The optimal text structure in a patient information leaflet

Evaluation of the current and revised text structure in a patient information leaflet to increase findability of information.

Master Thesis

Noortje Arts

3335828

Date: 01 August 2012

University of Utrecht

Faculty of Humanities

Master: Communication studies

Supervisors

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Abstract

There is much discussion about how the structure in a patient information leaflet should be. This research is conducted to compare the revised text structure, as proposed by Pander Maat and Lentz (2011), with a current text structure of a patient information leaflet (PIL). The structure in which the information is represented in a PIL is of great importance. Readers often experience difficulties with the readability and usability of PILs. This study can contribute in improving the text structure in a patient information leaflet so that it is easier for patients to locate correct information in a PIL. We focussed mainly on the grouping of topics, the presentation of the information and the phrasing of the headings. The outcome of this study has demonstrated the strengths and weaknesses of both the revised and current PIL. First we looked at the influence of the text structure (current and revised) on the findability of the information in a PIL. Secondly we examined the participant's perception on the current and revised PIL. We expected that the revised text structure could help to improve the findability and appreciation of the leaflet but also the compatibility between the PILs structure and the readers' medication schema. The findability scores have been measured on the number of correct locations on scenario questions. The perception was measured by how participants appreciated and evaluated these text structures. The objective was to find out whether the revised text structure has a positive effect on the findability and perception of the PIL. The outcome of this study demonstrates the strengths and weaknesses of both the revised and current PIL.

The effect of a PIL with the revised text structure as opposed to a current text structure on the user's ability to find the information is as follows: whereas the main structure was better in the revised text structure, the quality of the subheadings are better in the current text structure. The expectation that a PIL with a revised text structure results in better findability of information in a patient information leaflet than a PIL with a current text structure is partly confirmed because the manipulation of the main headings is successful. At the other hand the quality of subheadings is less profitable. The perception and appreciation of the organisation of the information, wording and overall design was slightly higher for the revised PIL. The expectation that a PIL with the revised text structure is perceived in a more positive way than a PIL with a current text structure receives some support.

Further research is essential to explore the positive aspects of both current and revised PIL to optimize the text structure in a patient information leaflet. These results can be a guideline for future research intended to improve the readability of patient information leaflets.

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1. Introduction

In communication studies much research has been done to improve the usability of patient information leaflets (Kenny et al. 1998: 473). These printed health education materials are often used in healthcare organizations to inform, educate or promote patient's wellbeing (Gal et al. 2005: 485). A patient information leaflet (PIL) is the most common form of information source concerning medicines (Raynor et al. 2009: 700). Previous studies showed that there are difficulties with the readability and usability of PILs (Dollahite et al. 1996 In: Gal et al. 2005: 485). A few reasons for the complexity of PILs are the phrasing of the information (readability) and its presentation (layout). Readers often find the text too difficult or technical and the organization of the main- and subheadings not clear enough (Raynor et al. 2009: 701). There is also the fact that many PILs, in spite of their topic, "require relatively high" level of reading skills which not all PIL readers have. This can make a PIL text intimidating and unreadable (Gal et al. 2005: 485; Raynor et al. 2009: 701). According to this and other studies, patients are not always able to understand the information in PILs "because of their content, writing style or organization" (Gal et al. 2005: 485). One of these previous studies was done by Pander Maat (2008). He analysed potential problems with the comprehension of a leaflet through a diagnostic study. Subsequently Pander Maat (2008) emphasized that readers might encounter problems in understanding the medicine leaflets and finding the correct information in the leaflet. Only 75% of the requested information was found in the text. One of the findability problems occurred when a topic in the text was mentioned more than once and could be found under several headings (Pander Maat 2008: 34). He suggested that there should be a follow-up study concerning specific comprehension problems readers cope with. According to him a first step in restructuring the current template of a PIL was creating a text design from the list of comprehension problems obtained in earlier studies (Ibid.: 36).

The European regulations contain rules for the content and structure of the text in PILs. The current template of a PIL is published by the 'Quality Review of Documents' (QRD) Group. This set of rules is monitored by a committee of the European Medicines Agency (EMEA)[1]. The current template prescribes the structure of a text in a PIL. Because this current text structure showed some problems in accessibility and comprehension of PILs, a former project by Pander Maat and Lentz (2010) was established to improve PILs while keeping the current EU regulations

[1] EMEA (2011). QRD-template version 8, 2011. Retrieved from http://www.emea.europa.eu/docs/en_GB/document_library/Template_or_form/2009/10/WC500004368.pdf (10 June 2012, 13:57).

in mind (Pander Maat et al. 2010: 113). They tested three PILs "to find out whether readers could locate and comprehend relevant information" (Ibid: 118). This research showed that even though the EU regulations make sure that PILs are consistent in their structure and content, it does not guarantee a better usability (Ibid: 118). The most recent card-sorting study (refer to paragraph 2.3 for more details) of Pander Maat and Lentz (2011) suggests that readers encountered problems in locating the correct information in a PIL because readers' expectations and the current template did not match. Furthermore, readers' interpretation of the wording of the headings were different than the intented meaning of the headings. In addition, readers had a different view about the order and classification of the information (Pander Maat et al. 2011: 235). These findings confirm previous results where readers have difficulties to find information in a PIL (Ibid: 235). As a result of the recent study of Pander Maat and Lentz (2011) a revised template (i.e. text structure) was defined. Based on these studies it became clear that the structure in which the information is represented in a PIL is of great importance. Further research is essential to confirm that a revised text structure will actually improve the findability of information in PILs (Ibid: 235).

The research as described in this paper will test a revised text structure based on an empirical previous study as proposed by Pander Maat and Lentz (2011). The main focus is on the grouping of topics, the structure of the main- and subheadings and the phrasing of the headings (Pander Maat et al. 2011: 235). Furthermore, a proposed revised text structure of a PIL will be compared to a current text structure according to the QRD template. Hence we can formulate the following research question:

What is the effect of a revised text structure as opposed to a current text structure on the findability and the user's perception of information in a patient information leaflet?

The outcome of this study will demonstrate the strengths and weaknesses of a revised and current text structure in a patient information leaflet. By means of this research, a revised structure as proposed by the University of Leeds and the University of Utrecht will be evaluated. Theo Raynor from the University of Leeds participated in this research and worked along to improve the revised text structure and perform an effective study.

In this study the following topics will be discussed: start with, the relevant theory will be reviewed in chapter 2. The method will be elaborated in chapter 3. In chapter 4 we go through the results, followed by chapter 5 in which the conclusion will be discussed. We will conclude this research with the discussion including the limitations and recommendation for future research.

2. Theoretical background

Patient information leaflets (PILs) are intended to inform and instruct patients on how and when they should use medicines but also to understand its purpose, benefits and risks (Gustafsson et al. 2005: 35). PILs have been evaluated since the 1960s and during the last few years several studies (e.g. Gal et al. 2005; Gustafsson et al. 2005; Kenny et al. 1998; Koo et al. 2003; Morrow et al 1991) often concentrated on the usage and impact of PILs on patients (Koo et al. 2003: 259). The European Medicines Agency (EMEA) ensures that all medicines should have a written document, a PIL, that provides patients with the appropriate information about medicines (Gustafsson et al. 2005: 35). "Without instructions, warnings and risk-benefit information, it is not possible to prescribe, dispense or take medicines appropriately" (van der Waarde 2008: 216). However, the ability of consumers to read and process information in a PIL depends to a great extent on the patient's ability to interpret the content and the way the information is phrased and structured (Gustafsson et al. 2005: 35). Raynor and Knapp (2000) discovered in their research that only 60% of the patients read only a part of the PIL or the whole text and merely 20% of the patients did not notice the PIL at all (Ibid: 35). In order to have the medicines correctly used by patients, the information in a PIL should be informative and, most importantly, understandable. In this study we will look at the presentation of the information by looking at the order of the topics and the phrasing of the headings in a PIL (Pander Maat et al. 2011: 235). "Layout and format are crucial – if people cannot find the information, it does not matter how well it is expressed"[2].

2.1 Patient information leaflets

PILs have been available in Europe since 1977. Because the content and format of PILs are produced in many different ways, the European Economic Community published a Council Directive 92/27/EEC (Koo et al. 2003: 260). In 1998 the European Community provided pharmaceutical companies this directive which consists of rules concerning a PILs template (i.e. structure) (Pander Maat et al. 2011: 220). Since this directive it is mandatory that medicines sold within the European Union (EU) have comprehensive PILs that are written in a language of that specific country and comply to the regulations of this directive (Gustafsson et al. 2005: 35; Koo et al. 2003: 260). These regulations are made to make sure that all PILs within the EU have a

[2] Raynor, D.K. (2008) *Readability testing of patient leaflets – where to now?*. Website: www.luto.co.uk/media/57263/3328_p7_luto.pdf (17 *June 2012, 22:33).*

similar standard structure and the QRD group ensures that these rules are followed (Pander Maat et al. 2010: 113; Raynor 2008: 17). This standard QRD template provides the current text structure of the PIL nowadays within the EU. "The QRD structure is available in 24 languages and has three aims: make information in package leaflets more consistent across Europe, to help the pharmaceutical industry write package leaflets, and to make it easier for patients to understand information" (van der Waarde 2008: 217).

To ensure that the content of a PIL is optimal, the information has to be understandable, accurate and detailed. The information must be helpful for readers and designed or organised in a way that it is easy to read and understand (Krass et al. 2002: 29). To meet these requirements a PIL structure (QRD template) has to consists of four elements: the content, the order of the information, the headings to indicate specific paragraphs and subparagraphs and the phrasing of the heading (Pander Maat et al. 2010: 113; Pander Maat et al. 2011: 220). A fixed structure in a PIL can benefit because it helps readers to scan the PIL and find relevant information. Furthermore, it helps readers to learn "the text by genre through building a mental representation of its structure" (Pander Maat et al. 2011: 220). In order to gain more knowledge about the mental representation of a PIL structure we have to evaluate the reading process. How do people understand and retrieve the correct information out of a PIL?

2.2 Reading process

Leaflets are often seen as too long or complex. Many medicine users find it difficult to understand the information in a PIL because of its complex structure and difficult wording. It is important, however, that medicine users are able to understand the information in order to use the medication in the best way possible and be aware of all key safety issues about the medicine (Koo et al. 2003: 265; Dolk et al. 2011: 46-47). Numerous studies (e.g. Dolk et al. 2011; Pander Maat et al. 2011; Krass et al. 2002; Koo et al. 2003; Dickinson et al. 2001) have shown the importance of communication in relation to medicines. But what makes a text in a PIL problematical? To start with, we will first look at Kintsch's construction integration model to understand how readers comprehend a text and the process of making a representation of a text. Readers can make a specific representation if they know how to obtain the required information (Noordman et al. 2000: 35). The construction integration model consists of three levels regarding the mental text representation (Kintsch et al. 1988: 180). A mental representation is the mental image (representation) that readers make of a text (Sanders et al. 2002: 112). The first level is the *surface representation* which consists of the literal words in a text (Frank et al. 2007: 134) At the second level of the text representation the reader links a set of propositions to each other. This is

called the *propositional representation* (Kintsch et al. 2005: 210). Propositions include information with regard to the content of the text and its sentences (Noordman et al. 2000: 36). The connections between these propositions make a text coherent (Kintsch et al. 2005: 210). Hence, "a text is coherent when paragraphs and larger sections are clearly related to one another and to the main topic" (Kools et al. 2008: 834). At the third level the reader forms a *situation model*. "A situation model links a readers' background knowledge and personal experience, goals and purposes with information from the text" (Kintsch 2009: 225). A situation model is a mental representation from background knowledge of textual elements[3] (Kintsch et al. 2005: 211). Differend elements contribute to the creation of a mental representation including the state of affairs in a text, the propositions and the readers' prior knowledge (Zwaan et al. 1998: 162). During the creation of a situation model readers extend their knowledge about a text by including information based on their prior knowledge (Sanders et al. 2002: 113). To make an optimal mental representation it is important to recognize a text structure or organization in a text. This situation model gives the reader the tools to process, interpret, integrate and understand the information in a PIL and take action according to the instructions (Zwaan 1999: 15; Zwaan 1998: 163; Dolk et al. 2011: 47).

Every reader creates his or her own situation model of a text because they all obtain knowledge in a different way. It could be that some readers have the same reading comprehension ability but because of their different prior knowledge perceive the same text in a different way (Johnston 1984: 220). Building a situation model does not occur automatically. "Both text and readers variables, such as sentence length and literacy, influence text comprehension" (Dolk et al. 2011: 47). Prior knowledge can influence how a reader perceives a text and can function as a schema consisting of background knowledge (Johnston 1984: 220; Dolk et al. 2011: 47). If readers do not comprehend a text, they might use their prior knowledge of a particular topic to understand the essence of the text (Stahl et al. 1986: 310). It is difficult to find out if readers do not understand the text because of their reading comprehension abilities or because of their prior knowledge. Therefore it is important to construct a text that connects to both the readers' prior knowledge and the readers' comprehension abilities. A patient can have difficulties with reading a PIL because of his or her prior knowledge whereas another patient can have sufficient prior knowledge but does not understand the text because of inadequate reading comprehension skills (Johnston 1984: 220). The solution here would be creating a PIL that

[3] Kintsch, W., K. Anders Ericsson (1995) *Long Term Working Memory*. Website: http://comminfo.rutgers.edu/~kantor/t/MLIS/551/public_dump/morris_a_11.html (24 June 2012, 17:19).

provides both comprehensible text and text structure which readers with insufficient prior knowledge would understand.

2.2.1 Schema's

To make a comprehensive and adequate representation of the information given in a PIL readers must create a schema. Morrow (1998) found out that readers have a particular schema to process medical information. "A schema is a mental representation of stereotypical situations" (Zwaan et al. 1998: 162). A good example here would be Schank and Abelson's (1977) restaurant schema. This schema includes knowledge about human affairs, supporting assets like food and furniture and other aspects when visiting a restaurant like exchanging money for food (Zwaan et al. 1998: 162; Sweller et al. 1998: 256). When readers have to read a PIL they group the information about the medicine into three categories: identifying the medicine, then the instructions on how to take it and at last the information about the side effects (Morrow et al. 1998: 233). Readers that participated in a previous study of Morrow et al. (1998) remembered the PILs that were organized to this schema better then the PILs without this structure (Ibid.: 233).

To create a good representation on the information from a PIL, readers must categorize the obtained information and combine it with their prior knowledge about taking medication (Ibid.: 233). Readers will recognize particular organisation of text types like a PIL because of their schema knowledge (Kools et al. 2008: 834). Schema knowledge is formed by the text type, prior knowledge and reading comprehension skills (Ibid: 842). For example, if a PIL reader is familiar with what kind of information can be expected, like instructions, and the way the information is organised, he will understand the content better (Morrow et al. 1991: 378). Furthermore, older and younger readers that have the same schema for taking medication organize medical information in the same way (Morrow et al. 1998: 231). Therefore it is important that medical instructions connect with the readers' medication schema so that they remember medical information and anticipate on them (Pander Maat et al. 2011: 220). Readers will then better recall the information and it will improve the usability of the PIL instructions (Ibid: 220). In the next paragraph we will find out if the current text structure in a PIL reflects the medication schema of readers.

