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. HIV 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, Bracknell, TW9 9GS, U.K. and all enquiries should be sent to this address.

The manufacturer is Glaxo Welcome Operations, Greenford, Middlesex, UB6 9NN.

This leaflet was last revised in November 2008.

Zovirax, the Halfl Clock Device and AT Blister Or Tinge are registered trade marks of the GlaxoSmithKline group of companies.