2.3 Findability: the structure of a PIL

Previous research has shown that readers have difficulties locating information in a PIL (Pander Maat et al. 2009, 2011). According to Pander Maat and Lentz (2011) the design of the current QRD structure is not built on research. Furthermore, previous studies (Morrow et al. 1996;

Morrow et al. 2000; Pander Maat et al. 2009; Pander Maat et al. 2010) did not focus solely on the structure of a PIL. Pander Maat and Lentz (2011) designed a study to test a current text structure (Pander Maat et al. 2011: 221). They used two card-sorting studies, the closed card-sorting and open card-sorting test. With a card-sorting study it is possible to investigate the text structure of a PIL and the navigation abilities in readers (Pander Maat et al. 2011: 218; Spencer 2009: 6). In short, with the card-sorting method researchers are able to find patterns how readers interpret the content and structure of a text. By understanding the reader's mental schemas it is possible to discover how they find information in a text[4] (Spencer 2009: 34, 36). It is important to know that this usability method will not deliver a final text structure but it will provide a guideline to improve the text structure in for example a PIL. As stated before the card-sorting method has two options: the open card-sorting and the closed card-sorting. The open card-sorting is a sorting task in which participants classify cards without a fixed structure. The closed card-sorting method is a findability study in which participants classify cards in a fixed structure (Spencer 2009: 7). In the study of Pander Maat and Lentz (2011) participants were asked, during the closed card-sorting method, to answer several scenario questions on medication usage. They had to explain under which heading in a PIL with a current text structure they expected to find the information. Furthermore, in the open card-sorting method, participants have been requested to sort sentences that could be found in the PIL. After that they were asked to place them under self named headings. Using a factor analysis it was possible to find out which sentences were clustered. The information in the strongest clusters were located under the same heading. The results showed that participants had difficulties locating the correct information but also that a current text structure causes many findability problems. These findability problems include both finding information about ingredients and directions for use. These results clarified that the EU current text structure of a PIL does not match the readers' medication schema (Pander Maat et al. 2011: 218, 220, 221, 235). The differences between the readers' interpretation and a current text structure include wording of the headings, classifying and grouping information (Pander Maat et al. 2011: 218, 235).

[4] Spencer, D., T. Warfel (2004) *Cardsorting a definitive guide*. Website: http://www.boxesandarrows.com/view/card_sorting_a_definitive_guide (13 June 2012, 22:16).

Given their ordering decisions, participants seem to prefer the following text structure (Pander Maat et al. 2011: 218):

- Purpose of the medicine
- Directions for use
- Potential problems
- Packaging and storage

Remarkably this structure corresponds to the structure of Morrow et al. (1998) were they investigated if older and younger adults share a medication-taking schema. The following structure was better remembered (Morrow et al. 1998: 233):

- Identifying the medication (name, purpose)
- How to take (dose and schedule)
- Outcomes (side effects)

Based on the results Pander Maat and Lentz (2011) proposed a revised text structure of a PIL. This proposal reflects the preferred structure of the participants. This first version of a revised text structure had the following order:

- Medicine – goal and ingredients
- Usage – directions
- Usage – potential problems
- Medicine – other aspects (package and storage)

This first draft was adjusted and changed in cooperation with Theo Raynor (University of Leeds) into the following revised text structure:

- About this medicine and what it is used for
- Directions for use
- Possible problems with this medicine
- Package, storage and disposal
- Ingredients and registration.

After several consultations the main heading 'Directions for use' was changed into 'Taking the medicine'. This was eventually presented as the final revised text structure. The structures presented above consist only of main headings. Refer to appendix 4 for the complete PIL including subheadings. Pander Maat and Lentz (2011) predicted that a PIL presented in this text structure will improve the findability of information about the medicine and its usage. In this study we will test the proposed revised text structure and compare it to a current text structure in a PIL (Pander Maat et al. 2011: 235).

2.4 Signaling structure

It is important that the overall structure of the text in a PIL is coherent. The different parts in a text should relate to each other. In general, readers will remember more and read faster when the information in a text is systematically organized (Meyer 2003: 208). Furthermore, the topics presented in a text should be hierarchically structured based on their importance (Ibid.: 208). Instructions in a PIL are generally clearer when the most important topics in a text are located at a high level in the structure and the less important topics at a lower level (Lentz et al. 2004: 392; Morrow et al. 1991: 379). For example, it is more important to know what the side-effects are and how to react to them than to know which manufacturer produced it. This level construction is part of the overall structure of a text and constitutes a logical order of the presented information. However the purpose of the text and its hierarchy can be misinterpreted if readers have a different medication schema to process the information or no schema at all (Meyer 2003: 208).

Part of a good structured text is the signalling of its organisation. "Signals are stylistic writing devices that highlight aspects of the context or structural organization" (Meyer 2003: 212). These stylistic writing devices include headings and subheadings that point out the relational structure between parts in a text. Signals also help readers to remember certain topics from a text (Meyer 2003: 212, 214). Therefore it is important that a text contains signals especially if the content concerns people's health for example in PILs (Ibid: 216). Signals like headings help readers to understand the structure of a text and make it easier for them to understand its content. For example by making inferences between different topics (Raynor et al. 2009: 703; Kools et al. 2008: 834). However, the importance of signals depends on how difficult the text structure is and the readers' comprehension abilities and motivation. When a text structure is complex and the readers' comprehension abilities and motivation are relatively low, signals are more important (Meyer 2003: 212-214). PIL readers often look for specific information when they have questions instead of reading the whole text (Kools et al. 2008: 833). The use of headings will improve accessibility and creates a text structure that will help readers to find the relevant information (Raynor et al. 2009: 703; Kools et al. 2008: 834). Headings will also help readers to activate the appropriate schemas and form a situation model with new and stored information. It is important to use clear and concise headings that attract attention but a PIL text should not consist of too much headings because it might confuse readers (Williams et al. 1992: 64; Raynor et al. 2009: 704; Tutty et al. 1999: 12). Many headings do not make a text easier when readers are looking for information (Kools et al. 2008: 842). "A heading should be brief and indicate a definite message to the reader" (Tutty et al 1999: 13).

This research examines whether a revised text structure will improve findability of information in PILs and have a better connection to the schema of readers. However, first we will examine the current and revised text structure.

2.4.1 The current text structure

The current text structure consists of six main headings. See table 2.1 for the current structure of a PIL according to the QRD structure (EMEA 2011: 24).

Table 2.1 The current text structure of a PIL

1. **What X is and what it is used for**
2. What you need to know before you <take> <use> X
• Do not <take> <use> X <:> • Warnings and precautions • Children <and adolescents> • Other medicines and X • X with <food> <and> <,> <drink> <and> <alcohol> • Pregnancy <and> <,> breast-feeding <and fertility> • Driving and using machines • <X contains {name the excipient(s)}>
3. How to <take> <use> X
• <Use in children <and adolescents>> • <If you <take> <use> more X than you should> • <If you forget to <take> <use> X> • <If you stop <taking> <using> X>
4. Possible side effects
• <Additional side effects in children <and adolescents>>
5. How to store X
6. Contents of the pack and other information
• What X contains • What X looks like and contents of the pack • Marketing Authorization Holder and Manufacturer

2.4.2 The revised text structure

The revised text structure consists of five main headings. Refer to table 2.2 for the revised text structure of a PIL as proposed in a previous study by Pander Maat and Lentz (2011).

Table 2.2 The revised text structure of a PIL

1. About this medicine and what it is used for

- What this medicine is
- What it is used for
- How it works

2. Taking the medicine

- How to take
- How much to take
- When to take
- How long to take
- If you want to stop taking this medicine
- If you forget to take
- If you take too much

3. Possible problems with this medicine

- People who cannot take this medicine
- Allergies
- People who should check with their doctor before taking this medicine
- Possible side effects
    - Stop taking this medicine and tell your doctor straight away if you notice:
    - Talk to your doctor if you have any of the side effects listed below, and they trouble you
- Taking X with other medicines
    - Tell your doctor if you are taking:
- How food, drinks and alcohol affect this medicine
- Driving and using tools or machines
- Pregnancy and breast feeding
- Tests

4. Packaging, storage and disposal

- Contents of the pack and appearance
- Storage
- Disposal

5. Ingredients and registration

- Ingredients
- Authorization holder and manufacturer

2.5 Research goal

Results in a previous study of Pander Maat and Lentz (2011) showed that participants had difficulties locating the correct information in a current text structure of a PIL (Pander Maat et al. 2011: 235). Pander Maat and Lentz (2011) recommended that a PIL in a revised text structure could help to improve the compatibility between the PILs structure and the readers' medication

schema. In addition, a revised text structure might improve localizing the correct information about the medicine and its use (Ibid: 218, 235). Therefore we will look at the grouping of information in a PIL and the wording of the headings. This will be done by using a PIL with a current text structure and one with a revised text structure.

2.5.1 Research question

According to the study of Pander Maat and Lentz (2011) and other research, we expect that a revised text structure will improve findability and appreciation of the leaflet since this structure is more compatible with the medication schema of readers. Based on this knowledge we can formulate the following research question:

What is the effect of a revised text structure as opposed to a current text structure on the findability and the user's perception of information in a patient information leaflet?

To get a clear view on the findability of information in a PIL and the readers' perception of the current and revised text structure we divided the research question in two sub-questions.

Sub-question 1:
What is the effect of a PIL with a revised text structure as opposed to a current text structure on the user's ability to find the information?

These expectations merge into the following hypotheses:
H1: A PIL with a revised text structure results in better findability of information in a patient information leaflet than a PIL with a current text structure.

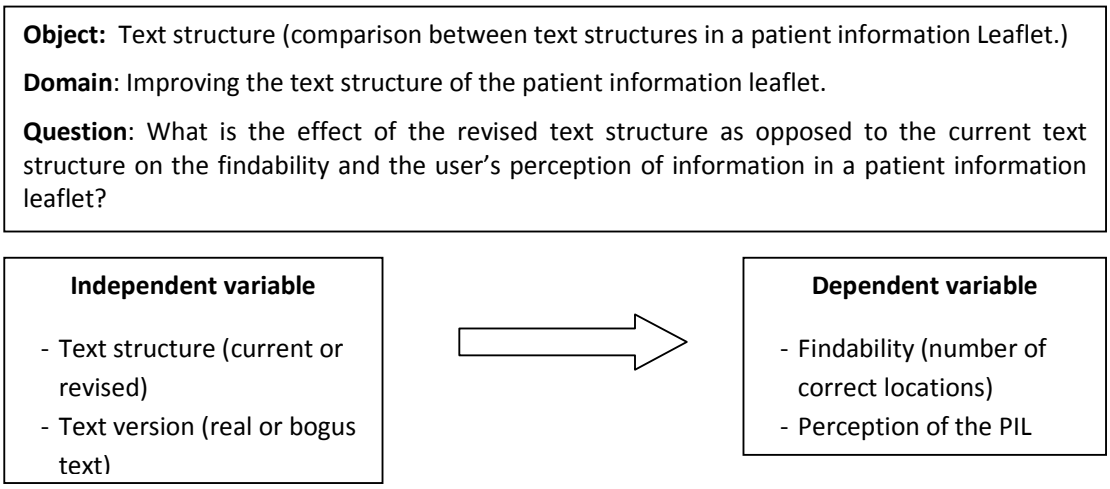
Sub-question 2:
What is the effect of a PIL with a revised text structure as opposed to a current text structure on the user's appreciation of the leaflet?

These expectations merge into the following hypothesis:
H1: A PIL with a revised text structure is perceived in a more positive way than a PIL with a current text structure.

2.5.2 Independent and dependent variables

The independent variables in this study are the text structure and the text version. The two structures are the current and revised text structures. The text versions are the version with real text, English or Dutch, and a bogus text. A bogus text is an unreadable text except for the headings and subheadings, which are in English or Dutch. This ensured that the participants concentrated on the text structure of PIL which prevented possible influences from the content. When readers only see headings they will not be distracted by the text in the PIL (Pander Maat et al. 2011: 235). The language of the headings and subheadings depends on the country where the interviews take place, The Netherlands or United Kingdom. Technically these versions are the independent variables. However, the variable text version is conceptually approached as a moderating variable instead of a independent variable because we are not testing the effect of a real or bogus text in a PIL. The findability of the information in a PIL and the perception of the PIL are the dependent variables. The objective is to find out which text structure has a positive effect on the findability and perception of the PIL. The number of correct locations will clarify if the findability of information in a PIL is better for a revised or current text structure. The perception of the PIL refer to the appreciation of the organisation of the information, wording and overall design. Figure 2.1 gives a clear overview of the conceptual model we will use for this study.

Figure 2.1: Conceptual model



3. Method

In this chapter the method used in this study will be discussed. The difference between a current and revised text structure on the findability and the users perception of information in a PIL have been examined. The findability scores have been measured based on the number of correct locations in a revised text structure as opposed to a current text structure. The perception was measured by how participants appreciated and evaluated these text structures. The participants were confronted with several scenario questions on medication use and were asked under which heading they would look to find the correct answer to each question (Pander Maat et al. 2011: 219). The perception and quality of the PIL was measured with five comprehension questions and a scale with positive and negative statements based on the CIRF (Consumer Information Rating Form) of Koo e.a. (2007) (refer to paragraph 3.3 for more details). At the end of each question set, four open questions about the participants perception of the PIL were asked. Finally a so called 'split-run test' was used to determine which text structure (revised or current) the participants preferred.

The research was accomplished by using members of the public in The Netherlands through the database of Medilingua and CG Selecties and in the United Kingdom through the database of LUTO LDT. Research. This study was done in two countries to enlarge its reliability and validity. A fictitious medicine based on a existing medicine was used to test the current and revised text structure. In this way the results can be applied to all sorts of PILs.

3.1 Research design

This research will consist of two approaches. In the first approach both PILs will be shown in a readable text. This will be done to create a realistic situation in which a medicine user has to read a PIL. In the second approach only the headings of both PILs are readable, the rest of the text is not readable (a bogus version). This research is important because we cannot decide to change a current text structure for PILs if we do not have solid evidence that a revised text structure is indeed more effective (Ibid.: 236). With an experimental test we will find out which text structure is the best possible structure for future PILs (Ibid.: 236).

Since this research design has two independent variables a factorial design was used. A factorial design investigates the effect of simultaneous manipulation of different independent variables (Van den Bergh 2006: 94). Four versions of a PIL were constructed for this experimental research. Version 1 and 2 consisted of PILs with the real text, version 3 and 4 of PILs with the bogus text. Version 1 and 3 included a current text structures in a PIL and version 2 and 4 a revised text structures in a PIL. We analysed the real and bogus text version in a current

text structure and the real and bogus text version in a revised text structure (Pander Maat et al. 2011: 52). This leads to a 2x2 research design as presented in table 3.1.

Table 3.1 Outline of research design

	Current text structure	**Revised text structure**
Real text version	(1)	(2)
Bogus text version	(3)	(4)

The objective of this study is to find out if a revised text structure 2 and 4 will lead to more correct locations compared to a current text structure 1 and 3. This means that we will examine if the real text in both current and revised text structure (version 1 and 2) lead to the same correct locations as the bogus text in both current and revised text structure (version 3 and 4). Therefore we distinguish two independent variables. The first independent variable is the text structure (see paragraph 2.4.1 and 2.4.2).:

- The current text structure is based on the European Union QRD template.
- The revised text structure is based on previous research of Pander Maat and Lentz (2011).

The second independent variable is the text version (see appendix 4):

- The original PIL text, with headings and text in English or Dutch (real text).
- A "dummy text" in which only the headings and sub-headings were readable in English or Dutch. The rest of the text was unreadable (bogus text).

First, the participants were divided into two groups, participants from the United Kingdom and from The Netherlands. Then the participants were randomly assigned into the eight conditions. To ensure that the conditions within this research were similar, the demographic criteria for each condition were equal for the number of men and women in the age categories. The details will be discussed in paragraph 3.4. All participants received two text structures of which one in bogus and one in real text. This makes it a within-subject design which means that participants in this study are participating in both control- and experimental group. Part of the participants received a revised text structure in the real text version and another part of the participants received a revised text structure in the bogus text version. Part of the participants was given a current text structure in the real text version and another part of the participants a current text structure in the bogus text version. Because each participant received two text structures with different text versions they had to participate in two tests. In the first test they were given one text structure with a text version in the second test another combination. See table 3.2 for an overview.

Table 3.2 Research design per condition (N=16 in each condition)

Condition	First test	Second test	Questionset (QS) in 1st and 2nd test
1	Bogus current text structure	Real revised text structure	QS1-QS2
2	Real revised text structure	Bogus current text structure	QS2-QS1
3	Bogus current text structure	Real revised text structure	QS2-QS1
4	Real revised text structure	Bogus current text structure	QS1-QS2
5	Real current text structure	Bogus revised text structure	QS1-QS2
6	Bogus revised text structure	Real current text structure	QS2-QS1
7	Real current text structure	Bogus revised text structure	QS2-QS1
8	Bogus revised text structure	Real current text structure	QS1-QS2

Each condition consisted of sixteen participants. A participant received a PIL in the first and second test. After they scanned the PIL the participants have been requested to find the correct location on 25 scenario questions in each PIL. Groups 1 and 3 first read a PIL with a current text structure in a bogus text and answered the first 25 scenario questions, followed by reading a PIL in a revised text structure in a real text and answering the next 25 scenario questions. Groups 2 and 4 did this the other way around. Groups 5 and 7 first read a PIL with a current text structure in a real text and answered 25 scenario questions followed by a PIL with a revised text structure in bogus text and answered 25 scenario questions. The last two groups, 6 and 8, did this the other way around. In this way we could prevent that an order effect occurred. This will provide a specific examination of the appropriate way to present headings in the PIL. To summarize, condition 1-3-5-7 vs. 2-4-6-8 differ in which text structure goes first. Conditions 1-2-3-4 have been presented with a current text structure containing the bogus text and a revised text structure containing the real text. Conditions 5-6-7-8 were presented with a current text structure containing the real text and a revised text structure containing the bogus text. Conditions 1-2-3-4 vs. conditions 5-6-7-8 differ in which structure goes with which text version. The difference between condition 1-3 and 5-7 are which questionset (1 or 2) participants received in the first and second test. This will be further explained in paragraph 3.3.2. The same research design was used in both the United Kingdom and The Netherlands. If the results on the current and revised text structure from The Netherlands and the United Kingdom are comparable we can assume the results are not dependent on the country (Van den Bergh 2006: 83).

3.1.1 Dependent variables

The effect of the revised and current text structure have been measured on two dependent variables, findability and the perception of the PIL. The findability of the information was measured by the number of correct locations on the scenario questions. The perception of the PIL refer to the appreciation of the organisation of the information, wording and overall design. How users perceive the PIL in a current text structure and a revised text structure. Perception was measured in three ways: scale questions, open questions and a split-run test. This will be elaborated in paragraph 3.3.

3.1.2 User testing

For this study we have used the 'user testing' method in which potential users of a medicine were interviewed individually to determine whether they found key pieces of information. The user testing method is commonly used across Europe to test PILs. User testing is a diagnostic test that evaluates the performance of readers when they have to look up the right location in a PIL. With a user testing method we would like to gain inside into the readers' experience in finding information in PILs. When using this method there are three steps to consider (Pander Maat et al. 2011: 51; Raynor 2008: 17):

- Step one: selecting subjects for the PIL that are relevant to the usage of the medicine
- Step two: designing a questionnaire with scenario questions that reflect the chosen subjects from a PIL.
- Step three: the participants had to be recruited from the target patient group.

Each participant had to be interviewed separately with the questionnaire. An oral interview that should give valuable information about the findability of information in a PIL. This form of interview will not only give us information about performance but also what kind of problems readers face when they search for the information in a PIL (Pander Maat 2008: 34). Moreover, the participants can be observed on how they look for information in a PIL as well as their verbal and non-verbal expressions during this process. The people in this research that participated in user testing had to imagine taking the medicine but not actually using the medicine. What user testing is trying to achieve is simulating a real situation where, in this case, someone is prescribed a medicine and has to consult the PIL (Raynor 2008: 17).

3.2 Materials

The material in this research consisted of a PIL for the medicine Carbamazepine. To be sure that participants would not recognize the name of the medicine we changed the name in Pharmazine instead of Carbamazepine. "Carbamazepine is a anticonvulsant, used for epilepsy, a painful illness of the face called 'trigeminal neuralgia' and to control serious mental health problems" (Dolk 2009: 18). In this research the PIL has been adapted to fit the current and revised text structure. Four PIL versions were created for this specific purpose. The design of the PILs have been created by a professional in a specialized document design program Adobe InDesign CS6. Refer to table 3.1 for these PIL versions. The well written and well-designed current and revised package leaflet consisted of structural improvements by Karel van der Waarde, a specialist in graphic design.

The participants were informed that the leaflet is not the original version and that they should not rely on its specific content so they would not apply the information to their own situation. The PILs have been presented on double-sided A4 format (210 mm x 297 mm). The difference in using a A4 format instead of a original PIL is its larger font. We chose to present the PILs in a A4 format because we could present the current and revised text structure in a similar way. Furthermore, because this research is about the structure and not the content we presented the PILs in a A4 format. The headings were portrait in verdana-bold 10,5 points, the subheadings in verdana-bold 11 points and the text in verdana 9 points. In this study the text in the PIL was printed in black and white on a normal A4 quality paper (80 gram per m^2). It consisted of five columns on one side and five on the backside. Original PILs are normally printed on thinner paper and consist of two columns. It is possible that the presentation of the PIL in a A4 format could create localization difficulties. To minimize possible effects on the presentation in a A4 format, all presentations were identical for each condition (Pander Maat et al. 2010: 114; Dolk 2009: 19).

3.2.1. The English and Dutch version of the PIL

For this study we used an actual medicine leaflet to reproduce the PIL in the best way possible. This simulated a real life situation where a person read a PIL since he was prescribed a certain medicine. The actual English[5] and Dutch[6] Carbamazepine PIL have been manufactured by the

[5] TEGRETOL® 100, 200 and 400 mg Tablets(Carbamazepine): http://www.medicines.org.uk/emc/medicine/4095. This version was last revised in September 2010.

[6] TEGRETOL® 100 and 200 mg Tablets (Carbamazepine): http://www.exmedica.nl/bijsluiter/tegretol/h03899. This version was last revised in February 2011.

pharmaceutical company Novartis. The trademark of this medicine is Tegretol. The Carbamazepine PIL was used in this study because this medicine is not a common drug so it was expected that most people are not familiar with the content of this PIL.

The text of the English and Dutch Carbamazepine leaflets have been used as a text for the PILs in this study. The structure of these leaflets is the same and complies to the current QRD structure as prescribed by the EMEA. Even though both the English and Dutch text are fairly similar there are a few differences in the content and layout. We used the content and layout of both English and Dutch leaflets to fit the current and revised text structure. For both the English and Dutch version of the Pharmazine (Carbamazepine) PIL, refer to appendix 4. The English version of the PIL was used for the interviews in the United Kingdom and the Dutch version of the PIL was used for the interviews in The Netherlands.

3.2.2 The current and revised text structure

The text of the Carbamazepine PIL was transferred into a PIL with a current text structure and a PIL with a revised text structure. Not the content but the construction of the headings varies in each version of the text structure.

A current text structure of a PIL according to the QRD structure (EMEA 2011: 24) consists of six main headings. See paragraph 2.4.1 for the layout of a current text structure. A revised text structure of a PIL as proposed in a previous study by Pander Maat and Lentz (2011) consists of five main headings. See paragraph 2.4.2 for the layout of a revised text structure.

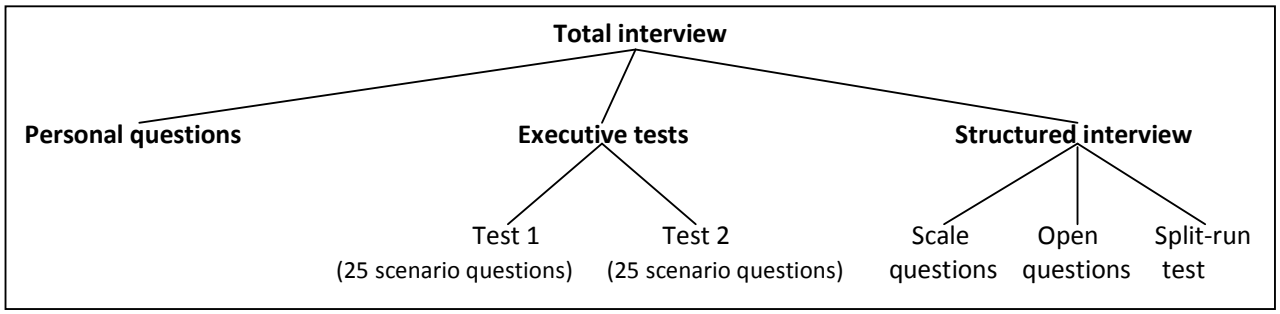
3.2.3 Text version

The text version consisted of a paper version of the PIL with either the original (real) text of the PIL or the bogus text in which only the headings are readable. In the PIL with the real text both the headings and the text were presented in English or Dutch. The interviews and materials in both United Kingdom and The Netherlands have been presented in the native language of these countries. In the version with the bogus text only the headings were shown in English or Dutch language, the rest of the text was unreadable. This bogus text was made by first changing all the vowels: a into e, e into i, i into o and o into u. Subsequently several consonants were exchanged. This was realised through the function find and replace on the computer. Both the bogus text and the real text were presented in a current and revised text structure. This resulted in four different PIL versions in the English language and four versions in the Dutch language.

3.3 Instruments

The entire interview consisted of four parts: personal questions, two executive tests and their corresponding sets of 25 scenario questions and a structured interview including perception questions (see figure 3.1). The instruments in this study were the scenario questions and a structured interview. With these instruments the findability and perception of the PIL were measured. The findability of the information was measured by the number of correct localizations on the scenario questions. The perception of the PIL was measured by a structured interview which consisted of scale questions, open questions and a split-run test. These instruments will be elaborated in the next paragraphs.

Figure 3.1 Interview outline



3.3.1 Personal questions

The personal details (name, date of birth, educational background and job title) were obtained through a participant database (see paragraph 3.4.1 for more details). These data have been verified at the beginning of the interview.

3.3.2 Scenario questions

The dependent variable findability was measured through scenario questions. These scenario questions were based on previous studies about PILs (Dolk 2009: 23; Dickinson 2001: 155; Pander Maat 2008: 40-45; Gustafsson et al. 2005: 36). They covered several issues about medicine usage, in other words the medical topics that have been presented in the PIL. The findability score was the percentage of the correct locations. By means of these scenario questions the participant's ability to find and localize key points of information from the leaflet have been tested. All participants were interviewed individually and have been asked to find the correct location to scenario questions in a current as well as revised text structure.

Because we examined the findability of information in a PIL, that either has a current or revised text structure, the scenario questions reflected the information under the main- and subheadings (i.e. topics) within those structures. The scenario questions did not use terms occurring in headings because that would make it easier for the participants to find the correct location. Therefore, each question represented the subject of the main heading or subheading. Two question sets of 25 questions have been developed to avoid that participants got the same questions in both tests. In that case finding the correct locations could have been influenced by their prior knowledge by which they could have reproduced the correct locations on the scenario questions of the previous test. The questions as presented in both sets were comparable but not identical. For example, the correct location to question 2 of set 1: '*Imagine you have epilepsy. Did the doctor prescribe the right medicine for you?*' and the similar question 2 of set 2: '*Imagine you have mood swings. Is this the right medicine for you?*' is found under the revised heading: 'What it is used for' and the current heading: 'What Pharmazine is and what it is used for'. In this way scenario questions covered the information under similar headings of the revised and current PIL but were not identical (refer to appendix 2 for the scenario questions in English and Dutch).

For each set of scenario questions four versions have been developed. To prevent any order effect, the questions within each set were exactly the same but placed in a different order to avoid that the results could be influenced by a certain question order. For the two sets of scenario questions there were in total eight versions. In none of these versons, scenario questions for certain headings or subheadings are put in the same order (or closely together) as the headings or subheadings appear in the PIL.

The eight different versions of the scenario questions cover conditions 1 to 4. Since for conditions 5 to 8 a different PIL structure was used, the same eight versions apply for these conditions. The PILs as used for conditions 1 to 4 contain a revised text structure with the real text and a current text structure with the bogus text. The PILs as used for condition 5 to 8 contain a revised text structure with the bogus text and a current text structure with the real text. See table 3.3 for an overview of all question sets.

Table 3.3 Question set design per condition (N=16 in each condition)

	Question sets	
Condition	**First test**	**Second test**
1	Question set 1 version 1	Question set 2 version 1
2	Question set 2 version 2	Question set 1 version 2
3	Question set 2 version 3	Question set 1 version 3
4	Question set 1 version 4	Question set 2 version 4
5	Question set 1 version 1	Question set 2 version 1
6	Question set 2 version 2	Question set 1 version 2
7	Question set 2 version 3	Question set 1 version 3
8	Question set 1 version 4	Question set 2 version 4

All versions of the questionnaires were translated into English or Dutch. Refer to table 3.4 for a few questions to give an idea of how they are formulated. In this table both English and Dutch questions are presented as well as the name of the heading (in the current and revised text structure) where the correct location is found. The complete versions of both questionnaires can be found in the appendix 2.

Table 3.4 Example scenario questions of question set 1 and 2 in English and Dutch

Question	**Question Set 1** (questions in English and Dutch and the heading where the correct location is found)					
	English	**Dutch**	**Revised heading English**	**Revised heading Dutch**	**Current heading English**	**Current heading Dutch**
1	Suppose you want to know what the active component in this drug does for you. Where can you find this information in this leaflet?	Stel, u wilt weten wat de werking is van het actieve bestanddeel in dit geneesmiddel. Waar kunt u deze informatie in deze bijsluiter vinden?	What this medicine is *(subheading)*	Wat is dit voor geneesmiddel *(subheading)*	What Pharmazine is and what it is used for *(main heading)*	Waarvoor wordt dit middel gebruikt *(main heading)*
4	Suppose you have heart problems. Are you allowed to use this medicine?	Stel, u hebt hartproblemen. Mag u dit geneesmiddel gebruiken?	People who cannot take this medicine *(subheading)*	Wie kan dit middel niet gebruiken *(subheading)*	Do not take Pharmazine if: *(subheading)*	Wanneer mag u dit middel niet gebruiken? *(subheading)*
9	Can you have grapefruit and grapefruit juice if you are taking this medicine?	Mag u grapefruit en grapefruitsap hebben als u dit geneesmiddel gebruikt?	How food, drinks and alcohol affect this medicine *(subheading)*	Eten, drinken, alcoholgebruik en de werking van dit middel *(subheading)*	Pharmazinie with food, drink and alcohol *(subheading)*	Waarop moet u letten met eten, drinken en alcohol *(subheading)*
15	How many times a day should you take a dose of this medicine?	Hoeveel keer per dag moet u een dosis van dit geneesmiddel innemen?	When to take *(subheading)*	Wanneer neemt u dit middel in *(subheading)*	How to take Pharmazine *(main heading)*	Hoe gebruikt u dit middel *(main heading)*
18	Suppose you did not remember to take the medicine this morning. What should you do?	Stel, u bent vanmorgen vergeten om het geneesmiddel in te nemen. Wat moet u doen?	If you forget to take *(subheading)*	Als u een dosis vergeten bent *(subheading)*	If you forget to take Pharmazine *(subheading)*	Bent u vergeten dit middel in te nemen *(subheading)*
Question	**Question Set 2** (questions in English and Dutch and the heading where the correct location is found)					
	English	**Dutch**	**Revised heading English**	**Revised heading Dutch**	**Current heading English**	**Current heading Dutch**
1	Suppose you would like to know how this medicine affects your illness. Where can you find this information in this leaflet?	Stel, u wilt weten wat voor effect dit geneesmiddel op uw ziekte heeft. Waar kunt u deze informatie in deze bijsluiter vinden?	What this medicine is *(subheading)*	Wat is dit voor geneesmiddel *(subheading)*	What Pharmazine is and what it is used for *(main heading)*	Waarvoor wordt dit middel gebruikt *(main heading)*
4	Suppose you have had blood problems. Are you allowed to use this medicine?	Stel, u hebt bloedproblemen gehad. Mag u dit geneesmiddel gebruiken?	People who cannot take this medicine *(subheading)*	Wie kan dit middel niet gebruiken *(subheading)*	Do not take Pharmazine if: *(subheading)*	Wanneer mag u dit middel niet gebruiken? *(subheading)*
9	Imagine you would like to go to a party. Are you allowed to drink beer or wine?	Stel, u wilt naar een feest gaan. Mag u bier of wijn drinken?	How food, drinks and alcohol affect this medicine *(subheading)*	Eten, drinken, alcoholgebruik en de werking van dit middel *(subheading)*	Pharmazinie with food, drink and alcohol *(subheading)*	Waarop moet u letten met eten, drinken en alcohol *(subheading)*
15	At which times during the day should you take a dose of this medicine?	Op welke momenten van de dag moet u een dosering van dit geneesmiddel nemen?	When to take *(subheading)*	Wanneer neemt u dit middel in *(subheading)*	How to take Pharmazine *(main heading)*	Hoe gebruikt u dit middel *(main heading)*
18	Suppose you have not taken a dose earlier in the day and it is now time for your next dose. When should you take the medicine?	Stel, u hebt eerder op de dag nog geen dosis gehad en het is nu tijd voor de volgende dosis. Wanneer moet u het geneesmiddel innemen?	If you forget to take *(subheading)*	Als u een dosis vergeten bent *(subheading)*	If you forget to take Pharmazine *(subheading)*	Bent u vergeten dit middel in te nemen *(subheading)*

3.3.3 Structured interview

The dependent variable perception was measured with a appreciation questionnaire. To measure the evaluation of the participants and text appreciation five questions have been used that are based on the CIRF (Consumer Information Rating Form) of Koo et al. (2007). With these questions it is possible to measure the consumers' perception of the comprehensibility (5 items). The perceived comprehensibility of the information in a PIL was determined on a five point scale from '1' (very easy) to '5' (very difficult). The five items addressed the question 'how easy or hard would you say the information in the leaflet is to': read, understand, remember, locate information in and keep for future reference. The readers' evaluation concerning the layout of the PIL was measured with 15 items based on the CIRF of Koo et al. (2007) relating to the perception of the quality of the PILs design. This was measured on a semantic differential with positive and negative statements. In general, the negative adjective is positioned on the left and the positive on the right but to prevent a certain automatism in answering questions we mirrored some items. This part of the questionnaire was a hard copy. The appreciation questions and the design quality questions of the CIRF are illustrated in table 3.5. The items that were mirrored are indicated with an star.

Table 3.5 Consumer Information Rating Form (Pander Maat 2008: 31,50; Dolk 2009: 20, 21).

Comprehension	
How hard or easy would you say the information in the leaflet is to....	**Hoe makkelijk of moeilijk vindt u de bijsluiter om te....**
- Read - Understand - Remember - Locate information - Keep for future reference	- Lezen - Begrijpen - Onthouden - Informatie in te vinden - Vaker te gebruiken
Design and tone	
Below is a list of words on a scale describing the design, layout and tone of the leaflet. Which best describes your opinion? I find the leaflet:	**Hieronder staan een aantal woorden die het ontwerp, opmaak en toon van de bijsluiter beschrijven. Welke beschrijft uw mening het beste? Ik vind de bijsluiter:**
- Easy / Difficult - Clear / Unclear* - Logically structured / Illogically structured - Concise / Long-winded - Appealing / Unappealing - Interesting / Not interesting - Inviting / Uninviting* - Clarifying / Not clarifying - Personal / Impersonal - Well organized / Poorly organized* - Ideal print size / Poor print size - Encouraging in tone / Alarming in tone - Unbiased / Biased* - Attractive / Unattractive* - Ideal spacing between lines / Poor spacing between lines	- Makkelijk / Moeilijk - Duidelijk / Onduidelijk* - Logisch gestructureerd /Onlogisch gestructureerd - Beknopt / Langdradig - Aantrekkelijk / Onaantrekkelijk - Interessant / Oninteressant - Uitnodigend / Niet uitnodigend* - Helder / Niet helder - Persoonlijk / Onpersoonlijk - Goed georganiseerd / Slecht georganiseerd* - Goede grootte van de letters / Slechte grootte van de letters - Aanmoedigende toon / Alarmerende toon - Niet bevoordeeld / Bevooroordeeld* - Boeiend / Niet boeiend* - Ideale ruimte tussen de regels / Te weinig ruimte tussen de regels

The full version of this questionnaire in English and Dutch, as presented to the participants, can be found in appendix 2.

To get more feedback on how the participants perceived the leaflets the following open questions were asked (Question 1 and 4: Dickinson et al. 2001: 158; question 2: Dolk 2009: 24):

1. Overall, what do you think of the leaflet? Any particular good or bad points?
2. In particular, what did you think about the headings and subheadings? Any particular good or bad points?
3. In particular, what did you think about the order of the information in the leaflet? Any particular good or bad points?
4. Is there anything else about this leaflet that we have not talked about which you would like to mention?

The interview was concluded with a 'split run test'. A 'split run test' is an experiment in which the interviewer presents both versions (the current and revised PIL) to the participants. In this study we did the 'split run test' after the second test. The participant chose a preferred version. The PIL with a current text structure and revised text structure were presented on boards, the current version on one side and the revised version on the other side. The following question was asked: '*Which version of the medicine leaflet do you prefer?*'. The participants wrote their answer on a five point scale on a paper version of the questionnaire: 'I prefer version: A or B'. The position of the current and revised PIL differed between conditions, either left or right. For participants in condition 1, 3, 5 and 7 the current text structure (A) was shown on the left side and the revised text structure (B) on the right side of the board. For participants in condition 2, 4, 6 and 8 the revised text structure (A) was shown on the left side and the current text structure on the right side of the board. The participants were asked to explain their choice. The questionnaires with the 'split run test' can be found in the appendix 2.

3.4 Participants

For this research 128 participants were recruited, 64 participants from the Netherlands and 64 participants from the United Kingdom. The participants take part on a voluntary base and got a compensation for their participation at the end of the interview. The participants in the UK were paid £20 according to the LUTO standards and the participants from The Netherlands received either €15 in a gift voucher or cash according to the procedures of either Medilingua or CG Selecties. The University of Utrecht and the University of Leeds provided these payments. The participants were recruited one to two weeks before the research. They could decide right at the start of the interview if they wanted to take part. The risks of taking part in this study could be that some participants may find the task tiring or difficult, although this possibility was explained to them during the initial contact. Participants could ask to stop at any time during the interview.

3.4.1 Participant criteria

In this research the participants had to be 18 years or older. There were eight conditions (8 participants per condition per country). Each group of 8 participants had the following characteristics:

- At least 4 participants of each sex
- A maximum of 3 participants with a higher educational degree
- Each age group (20-30, 30-40, 40-50, 60-80) should contain at least 2 participants
- At least 2 participants who are unemployed or retired
- None of the participants should be familiar with the PIL in question or other medicines in the same group.

We performed a random sampling with disproportional stratification in which the participants were equally divided amongst the conditions. The participants were divided according to their personal details like age, sex and educational background. The participants were categorized into three educational levels:

1. The first level of education is the general certificate of secondary Education (GCSE). In The Netherlands this level is called technical and vocational training.
2. The second level of education is an education on 'A' levels or equivalent. This is called secondary education in The Netherlands.
3. The third and last level of education is the higher, academical education. This is a postgraduate, graduate, master and doctorate qualification.

To measure reading comprehension the participants were divided into two groups according to their literature usage: those who used literature in their job and those who didn't. When participants have to deal with paper work they work with literature. For example a secretary uses literature and a carpenter does not. Participants that use literature for their job could experience reading a PIL as an easier task than the participants who do not use literature. This selection made it possible to see if there were differences in the results between these two groups. Because we wanted to know if the participants had any experience in medicine they were asked whether they were prescribed any medication. It could be that participants who use medications are more familiar with PILs than participants that did not. As mentioned before, no one should be familiar with the medicine used for this research. With this selection we could see if there were any differences in the results between these two groups.

All personal details were obtained from the database of LUTO Research LTD, Medilingua and CG Selecties. Since we were only interested in the opinion of adults, only participants older than 18 years could apply for this study. Because participants have to find the appropriate

information in a English or Dutch PIL we have only recruited people with sufficient skills in reading and writing in these languages. For the study done in the United Kingdom the participants must be able to read and understand English and they had to pass the LUTO's usual screening criteria. Additionally, they should have not taken part in a user testing study in the last six months. For the study performed in The Netherlands the participants must be able to read and understand Dutch and had to pass the MediLingua screening criteria and the CG Selecties selection criteria. The criterion that participants cannot take part if they participated in an earlier user testing study within the last six months, was not met for a few participants. About 15 participants did not meet this criterion. We accepted these participants because this study was different than they were used to. Furthermore, people in real life do also have the opportunity to look at medicine leaflets within the previous months.

The personal details (name, date of birth, educational background, job title and contact details) were kept on the LUTO Research LTD, Medilingua and CG Selecties database for at least six months. This was to enable these organisations to possibly contact the participants in the future. The personal details were kept confidential and secure and were not shared with any third party, in accordance with the data protection act. At the moment a participant decided not to participate any longer in this study, their personal details were deleted from this research immediately.

3.4.2 Recruitment procedure United Kingdom

The participants from the United Kingdom were recruited via LUTO Research LTD, a university spin-off company. LUTO has significant expertise and experience in conducting user testing of medicine leaflets for patients. The LUTO participant database (n=10.000+) consists of members of the public who have taken part in user testing studies, or who have given their name as a potential participant. Each participant could join a user testing study once in every 6 months. LUTO works according to a protocol provided by the University researchers. The participants were invited to visit Leeds Innovations Centre in Leeds.

3.4.3 Recruitment procedure The Netherlands

The participants from The Netherlands were recruited via Medilingua and CG Selecties. Medilingua is a company that is specialised in translation of PILs and has expertise and experience in conducting user testing of medicine leaflets for patients. Medilingua has a participant database (n=±200) of members of the public who have taken part in user testing

studies, or who have given their name as a potential participant. CG Selecties is an organisation that facilitates qualitative research by recruiting participants. They have a participant database (n=65.000+) of members of the public who have taken part in several studies, or who have given their name as a potential participant. The participants from MediLingua were invited to visit the Medilingua office in Leiden and the CG Selecties participants were invited to visit the laboratory of the University Utrecht in Utrecht.

3.5 Procedure

The interviews took place in professional quiet rooms on suitable test locations in an informal atmosphere. The interviews were one-to-one between the interviewer and a participant. During each interview the participants read the PIL and the interviewer asked scenario questions about that particular PIL. The interviews were sound-recorded and the interviewer scored the given locations (correct or incorrect) and took notes of the participants comments (van der Waarde 2008: 218, 219). The procedure of the interview consisted of the following stages:

Stage 1: Introduction

The interviewer explained to the participant what could be expected during the interview. First, the participant was told that the entire interview would be recorded and during this research stored in the database of LUTO, Medilingua or CG Selecties. After the participant gave her or his consent the following steps of the procedure have been explained: *'The interview will take approximately 1 hour and includes two tests as well as two question sets. You will be given a patient information leaflet of a particular medicine. You have one minute to scan this medicine leaflet. After you explored the medicine leaflet you will be given 25 questions where I will ask you to imagine that: 'You went to the doctor and he or she prescribed this medicine for you for the first time. After receiving the prescription you get the medicine at the pharmacy and you go home. When you get back home you realize that you still have some questions about the medicine and you decide to look at the medicine leaflet'.* (The interviewer only said the following if the participant received the unreadable text: *You will be presented with a version in which the text has been made unreadable. But you are able to read the main- and subheadings.) Each question will be given to you on a card. Try to scan the leaflet to find the correct location to the questions and do not read the leaflet thorough with every question you get. You are asked to point out the heading where you believe the correct location is to be found. You have approximately 1 minute to answer each question. At the end of the interview you will receive a few questions to express your appreciation of both leaflets'.*

Participants received an information sheet (adapted from those used at LUTO for other user testing) in which all aspects of the interview have been elaborated (refer to appendix 1 for

details). Once it has been read there is the opportunity to ask questions about the interview. Subsequently the participants (from the United Kingdom only) received a consent form which stated that the participant agreed to take part in this study and that the participant is free to withdraw from the study at any time without giving a reason (the consent form can be found in appendix 1). Medilingua and CG Selecties had their own procedure regarding the permission of participants before the interviews took place.

Stage 2: The participant scans the medicine leaflet

In this stage the interviewer gave the participant the specific medicine leaflet and explained again that they could scan the leaflet briefly (approximately 1 minute) before the first test. Subsequently, the participants first received the PIL with either a revised text structure (with real or bogus text) or with a current text structure (with real or bogus text) followed by the other version.

Stage 3: Structured interview first test

In this stage the participant answered 25 scenario questions. The interviewer asked each question separately and then presented the questions on separate cards to avoid any misunderstanding. The cards were given one at a time. The interviewer asked the participant to find the correct locations to 25 scenario questions in the PIL. The participant could refer to the medicine leaflet while answering the questions. The participant had to look up the correct location in the leaflet and point to the heading of their choice. They did not have to answer the question in detail as long as they clearly mentioned or pointed at the chosen heading. While the participant answered each question, the interviewer made notes of the following aspects:

1. Location success: if the participant finds the correct location.
2. Comments: each intervention by the interviewer to clarify the question to the participant. This was only done if the participant asked for an explanation.
3. Headings and subheadings: the interviewer checked on the basis of a form (with the correct locations) whether the heading or subheading was correct. The headings of the current and revised leaflet were numbered.

4. Score: the score was based on location success. The interviewer scored each question individually. There were three scores:
   a. Found: the correct location to the question was found within one minute. In the following paragraphs we may refer to the correct locations as being the correct main- and subheading scores.
   b. Found with difficulty: the participant did not find the correct location within one minute. Sometimes a previous location was found after answering other questions. If participants needed more time than 1 minute to look for the correct location the interviewer would in some cases interrupt the search to ask where he or she thought the correct location could be found in the PIL. The interviewer continued to the next question if the participant did not know the correct location to the question.
   c. Not found: if the participant could not find the correct location to the question. Because he or she did not look at the right section of the medicine leaflet to find the correct location. Either the participant gave up the search or got stuck finding the correct location. In these circumstances the interviewer asked the participant whether he or she wanted to move on to the next question (if this was still within the one minute limit).

The results have been judged on two levels of localization scores, the correct subheading scores and the correct main heading scores. The first level, correct subheading scores, distinguish the correct and incorrect locations as an answer. The second level, correct main heading scores, distinguish correct, partly correct and incorrect locations as possible answers. This second level makes a distinction between locations. When an location was partly correct, i.e. when the main heading was found but not the subheading, the location was assessed as correct. This way of examination was introduced because the current and revised structure differs in the number of main- and subheadings, and to distinguish between problems with main headings and problems with subheadings.

<u>Stage 4: Open and closed questions about appreciation medicine leaflet in first test</u>

In this stage the interviewer asked a number of specific questions about the medicine leaflet used in the first test. These were open and closed questions about the participant's impression of this particular leaflet and their opinion of the main- and subheadings. The participant had to fill out a short questionnaire to evaluate the leaflet: how hard or easy was the leaflet, evaluation of its tone and the layout of the leaflet.

Stage 5: Structured interview second test

In this stage the interviewer gave the participant another medicine leaflet and a different questionnaire, which also consisted of 25 questions. The interviewer explained to the participant once more that they could look briefly at the medicine leaflet (approximately 1 minute) before the second test. Then the process described at stage 3 was repeated.

Stage 6: Open and closed questions about appreciation medicine leaflet in second test

The interviewer asked a number of specific questions about the medicine leaflet used in the second test. These were open and closed questions about the participant's impression of the leaflet and their opinion of the headings. See the process described at stage 4. This stage of the interview ended with the 'split run test', where the participant was asked which version, the revised or current leaflet, he or she prefered (refer to paragraph 3.3 for a explanation of the 'split run test').

Stage 7: Explanation of the study

As soon as the two tests were successfully completed the interviewer clarified the aim of the study to the participant. The interviewer said to the participant: '*The aim of this research is to compare the revised version of the structure of a medicine leaflet with the current version in order to create a better leaflet and maximize the readability of medicine leaflet*s. *These tests will determine whether people can find the information and how it takes them to find it*.' The interviewer showed the participant the revised and current versions of the medicine leaflet in real text to demonstrate the different structures.

3.6 Data analysis

The data was analysed using the statistical program SPSS 18.0 for Windows. We used Chi²-tests for findability results and ANOVA's for evaluation results.

3.6.1 Findability and perception

First we looked at the findability scores as explained in stage 3 of paragraph 3.5 to find out which text structure (revised or current) was better understood. More correct locations suggest higher findability. The results have been judged on two different levels, the correct subheadings and the correct main headings. The correct main- and subheadings levels distinguish correct from incorrect locations (see paragraph 3.5 for an explanation). The scores of these levels is as follows, the score 0 is incorrect and the score 1 means correct (see table 3.6). These scores have been given to the localization scores on the scenario questions of each participant.

Table 3.6 Description localization scores

	Correct subheadings	**Correct main headings**
	Score	**Score**
Correct main- and subheading	1	1
Correct main heading but incorrect subheading	0	1
Incorrect main heading	0	0
Not found	0	0

First a T-test was used to determine if factors like country, bogus and real text version, question set combination and the text structure the participants received first, influenced the correct localization scores and if these results could be combined. When the T-test shows that there is a significant difference between the results of a factor they cannot be combined. Then descriptive statistics was used to compare the results on the scenario questions in the current and in the revised text structure. Specifically, with the crosstabs the percentages between each question for both revised and current PIL could be generated and compared. To test the difference between the number of correct locations on a revised text structure and the correct locations on a current text structure the McNemar test was used.

Finally we looked at the perception scores of the participants on the revised and current PIL as explained in stages 4 and 6 in paragraph 3.5. The scores given on the CIRFs and the 'split run test' were both based on a five point scale. Perception has been measured with an ANOVA test with the factor text structure (both current and revised) as within-participant factor and a

series factors (first text structure, bogus or real text and current and revised text structure with question set 1 or 2) as between-participant factors. This was done to see if there is any interaction effect between the appreciation questions and the factors.

4. Results

In this chapter the results of this study will be elaborated. First a description of the participants will be given, followed by how the participants experienced the interview including remarks from the interviewer and participants. Next we will look at the independent variables that affect the findability of information in the PIL. These results are based on the number of correct locations of the scenario questions on both current and revised text structure. Finally the results on the perception will be evaluated. This will be done by analysing the data from the CIRF, the open questions about the evaluation of the PILs and the 'split run test'.

4.1 Participant description

In total 128 participants contributed to this research, 64 men and 64 women. The average age is 45 years. 68% of the participants in this research were between 27 and 62 years old. Participants from The Netherlands that did an interview within the last six month could be taken into account because they did not perform better than other participants. Table 4.1 gives an overview of the demographic characteristics of the participants. The figures in this table are absolute numbers.

Table 4.1 Demographical description of the participants (%)

	United Kingdom			**The Netherlands**			**Total**
	Male	**Female**	**Total**	**Male**	**Female**	**Total**	
Sex	32 (25,0%)	32 (25,0%)	64 (50,0%)	32 (25,0%)	32 (25,0%)	64 (50,0%)	128 (100%)
Age (sd)	45,5 (19,52)	43,8 (17,25)	44,7 (18,29)	44,2 (17,72)	44,9 (16,79)	44,5 (17,13)	44,6 (17,65)
Education							
1. (GCSE's)	6 (18,7%)	6 (18,7%)	12 (18,7%)	9 (28,1%)	11 (34,4%)	20 (31,3%)	32 (25,0%)
2. (A levels)	15 (46,9%)	14 (43,8%)	29 (45,3%)	16 (50,0%)	18 (56,2%)	34 (53,1%)	63 (49,2%)
3. (Grads)	11 (34,4%)	12 (37,5%)	23 (35,9%)	7 (21,9%)	3 (9,4%)	10 (15,6%)	33 (25,8%)
Using literature in job							
1.Yes	17 (53,1%)	20 (62,5%)	37 (57,8%)	15 (46,9%)	16 (50,0%)	31 (48,4%)	68 (53,1%)
2. No	15 (46,9%)	12 (37,5%)	27 (42,2%)	17 (53,1%)	16 (50,0%)	33 (51,6%)	60 (46,9%)
Experience medication							
1. Yes	8 (25,0%)	18 (56,2%)	26 (40,6%)	13 (40,6%)	13 (40,6%)	26 (40,6%)	52 (40,6%)
2. No	24 (75,0%)	14 (43,8%)	38 (59,4%)	19 (59,4%)	19 (59,4%)	38 (59,4%)	76 (59,4%)

Because the participants were equally divided amongst the conditions, we were able to gain significant results about the total target group. The participants were divided according to their personal details like age, sex and educational background. Table 4.1 shows that the participant criteria (see paragraph 3.4.1) are met. The distribution of sexes is equal, 32 men and 32 women in both the United Kingdom and The Netherlands. Furthermore, within each country each conditions consisted of 8 participants (4 men and 4 women). The average age of the participants between the two countries is 45 and therefore also equal. The standard deviation, concerning the distribution of age in both countries, is also quite equal. The educational level between the participants of both countries is not quite balanced but as the criterion mentioned, each condition should consist of maximum 3 participants with an higher education (grads) and the rest could fall into the first two levels of education (GCSE's and A levels). Which means that within each country no more than 24 participants have an higher education. If we look at the usage of literature on the job we can see that 58% of the participants from the United Kingdom and 48% of the participants from The Netherlands use literature on the job. This is fairly equally divided. In both countries 41% of the participants are currently taking medicines.

4.1.1 Participant observation

Overall the participants experienced some difficulties with the interview. This was caused by the different approach of this user testing method which was unknown to them. The first unknown factor was that they could scan the leaflet briefly for 1 minute before the first and second test. They were used to read the leaflet thoroughly. Secondly they were not used to answer 25 questions for each PIL. The third unknown factor that the participants experienced was that they were not able to look up the correct locations in the content but only from the headings and subheadings. Furthermore, the participants found it strange that one of the PILs was in an unreadable text. The last unusual factor in this study was that the appreciation questions were about the headings and subheadings only and not the content. These factors made the interview difficult and raised many questions. All questions were clarified by the interviewer. A few examples of these questions and answers are:

1. Participant: 'But how do I answer the questions if the text is unreadable?' Interviewer: 'You only have to look at the headings or subheadings to see where you would look to find the answer to the question, so not at the unreadable text.'
2. Participant: 'Am I supposed to read the whole leaflet in 1 minute?'. Interviewer: 'You do not have to read the whole leaflet thoroughly as long as you know what kind of headings and subheadings are mentioned and have an overview about what is mentioned in the leaflet.'

3. Participant: 'How do I know if I find the headings personal or impersonal?' Interviewer: 'Do you think the headings or subheadings speak to you as a medicine user or do you think they are formal?'

In general the participants in the United Kingdom were patient and listened carefully what was expected from them. They asked questions if there were uncertainties and participated throughout every part of the interview. The participants from The Netherlands were in general more dominant and had more difficulties cooperating, although they did ask many questions, they also had many comments on the study referring to the unreadable text and answers they had to give. The participants from the United Kingdom participated slightly better than the participants from The Netherlands.

4.2 Findability

In this paragraph the findability scores will be discussed. The findability scores are based on the correct locations on the 25 scenario questions per leaflet. These scenario questions reflect the main- and subheadings in the revised and current text structure. More correct locations indicate a higher findability of information in the PIL.

We started by examining if the factors like country (UK or NL), first text structure (current or revised), text version (bogus or real text) and question set (QS1 or QS2) influenced the results. To determine if the results from the two countries can be combined the results from the United Kingdom (N=64) and The Netherlands (N=64) are compared to see if there is a significant difference between the means of those results. As depicted in table 4.11 in the United Kingdom the average of correct localization scores for the current PIL was 17,20 (sd = 3,25) and for the revised PIL 15,48 (sd = 2,8). In The Netherlands the average of correct localization scores for the current PIL was 18,14 (sd = 2,89) and for the revised PIL 15,95 (sd = 3,15). Refer to table 4.11 for an overview of these results.

Table 4.11 Factor country (mean (sd))

	Current PIL	**Revised PIL**
The United Kingdom	17,20 (sd = 3,25)	15,48 (sd = 2,8)
The Netherlands	18,14 (sd = 2,89)	15,95 (sd = 3,15)

The differences between the averages of the two countries is not significant for the current PIL (F (1,73) 126; p = 0.086) and not significant for the revised PIL (F (0,89) 126; p = 0.377). This

means that we can combine the results from the two countries because there is no large difference between these results.

Next we examined if the factor which text structure (current or revised) the participants received first had any influence on the correct localization scores. If we look at table 4.12 we see that participants that received the current PIL first had an average of correct localization scores for the current PIL of 17,06 (sd = 2,91). Participants that received the revised PIL first had an average of correct localization scores for the current PIL of 18,28 (sd = 3,16). If we look at the results for the revised PIL we see that participants that received the current PIL first had an average of correct localization scores for the revised PIL of 15,94 (sd = 2,51). Participants that received the revised PIL first had an average of correct localization scores for the revised PIL of 15,50 (sd = 3,40). See table 4.12 for an overview of these results.

Table 4.12 Factor first text structure (mean (sd))

	Current PIL	**Revised PIL**
Current text structure – Revised text structure	17,06 (sd = 2,91)	15,94 (sd = 2,51)
Revised text structure – Current text structure	18,28 (sd = 3,16)	15,50 (sd = 3,40)

The differences in averages between these results on the text structure is significant for the current PIL (F (-2,27) 126; p = 0.025) and not significant for the revised PIL (F (0,83) 126; p = 0.437). This means that there is a difference in averages between the results of the current PIL with regard to which text structure they received first. If participants receive the revised PIL first they locate on average approximately 1 question more correctly on the current PIL than if they receive the current PIL first. We can state that participants got familiar with the current PIL through the revised PIL they received in the first test. This factor had minimum influence on the results, since there is only a small difference between the localization scores of the current and revised PIL. The current text structure has a small advantage in comparison to the revised text structure. We will combine these results but it is important to bare this in mind when the results are presented later on in this report.

The following factor we examined was the text structure (current or revised) with text version (bogus or real text). As depicted in table 4.13 participants that received the current PIL with the bogus text and the revised PIL with the real text had an average of correct localization scores for the current PIL of 17,13 (sd = 3,04) and for the revised PIL of 16,95 (sd = 2,67). Participants that received the current PIL with the real text and the revised PIL with the bogus

text had an average of correct localization scores for the current PIL of 18,22 (sd = 3,06) and for the revised PIL of 14,48 (sd = 2,78).

Table 4.13 Factor text version (mean (sd))

	Current PIL	**Revised PIL**
Current with bogus text – Revised with real text	17,13 (sd = 3,04)	16,95 (sd = 2,67)
Current with real text – Revised with bogus text	18,22 (sd = 3,06)	14,48 (sd = 2,78)

The differences in averages between these results on the text structure is significant for the current PIL (F (-2,03) 126; p = 0.045) and significant for the revised PIL (F (5,12) 126; p = 0.000). This means that there is a difference in averages between the results of the current and revised PIL with the bogus or real text. If participants received the current PIL with the real text they found one correct location more in the current PIL than if they received the current PIL with the bogus text. If participants received the revised PIL with the real text they found approximately 2,5 correct locations more in the revised PIL than if they received the revised PIL with the bogus text. This means that the bogus text had little influence on the localization scores but this has a minimum effect on the results. It is more difficult for the revised text structure to stand-alone than the current text structure. Furthermore, it is understandable that the bogus text make it more difficult to read both current and revised text structure. We will combine these results but it is important to bare this in mind when the results are presented later on in this report.

The last factor we examined was the question set combination 1 or 2. As depicted in table 4.14 participants that received the current PIL with question set 1 and the revised PIL with question set 2 had an average of correct localization scores for the current PIL of 17,45 (sd = 3,07) and for the revised PIL of 15,48 (sd = 3,05). Participants that received the current PIL with question set 2 and the revised PIL with question set 1 had an average of correct localization scores for the current PIL of 17,89 (sd = 3,11) and for the revised PIL of 15,95 (sd = 2,92). Refer to table 4.14 for an overview of these results.

Table 4.14 Factor question set (mean (sd))

	Current PIL	**Revised PIL**
Question set 1	17,45 (sd = 3,07)	15,95 (sd = 2,92)
Question set 2	17,89 (sd = 3,11)	15,48 (sd = 3,05)

The differences in averages between these results on the text structure is not significant for the current PIL (F (-0,80) 126; p = 0.425) and not significant for the revised PIL (F (-0,89) 126; p = 0.377). This means that there is no significant distinction of the averages between the results of the current and revised PIL with question set 1 or 2. As a result we may state that the question sets 1 and 2 had no influence on the localization scores and we will combine these results.

We found that text version and first text structure influenced each other. If participants received the current or revised PIL with the real text they could have had support through the content in the PIL. Furthermore, participants could have also had support in locating the correct headings in the second test because they already saw a current or revised PIL in the first test.

4.2.1 Findability scores

In this paragraph we will discuss the correct localization scores for the current and revised main- and subheadings (*N = 128*). As mentioned before in paragraph 3.5 the results have been judged on two levels of localization scores, the correct subheading scores and the correct main heading scores. The correct localization scores in the first level are the correct subheadings. However there are exceptions in the current text structure because the correct location to a scenario question is sometimes a main heading instead of a subheading. This exception only applies for the current PIL because the current text structure does not have subheadings under every main heading. The correct localization scores at the second level are only the correct main headings. This means that the correct location is the main heading even if the correct subheading is not found. The location is partly correct.

Because we will present the findability scores in both the correct subheadings level versus the correct main headings level for both current and revised PIL we will have to examine if the scenario questions within the two levels are each reliable as a construct. This is done by calcultating the Cronbach's alpha of these groups. The Cronbach's alpha for the scenario questions on the localization scores for the revised and current text structure are not extremely high so therefore not really reliable as a construct. The scenario questions for the correct subheadings have a Cronbach's alpha of .62 in the current PIL and .53 in the revised PIL. If we only look at the localization scores on the correct main headings the scenario questions have a Cronbach's alpha of .62 in the current PIL and .47 in the revised PIL. These have to be at least .70 or higher. We will use them as summary measures, without pretending they are single-construct measures. As mentioned in paragraph 3.7 we will only discuss the significant localization differences.

As depicted in table 4.15 the results on the correct localization scores of the main headings for the current PIL have an average of 20,10 (sd = 2,74) and for the revised PIL of 21,21 (sd = 2,03). The difference in averages is significant (t = 4.34, df = 127, p < .001). The results on the correct localization scores of the subheadings for the current PIL have an average of 17,67 (sd = 3,09) and for the revised PIL of 15,72 (sd = 2,99). The difference in averages is significant (t = 6.36, df = 127, p = < .001). See table 4.15 for an overview of the correct localization scores for both levels.

Table 4.15 Correct localization scores (mean (sd))

	Current PIL	**Revised PIL**
Correct main headings	20,10 (sd = 2,74)	21,21 (sd = 2,03)
Correct subheadings	17,67 (sd = 3,09)	15,72 (sd = 2,99)

These overall results also show that the revised PIL has more correct localization scores for the main headings and the current PIL has more correct localization scores for the subheadings. From these results we can state that the main headings represent the overall structure of both the current and revised PIL and the subheadings represent the clarity of the PILs subheadings. The quality of the subheadings refers to the comprehensibility of the PIL. These outcomes suggest that the interpretation of the main headings is better in the revised text structure and the quality of subheadings is better in the current text structure.

Next we will examine the specific differences between the revised and current text structure. First we will look which correct localization scores on the main headings in the current and revised PIL differ significantly from each other. Then we will look which correct localization scores on the subheadings in the current and revised PIL differ significantly from each other. This will give us more insight why the interpretation of main headings is better in the revised text structure and why the quality of subheadings is better in the current text structure. The structure of Morrow et al. (1998) will be used to organize the overall results (refer to paragraph 2.3 for a description of the medication-taking schema of Morrow). The structure of Morrow et al (1998) is as follows:

1. Identifying the medication (name, purpose)
2. Instructions on how to take the medicine (dose and schedule)
3. Information about side effects

The following current and revised main headings are subdivided into the following structure:

1. Identifying the medication (name, purpose)

Main headings current text structure:

- What Pharmazine is and what it is used for
- Contents of the pack and other information

Main headings revised text structure:

- About this medicine and what it is used for
- Ingredients and registration

2. Instructions on how to take the medicine (dose and schedule)

Main headings current text structure:

- How to take Pharmazine
- How to store Pharmazine

Main headings revised text structure:

- Taking the medicine
- Package, storage and disposal

3. Information about side effects

Main headings current text structure:

- What you need to know before you take Pharmazine
- Possible side effects

Main headings revised text structure:

- Possible problems with this medicine

Refer to appendix 4 for more information about which specific subheadings belong under each main heading of both current and revised PIL. Because we will present the findability scores in this structure we will have to examine if the three groups in this structure are each reliable as a construct. This is done by calcultating the Cronbach's alpha of these groups. The Cronbach's alpha of these three groups is rather low. Group 1 has a Cronbach's alpha of .45 for the correct location scores of the main headings in the current and revised PIL. Group 1 has a Cronbach's alpha of .29 for the correct location scores of the subheadings in the current and revised PIL. Group 2 has a Cronbach's alpha of .42 for the correct location scores of the main headings in the current and revised PIL. Group 2 has a Cronbach's alpha of .54 for the correct location scores of

the subheadings in the current and revised PIL. Group 3 has a Cronbach's alpha of .19 for the correct location scores of the main headings in the current and revised PIL. Group 3 has a Cronbach's alpha of .20 for the correct location scores of the subheadings in the current and revised PIL. Because we will use them as summary measures, without pretending they are single-construct measures we can still use the structure of Morrow et al. (1998) in spite of the low Cronbach's alphas.

The main headings

The revised and current text structure have a different interpretation of the main headings. According to the previous results the correct location scores on the main headings are higher in the revised text structure as opposed to the current text structure. 8 (32%) out of 25 scenario questions were significantly better for the revised text structure and 2 (8%) were significantly better for the current text structure. Refer to appendix 3 for these results. These results show that the interpretation of the main headings is better in the revised text structure than in the current text structure. Here we will discuss which main headings are better in the revised PIL. Only the significant differences between the correct locations of the main headings in the revised and the current PIL will be discussed. As mentioned before the interpretation of the main headings will be elaborated according to the structure of Morrow et al (1998).

1. Identifying the medication

The results on the correct localization scores of the main headings in the first group for the current PIL have an average of 3,09 (sd = 1,15) and for the revised PIL of 3,34 (sd = 1,17). The difference in averages is significant ($t = 2.05$, $df = 127$, $p < .05$).

Table 4.16 provides the scenario questions for which the McNemar test was significant. As depicted in this table the differences in the first group between the correct localization scores of the main headings in the current and revised PIL are found in scenario question 1 '*Suppose you want to know what the active component in this drug does for you. Where can you find this information in this leaflet?*' (QS1) and the corresponding question from question set 2 '*Suppose you would like to know how this medicine affects your illness. Where can you find this information in this leaflet*?' (QS2). As well as scenario question 3 '*Suppose you have mood swings and you want to know how this medicine affects your mood swings. Where can you find this information in this leaflet?*' (QS1) and '*Suppose you have epilepsy and you want to know what this medicine will do for your illness. Where can you find this information in this leaflet?*' (QS2). These questions refer to the main heading 'What Pharmazine is and what it is used for' in the current PIL and main heading 'About this medicine and what it is used for' in the revised PIL.

These main headings refer to the first category (identifying the medication) of the structure of Morrow et al. (1998). 67,2% of all participants found the correct main heading to scenario question 1 in the revised PIL. 41,4% of the participants found the correct main heading to scenario question 1 in the current PIL. 50,0% of the participants found the correct main heading to scenario question 3 in the revised PIL. 35,9% of the participants found the correct main heading to scenario question 3 in the current PIL. Refer to table 4.16 for the total number of correct responses for each main heading in the current and revised PIL in group 1.

Table 4.16 Number of correct responses and percentages group 1 (%)

Main headings	**Current PIL**	**Revised PIL**
Current: What Pharmazine is and what it is used for		
Scenario question 1:	53 (41,4%)	
Scenario question 3:	46 (35,9%)	
Revised: About this medicine and what it is used for		
Scenario question 1:		**86 (67,2%)**
Scenario question 3:		**64 (50,0%)**

Even though many participants did not know which specific subheading to choose under the main heading 'About this medicine and what it is used for' in the revised PIL they did know that answer to the first and third question should be under this main heading. The revised main heading 'About this medicine and what it is used for' has more correct location scores in comparison to the same main heading in the current PIL 'What Pharmazine is and what it is used for'.

The correct localization scores that reflect the main heading 'Contents of the pack and other information' in the current PIL and the main heading 'Ingredients and registration' in the revised PIL were not significantly different, which means that we can not draw a conclusion regarding to these main headings based on these results.

2. Instructions on how to take the medicine

The results on the correct localization scores of the main headings in the second group for the current PIL have an average of 9,42 (sd = 1,47) and for the revised PIL of 9,27 (sd = 1,12). The difference in averages is not significant ($t = 1.06$, $df = 127$, $p > .05$). We will use them as summary measures, without pretending they are single-construct measures.

The scenario questions for which the McNemar test was significant are shown in table 4.17. As depicted in this table the differences in the second group between the correct localization scores of the main headings in the current and revised PIL are found in scenario question 14 '*Suppose you are 40 years old and you are taking the medicine presented in this leaflet for epilepsy. What is the lowest dose you can take?*' (QS1) and '*Suppose you are 74 years old and you have epilepsy. What does the leaflet tell you about the recommended dose?*' (QS2). 83,6% of the participants found the correct main heading to scenario question 14 in the revised PIL. 73,4% of the participants found the correct main heading to scenario question 14 in the current PIL. Also for scenario question 7 '*Suppose your four year old son has mood swings. Can he have this medicine?*' (QS1) and '*Suppose your two year old daughter suffers from seizures and you wonder if she can have this medicine?*' (QS2). 18,0% of the participants found the correct main heading to scenario question 7 in the revised PIL.62,5% of the participants found the correct main heading to scenario question 7 in the current PIL. Furthermore, the difference in the second group was also found in scenario question 19 '*You want to know if you can end the treatment without first discussing it with your doctor. Where can you find this information in this leaflet?*' (QS1) and '*Suppose you have problems with this medicine and you do not want to take this medicine any longer. What should you do?*' (QS2). 73,4% of the participants found the correct main heading to scenario question 19 in the revised PIL. 85,2% of the participants found the correct main heading to scenario question 19 in the current PIL. These questions refer to the main heading 'How to take Pharmazine' in the current PIL and main heading 'Taking the medicine' in the revised PIL. The differences also appear to be between current and revised correct localization scores of scenario question 23 '*Suppose the doctor tells you to stop taking the tablets. What should you do with the rest of the tablets?*' (QS1) and '*Can you flush the unused medicine down the toilet?*'(QS2). These questions refer to the main heading 'How to store Pharmazine' in the current PIL and main heading 'Package, storage and disposal' in the revised PIL. 94,5% of all participants found the correct main heading for scenario question 23 in the revised PIL. 73,4% of all participants found the correct main heading for this question in the current PIL. Refer to table 4.17 for the total number of correct responses for each main heading in the current and revised PIL in group 2. These main headings refer to the second category (Instructions on how to take the medicine) of the structure of Morrow et al. (1998).

Table 4.17 Number of correct responses and percentages group 2 (%)

Main headings	**Current PIL**	**Revised PIL**
Current: How to take Pharmazine		
Scenario question 7:	**80 (62,5%)**	
Scenario question 14:	94 (73,4%)	
Scenario question 19:	**109 (85,2%)**	
Revised: Taking the medicine		
Scenario question 7:		23 (18,0%)
Scenario question 14:		**107 (83,6%)**
Scenario question 19:		94 (73,4%)
Current: How to store Pharmazine		
Scenario question 23:	94 (73,4%)	
Revised: Package, storage and disposal		**121 (94,5%)**
Scenario question 23:		

The results of the second group (Instructions on how to take the medicine) appear to be in favour of the current PIL because there is only one scenario question (14) were the revised PIL scores better and two scenario questions (7 and 19) were the current PIL has more correct localization scores. These questions relate to the main heading 'How to take Pharmazine' in the current PIL and main heading 'Taking the medicine' in the revised PIL. Question (23) that relates to the main heading 'How to store Pharmazine' in the current PIL and main heading 'Package, storage and disposal' in the revised PIL has more correct localization scores in the revised PIL. From these results we can conclude that there is no clear outcome that the second group 'Instructions on how to take the medicine' is better in the revised or current text structure.

3. Information about side effects

The results on the correct localization scores of the main headings in the third group for the current PIL have an average of 7,59 (sd = 1,10) and for the revised PIL of 8,59 (sd = 0,62). The difference in averages is significant ($t = 9.50$, $df = 127$, $p < .001$).

Table 4.18 provides the scenario questions for which the McNemar test was significant. This table shows the differences in the third group between the correct localization scores of the main headings in the current and revised PIL are found in scenario question 6 '*Is it likely for your doctor to examine you before and during the treatment*?' (QS1) and '*What type of check-up do you have if taking this medicine*?' (QS2). 77,3% of all participants found the correct main heading to scenario question

6 in the revised PIL. 32,0% of the participants found the correct main heading to scenario question 6 in the current PIL. Also from scenario question 10, '*Suppose you think you might be sensitive to medicines like Pharmazine. What should you do?*' (QS1) and '*Suppose you cannot have some types of food and you are unsure if you can use this medicine. What should you do?*' (QS2). 96,1% of all participants found the correct main heading to scenario question 10 in the revised PIL. 81,3% of the participants found the correct main heading to scenario question 10 in the current PIL. The differences also appear to be in scenario question 12 '*Suppose you want to go to the shop with the car. Are you able to do this while taking this medicine?*' (QS1) and '*Suppose you want to mow the lawn. What does this leaflet tell you about this?*' (QS2). 97,7% of all participants found the correct main heading to scenario question 12 in the revised PIL. 85,9% of the participants found the correct main heading to scenario question 12 in the current PIL. These questions refer to the main heading 'What you need to know before you take Pharmazine' in the current PIL and main heading 'Possible problems with this medicine' in the revised PIL. Furthermore, the differences in group 3 between the correct localization scores of the main headings in the current and revised PIL are also found in scenario question 20 '*Suppose you get blistering of the lips while using this medicine. What should you do?*' (QS1) and '*Suppose you get a sore throat and a high temperature while using this medicine and are worried about this. What should you do?*' (QS2). This question refers to the main heading 'Possible side effects' in the current PIL and main heading 'Possible problems with this medicine' in the revised PIL. 98,4% of all participants found the correct main heading to scenario question 20 in the revised PIL. 85,9% of the participants found the correct main heading to scenario question 20 in the current PIL. All these main headings refer to the third category (Information about side effects) of the structure of Morrow et al. (1998). Refer to table 4.18 for the total number of correct responses for each main heading in the current and revised PIL from group 3.

Table 4.18 Number of correct responses and percentages group 3 (%)

Main headings	**Current PIL**	**Revised PIL**
Current: What you need to know before you take Pharmazine		
Scenario question 6:	41 (32,0%)	
Scenario question 10:	104 (81,3%)	
Scenario question 12:	110 (85,9%)	
Current: Possible side effects		
Scenario question 20:	110 (85,9%)	
Revised: Possible problems with this medicine		
Scenario question 6:		**99 (77,3%)**
Scenario question 10:		**123 (96,1%)**
Scenario question 12:		**125 (97,7%)**
Scenario question 20:		**126 (98,4%)**

Even though many participants did not know which specific subheading to choose under the main heading 'Possible problems with this medicine' in the revised PIL they did know that answer to the questions 6,10,12 and 20 could be located under this main heading. This revised main heading had more correct location scores in comparison to the main headings in the current PIL 'What you need to know before you take Pharmazine' and 'Possible side effects'. The main heading 'Possible problems with this medicine' in the revised text structure covers the same topics as the two main headings 'What you need to know before you take Pharmazine' and 'Possible side effects' in the current text structure.

Quality of subheadings

The revised and current text structure have different subheadings. We will examine whether the quality of the subheadings is better in current or revised PIL as well as which particular subheadings are better. According to the previous results, the correct location scores on the subheadings are better in the current text structure as opposed to the revised text structure. 10 (40%) out of 25 scenario questions were significantly better for the current text structure and 5 (20%) were significantly better for the revised text structure. Refer to appendix 3 for these results. Only the significant differences between the correct locations of the subheadings in the current and the revised PIL will be discussed. In some occasions we have to compare main headings from the current text structure with subheadings from the revised text structure because

the current PIL has less subheadings. As mentioned before the interpretation of subheadings will also be elaborated according to the structure of Morrow et al (1998).

1. Identifying the medication

The results on the correct localization scores of the subheadings in the first group for the current PIL have an average of 3,05 (sd = 1,18) and for the revised PIL of 2,52 (sd = 0,98). The difference in averages is significant ($t = 4.24$, $df = 127$, $p < .001$).

The scenario questions for which the McNemar test was significant are shown in table 4.19. As depicted in this table the differences in the first group between the correct localization scores of the subheadings in the current and revised PIL are found in scenario question 1 *Suppose you want to know what the active component in this drug does for you. Where can you find this information in this leaflet?* (QS1) and the corresponding question from question set 2 (QS2) is '*Suppose you would like to know how this medicine affects your illness. Where can you find this information in this leaflet*?'. 41,4% of all participants found the correct main heading to scenario question 1 in the current PIL. 7,8% of the participants found the correct subheading to scenario question 1 in the revised PIL. The correct locations to scenario question 1 can be found under the current main heading 'What Pharmazine is and what it is used for' and the revised subheading 'What this medicine is'. A difference is also found in scenario question 2 '*Imagine you have epilepsy. Did the doctor prescribe the right medicine for you?*' (QS1) and '*Imagine you have mood swings. Is this the right medicine for you?*' (QS2). 61,7% of all participants found the correct main heading to scenario question 2 in the current PIL. 42,2% of the participants found the correct subheading to scenario question 2 in the revised PIL. The correct locations to scenario question 2 can be found under the current main heading 'What Pharmazine is and what it is used for' and the revised subheading 'What it is used for'. These main- and subheadings refer to the first category (identifying the medication) of the structure of Morrow et al. (1998). Refer to table 4.19 for the total number of correct responses for each subheading in the current and revised PIL in group 1.

Table 4.19 Number of correct responses and percentages group 1 (%)

Subheadings *(current = main heading)*	**Current PIL**	**Revised PIL**
Current: What Pharmazine is and what it is used for		
Scenario question 1:	**53 (41,4%)**	
Scenario question 2:	**79 (61,7%)**	
Revised: What this medicine is		
Scenario question 1:		10 (7,9%)
Revised: What it is used for		
Scenario question 2:		54 (42,2%)

If we look at the first scenario question the following can be noticed: from the data about the chosen incorrect headings and subheadings (found in appendix 3) we can see that 49,2% of the participants chose the incorrect subheading 'How it works' and 9,4% of the participants chose the incorrect subheading 'What it is used for'. From this we can conclude that the participants through that the correct answer would be under the correct main heading in the revised PIL but they did not know which subheading to choose from. For the second question can be noticed that 18% of all participants chose the incorrect subheading 'People who should check with their doctor before taking this medicine' and 10,2% chose the incorrect subheading 'People who cannot take this medicine' in the revised PIL. These subheadings refer to precaution and check with your doctor or cannot take this medicine. This could be because the question states 'is this the right medine for you' and participants could interpret this as a warning or do not take this medicine. The question suggests that epilepsy and mood swings are contra- indications, not the illness to be treated. Even though the main heading 'About this medicine and what it is used for' in the revised PIL is clear, from these results it seems that the subheadings under this main heading do not make the information clearer.

2. Instructions on how to take the medicine

The results on the correct localization scores of the subheadings in the second group for the current PIL have an average of 8,73 (sd = 1,58) and for the revised PIL of 7,79 (sd = 1,34). The difference in averages is significant ($t = 6.49$, $df = 127$, $p < .001$).

Table 4.20 provides the scenario questions for which the McNemar test was significant. This table shows the differences in the second group between the correct localization scores of the subheadings in the current and revised PIL are found in scenario question 7 '*Suppose your four year old son has mood swings. Can he have this medicine?*' (QS1) and '*Suppose your two year old daughter suffers*

from seizures and you wonder if she can have this medicine?' (QS2). 59,4% of all participants found the correct subheading to scenario question 7 in the current PIL. 16,4% of the participants found the correct subheading to scenario question 7 in the revised PIL. The correct locations to scenario question 7 can be found under the subheading 'Children and adolescents' in the current PIL and the subheadings 'How much to take' and 'People who cannot take this medicine' in the revised PIL. A difference is also found in scenario question 8 '*Imagine you are already taking another medicine to treat a skin infection, as well as the medicine described in this leaflet. What should you do?*' (QS1) and '*Suppose you are already taking a medicine for asthma, as well as the medicine described in this leaflet. What should you do?*' (QS2). 84,4% of all participants found the correct subheading to scenario question 8 in the current PIL. 46,1% of the participants found the correct subheading to scenario question 8 in the revised PIL. The correct locations to scenario question 8 can be found under the subheading 'Other medicines and Pharmazine' in the current PIL and the subheading 'Taking Pharmazine with other medicines' in the revised PIL. A difference is also found in scenario question 15 '*How many times a day should you take this medication?*' (QS1) and '*At which times during the day should you take a dose of this medicine?*' (QS2). 97,7% of all participants found the correct main heading to scenario question 15 in the current PIL. 63,3% of the participants found the correct subheading to scenario question 15 in the revised PIL. The correct locations to scenario question 15 can be found under the main heading 'How to take Pharmazine' in the current PIL and under the subheading 'When to take' in the revised PIL. The differences also appear to be between the correct localization scores of the subheadings in the current and revised PIL in the scenario question 16 '*Over what period of time should you take this medication?*' (QS1) and '*Suppose you have doubts about keeping on with this medicine. What should you do?*' (QS2). 37,5% of all participants found the correct subheading to scenario question 16 in the current PIL. 49,2% of the participants found the correct subheading to scenario question 16 in the revised PIL. The correct locations to scenario question 16 can be found under the subheading 'If you stop taking Pharmazine' in the current PIL and under the subheading 'How long to take' in the revised PIL. A difference is also found in scenario question 19 '*You want to know if you can end the treatment without first discussing it with your doctor. Where can you find this information in this leaflet?*' (QS1) and '*Suppose you have problems with this medicine and you do not want to take this medicine any longer. What should you do?*' (QS2). 83,6% of all participants found the correct subheading to scenario question 19 in the current PIL. 68,8% of the participants found the correct subheading to scenario question 19 in the revised PIL. The correct locations to scenario question 19 can be found under the subheading 'If you stop taking Pharmazine' in the current PIL and under the subheading 'If you want to stop taking this medicine' in the revised PIL. A difference is also found in scenario question 23 '*Suppose the doctor*

tells you to stop taking the tablets. What should you do with the rest of the tablets? (QS1) and '*Can you flush the unused medicine down the toilet?*'(QS2). 73,4% of all participants found the correct main heading to scenario question 23 in the current PIL. 94,5% of the participants found the correct subheading to scenario question 23 in the revised PIL. The correct locations to scenario question 23 can be found under the main heading 'How to store Pharmazine' in the current PIL and under the subheading 'Disposal' in the revised PIL.

These main- and subheadings refer to the second category (Instructions on how to take the medicine) of the structure of Morrow et al. (1998). Refer to table 4.20 for the total number of correct responses for each subheading in the current and revised PIL in this group.

Table 4.20 Number of correct responses and percentages group 2 (%)

Subheadings *(current = main- and subheadings)*	**Current PIL**	**Revised PIL**
Scenario question 7:		
Current: Children and adolescents	**76 (59,4%)**	
Revised: How much to take and people who cannot take this medicine		21 (16,4%)
Scenario question 8:		
Current: Other medicines and Pharmazine	**108 (84,4%)**	
Revised: Taking Pharmazine with other medicines		59 (46,1%)
Scenario question 15:		
Current: How to take Pharmazine	**125 (97,7%)**	
Revised: When to take Pharmazine		81 (63,3%)
Scenario question 16:		
Current: If you stop taking Pharmazine	48 (37,5%)	
Revised: How long to take		**63 (49,2%)**
Scenario question 19:		
Current: If you stop taking Pharmazine	**107 (83,6%)**	
Revised: If you want to stop taking this medicine		88 (68,8%)
Scenario question 23:		
Current: How to store	94 (73,4%)	
Revised: Disposal		**121 (94,5%)**

These results state that the subheadings in the second group 'Instructions on how to take the medicine' are clearer in the current PIL. First of all the revised PIL does not have a subheading

'Use in children and adolescents' and from the data about the chosen incorrect headings and subheadings (found in appendix 3) we can see that 21,1% chose the incorrect subheading 'People who should check with their doctor before taking this medicine' in the revised PIL. Because there is no specific heading for children and adolescents in the revised PIL it was difficult for many participants to choose the right subheading. This subheading could suggest check with your doctor if your child can take this medication, although in the current PIL the information about children and adolescents is divided under three subheadings. For example 21% of the participants chose the incorrect subheading 'Use in children and adolescents' in the current PIL. This could be because several subheadings refer to children and adolescents and they chose this particular subheading. There should be one subheading referring to children and adolescents.

The subheading 'Other medicines and Pharmazine' in the current PIL is better appreciated than the subheading 'Taking Pharmazine with other medicines' in the revised PIL. 33,6% of the participants chose the subheading 'Tell your doctor if your are taking:' in the revised PIL. Participants could have chosen this subheading because the medicines for skin infection and asthma are presented here. But under this subheading it is not stated what patients have to do if they are taking another medicine i.e. call your doctor if you are taking another medicine. But it appears that participants were looking under the correct subheading 'Taking Pharmazine with other medicine'. We can conclude that the subheading 'Tell your doctor if your are taking' under the subheading 'Taking Pharmazine with other medicine' does not make the information clearer.

The information about when to take the medicine is preferred under the main heading 'How to take' instead of a extra subheading 'When to take'. 26,6% of the participants chose the incorrect subheading 'How much to take' and 10,2% chose the incorrect subheading 'How to take' in the revised PIL. Both subheadings are presented after the same main heading, 'Taking the medicine'. Instead of putting the information about how to take, how much to take and when to take under different subheadings it could be better to place the information under one subheading heading. But since the results are not clear about this we cannot confirm these recommendations. Why the subheading 'If you want to stop taking this medicine' in the revised PIL has more localization scores than the subheading 'if you stop taking pharmazine' from the current PIL is not clear.

However subheadings 'Disposal' and 'How long to take' seem to be better in the revised PIL. 43% of the participants chose the incorrect main heading 'How to take Pharmazine' in the current PIL instead of the subheading 'If you stop taking Pharmazine'. Participants could have chosen this incorrect heading because they linked the scenario question '*over what period of time should you take the medication*' to how to take the medication and not if you stop taking. From this

analysis we cannot conclude that the subheading 'How long to take' is better in the revised PIL. If we look at the differences between the results of scenario question 23, refering to disposal of the medicine, we can observe that 17,2% of the participants chose the incorrect subheading 'If you stop taking Pharmazine' in the current PIL instead of the correct subheading 'How to store'. The participant expected the information about disposal to be under 'if you stop with the medicine'. It seems that including a subheading 'Disposal' is more appreciated than placing the information about disposal under the main heading 'How to store'.

There is one exception, were revised and current PIL scored equally good, that is still worth mentioning. Question 22 is not significant but still noteworthy in this group. This question is correctly answered by every participant for both current and revised text structure. Question 22 is as follows, '*Suppose the doctor recently prescribed you this medicine, but you forgot to ask where to keep them. Can you keep this medicine in the refrigerator?*' (QS1) and '*Are there any recommendations on how to keep this medication?*' (QS2). These questions refer to the revised subheading 'Storage' and the current main heading 'How to store Pharmazine'. Perhaps the subheading 'Storage' could be an asset for the information about storage and disposal of the medicine as the subheading 'Disposal' is already proven to be better for the comprehensibility of a PIL.

3. Information about side effects

The results on the correct localization scores of the subheadings in the third group for the current PIL have an average of 5,89 (sd = 1,44) and for the revised PIL of 5,41 (sd = 1,72). The difference in averages is significant ($t = 2.59$, $df = 127$, $p < .05$).

The scenario questions for which the McNemar test was significant are shown in table 4.21. From this table we can see that the differences in the third group between the correct localization scores of the subheadings in the current and revised PIL are found in scenario question 4 '*Suppose you have heart problems. Are you allowed to use this medicine?*' (QS1) and '*Suppose you have had blood problems. Are you allowed to use this medicine?*' (QS2). 70,3% of all participants found the correct subheading to scenario question 4 in the current PIL. 56,3% of the participants found the correct subheading to scenario question 4 in the revised PIL. The correct locations to scenario question 4 can be found under the subheading 'Do not take Pharmazine if:' in the current PIL and the subheadings 'People who cannot take this medicine' in the revised PIL. A difference is also found in scenario question 6 '*Is it likely for your doctor to examine you before and during the treatment*?' (QS1) and '*What type of check-up do you have if taking this medicine*?' (QS2). 20,3% of all participants found the correct subheading to scenario question 6 in the current PIL. 58,6% of the participants found the correct subheading to scenario question 6 in the revised PIL. The correct

locations to scenario question 6 can be found under the subheading 'Warnings and precautions' in the current PIL and the subheadings 'Tests' in the revised PIL. A difference is also found in scenario question 10 *Suppose you think you might be sensitive to medicines like Pharmazine. What should you do?* (QS1) and '*Suppose you cannot have some types of food and you are unsure if you can use this medicine. What should you do?*' (QS2). 18,8% of all participants found the correct subheading to scenario question 10 in the current PIL. 35,9% of the participants found the correct subheading to scenario question 10 in the revised PIL. The correct locations to scenario question 10 can be found under the subheading 'Do not take Pharmazine if:' in the current PIL and the subheadings 'Allergies' in the revised PIL. A difference is also found in scenario question 11 '*What is the advice in this leaflet for women who are trying to have a baby?*' (QS1) and '*Suppose a woman wants to give mothers milk to her baby. Is she allowed to use this medicine?*' (QS2). 80,5% of all participants found the correct subheading to scenario question 11 in the current PIL. 64,8% of the participants found the correct subheading to scenario question 11 in the revised PIL. The correct locations to scenario question 11 can be found under the subheading 'Pregnancy and breast-feeding' in both current and revised PIL. A difference is also found in scenario question 12 '*Suppose you want to go to the shop with the car. Are you able to do this while taking this medicine?*' (QS1) and '*Suppose you want to mow the lawn. What does this leaflet tell you about this?*' (QS2). 76,6% of all participants found the correct subheading to scenario question 12 in the current PIL. 87,5% of the participants found the correct subheading to scenario question 12 in the revised PIL. The correct locations to scenario question 12 can be found under the subheading 'Driving and using machines' in the current PIL and the subheadings 'Driving and using tools or machines' in the revised PIL. A difference is also found in scenario question 20 '*Suppose you get blistering of the lips while using this medicine. What should you do?*' (QS1) and '*Suppose you get a sore throat and a high temperature while using this medicine and are worried about this. What should you do?*' (QS2). 85,9% of all participants found the correct main heading to scenario question 20 in the current PIL. 53,9% of the participants found the correct subheading to scenario question 20 in the revised PIL. The correct locations to scenario question 20 can be found under the main heading 'Possible side effects' in the current PIL and the subheadings 'Possible side effects; stop taking this medicine and tell your doctor straight away if you notice:' in the revised PIL. The last difference is found in scenario question 21 '*How likely is getting high blood pressure as a side effect after taking this medicine?*' (QS1) and '*How likely are you to have hearing problems as a side effect after using this medicine?*' (QS2). 94,5% of all participants found the correct subheading to scenario question 21 in the current PIL. 35,9% of the participants found the correct subheading to scenario question 21 in the revised PIL. The correct locations to scenario question 21 can be found under the subheading 'Possible side effects' in the current PIL

and the subheadings 'Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you.' in the revised PIL.

These main- and subheadings refer to the third category (Information about side effects) of the structure of Morrow et al. (1998). Refer to table 4.21 for the total number of correct responses for each subheading in the current and revised PIL in this group.

Table 4.21 Number of correct responses and percentages group 3 (%)

Subheadings *(current = main- and subheadings)*	**Current PIL**	**Revised PIL**
Scenario question 4:		
Current: Do not take Pharmazine if:	**90 (70,3%)**	
Revised: People who cannot take this medicine		72 (56,3%)
Scenario question 6:		
Current: Warnings and precautions	26 (20,3%)	
Revised: Tests		**75 (58,6%)**
Scenario question 10:		
Current: Do not take Pharmazine if:	24 (18,8%)	
Revised: Allergies		**46 (35,9%)**
Scenario question 11:		
Current: Pregnancy and breastfeeding	**103 (80,5%)**	
Revised: Pregnancy and breastfeeding		83 (64,8%)
Scenario question 12:		
Current: Driving and using machines	98 (76,6%)	
Revised: Driving and using tools or machines		**112 (87,5%)**
Scenario question 20:		
Current: Possible side effects	**110 (85,9%)**	
Revised: Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice:		69 (53,9%)
Scenario question 21:		
Current: Possible side effects	**121 (94,5%)**	
Revised: Possible side effects; Talk to your doctor if you have any of the side effects listed below and they trouble you.		46 (35,9%)

The results in the third group about the quality of the subheadings are a bit divided, although the current PIL has a bit more preference. The subheading 'Do not take Pharmazine if:' from the

current PIL has more correct localization scores than the subheading 'People who cannot take this medicine' from the revised PIL. From the data about the chosen incorrect headings and subheadings (found in appendix 3) we can see that 31,3% of all participants chose the incorrect subheading 'People who should check with their doctor before taking this medicine' in the revised PIL. From these results we can conclude that instead of dividing the information amongst the subheadings 'People who cannot take this medicine' and 'People who should check with their doctor before taking the medicine' it appears to be better to place all information under one subheading for example, 'Do not take Pharmazine if:' from the current PIL.

That the subheading 'Pregnancy and breast-feeding' shows different results in both current and revised PIL is notable since the wording of these subheadings is the same. Even though 29,7% of the participants chose the incorrect subheading 'People who should check with their doctor before taking this medicine' in the revised PIL. 10,9% of the participants chose the incorrect subheading 'Warnings and precautions' in the current PIL. Participants could have chosen this incorrect subheading because they interpret the question, being pregnant or breastfeeding, as a warning or consult your doctor when taking the medication. It could be that the location of the subheading is better in the current PIL than the revised PIL.

The subheadings 'Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you.' and 'Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice:' in the revised PIL did not result in more correct localization scores. The main heading 'Possible side effects' from the current PIL seem to be clearer. 20,3% of the participants chose the incorrect subheading to scenario question 20 'Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you.' Instead of the correct subheading 'Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice:' in the revised PIL. 16,4% of the participants chose the incorrect subheading 'Possible side effects' in the revised PIL. 51,6% of the participants chose the incorrect subheading 'Possible side effects' to scenario question 21 and 7,8% of the participants chose the incorrect subheading 'Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice:' in the revised PIL. Participants could have chosen these incorrect subheadings because they knew the answer could be found under the possible side effects heading but did not know under which specific subheading. The participants that found the correct location to scenario question 20 and 21 experienced difficulties to locate the answer in the revised PIL. It appears that instead of splitting up the information about possible side effects it would be better to keep all information under one heading called: Possible

side effects. However if the heading 'Possible side effects' should be presented as main- or subheading is still unclear.

The subheadings 'Tests', 'Allergies' and 'Driving and using tools or machines' seem to be better in the revised PIL. The subheading 'Tests' from the revised PIL appears to be better than the subheading 'Warnings and precautions' from the current PIL. 17,2% of the participants chose the incorrect main heading 'How to take Pharmazine' and 11,7% chose the incorrect main heading 'Possible side effects' in the current PIL. There could be several explanations for this outcome. There is not a specific subheading that refer to tests. Or participants might experience a question about examination as unfamiliar. Since the scenario question referred to medical tests it would have been easier to find the correct location under the subheading 'Tests' instead of in the text under the subheading 'Warnings and precautions'. If the information about tests should stand out more it could be an option to add a subheading 'Tests'. The same argument applies for the subheading 'Allergies'. 33,6% of the participants chose the incorrect subheading 'Pharmazine with food, drink and alcohol', 19,5% chose the incorrect subheading 'Warnings and precautions' and 15,6% chose the incorrect main heading 'Possible side effects in the current PIL. These incorrect answers might be a result of the following: Question 10 from QS2 suggest that the answer has something to do with food '*cannot have some types of food*'. Secondly, the question from QS1 mentions '*if you might be sensitive*' which can lead to subheading 'warnings and precautions' or 'possible side effects'. Information about allergies under the subheading 'Do not take Pharmazine if:' from the current PIL was more difficult to find than under the subheading 'Allergies' from the revised PIL. If the information about allergies should stand out more it could be an option to add a subheading 'Allergies'. The subheading 'Driving and using tools or machines' from the revised PIL resulted in more correct location scores than the subheading 'Driving and using machines' from the current PIL. The subheading 'Driving and using tools or machines' seem to be a bit more clearer.

4.2.2 Conclusions on the findability of the information in a leaflet

The manipulation on the main headings seems successful but the quality of subheadings appear to be less successful. The main structure (main headings) is better in the revised PIL for the group 'Identifying the medication' and 'Information about side effects'. The following conclusion could be drawn from the results about the interpretation of the main headings:

- Identifying the medication: the main heading 'About this medicine and what it is used for' from the revised PIL is better than the main heading 'What Pharmazine is and what it is used for' from the current PIL. From the previous results we could not state that the main heading

'Ingredients and registration' from the revised PIL is better than the main heading 'Contents of the pack and other information' from the current PIL.

- Instructions on how to take the medicine: it is not clear if the main headings 'Taking the medicine' and 'Package, storage and disposal' from the revised PIL is better than the main headings 'How to take Pharmazine' and 'How to store Pharmazine' from the current PIL. Therefore we cannot confirm that the directions for use should be placed after information about the medicine.
- Information about side effects: the previous results showed that it is better to have one instead of two main heading about side effects and possible problems with the medicine. The main heading 'Possible problems with this medicine' from the revised PIL led to better findability than the main headings 'What you need to know before you take Pharmazine' and 'Possible side effects' from the current PIL.

From the findability results we can conclude that the quality of the subheadings (substructure) is often better in the current PIL. Sometimes subheadings do not make a text easier and can even complicate the reading process. The following conclusion could be drawn from the results about the quality of the subheadings:

- Identifying the medication: although the main heading 'About this medicine and what it is used for' in the revised PIL is clear, it seems that the subheadings under this main heading do not make the information clearer.
- Instructions on how to take the medicine: some subheadings in the current PIL are preferred. There should be a subheading about children and adolescents and the subheading 'Tell your doctor if your are taking' under the subheading 'Taking Pharmazine with other medicine' does not make the information clearer. Furthermore, it appears that the subheading 'When to take' under the main heading 'Taking the medicine' in the revised PIL was not clear enough. It is remarkable that the subheading 'Disposal' seems to be better in the revised PIL. It looks like including a subheading 'Disposal' is more appreciated than putting the information about disposal under the main heading 'How to store'. Furthermore, from the previous results we cannot state that the subheading 'How long to take' is better in the revised PIL or the current PIL.
- Information about side effects: in this group the results about the quality of the subheadings are a bit divided, although the current PIL appeared to be a bit better. Instead of dividing the information amongst the subheadings 'People who cannot take this medicine' and 'People who should check with their doctor before taking the medicine' it seem to be better to place all information under one subheading for example, 'Do not take Pharmazine if:' from the

current PIL. That the subheading 'Pregnancy and breast-feeding' shows different results in both current and revised PIL is notable since the wording of these subheadings is the same. Therefore we cannot state which subheading is better. Instead of dividing the information about possible side effects between the subheadings 'Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you.' and 'Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice:' do not make the information about side effects easier. Why the subheading 'if you stop taking pharmazine' from the current PIL is better is not clear. The subheadings 'Tests', 'Allergies' and 'Driving and using tools or machines' appears to be better in the revised PIL. If the information about tests and allergies should stand out more it could be an option to add the subheadings 'Tests' and 'Allergies'.

The overview of the differences between the correct localization scores of the current and revised text structure can be found in appendix 3.

4.3 Perception

In this paragraph we will discuss the results of the participant's perception on the current and revised PIL. The perception includes comprehensibility and appreciation of both PILs. The dependent variable perception was measured with an appreciation questionnaire, open questions and the 'split run test'. First we will discuss the general impression of the participants of both PILs. Then the results of perception on the comprehensibility will be elaborated. Next the reader's evaluation concerning the layout of the PIL will be discussed. Subsequently the results of the 'split run test' will be elaborated to see which PIL, the current or revised, the participants preferred. Finally the conclusion of the participant's perception will be discussed.

4.3.1 Participants' general impression of the PILs

In this paragraph the general impression of the participants on both revised and current PIL will be discussed. Through open questions we received feedback on how the participants perceived both the current and revised PIL.

Participants that received the current PIL with the real text thought that the leaflet was well organized, especially the main headings 'the information in this PIL is patient friendlier and personal'. The layout is good, especially because of the bullet points and subheadings. But other participants thought that the current leaflet had too much text and an inconsisted layout. 'sometimes the text is enumerated with bullet points but under the main heading 'Possible side effects' the text is mostly placed consecutively without enumeration which makes the leaflet

unclear'. Participants thought that the main- and subheadings were perfectly understandable because of their wording. Other participants thought that some main heading should be divided into subheadings because a large chunk of text makes the layout unclear and the text not easy to read. For example the main heading 'Possible side effects' and the main heading 'How to store Pharmazine' should be broken down in several subheadings. The order of the information in the current PIL is sufficient and some of the participants preferred one subheading for the information about children and adolescents instead of several.

Participants that received the current PIL with the bogus text thought that the main- and subheadings were clear and that is was easy to find the information in the appropriate section 'the current PIL is clear and has a good layout with many bullet points'. Some participants found the current bogus PIL not clear because several headings refer to the same topic like ingredients and children and adolescents. Other participants thought that the main- and subheadings are quite informal and easy to read because there is no use of medical wording. 'Anybody would understand the information.' The headings in the current PIL are solid, broad and the subheadings are direct. Some participants thought that the layout of the headings in this PIL were not good. 'The current PIL seem to be missing headings like the heading 'disposal'. And also with the bogus text the participants thought that the heading 'Possible side effects' should have more subheadings to divide the information. Furthermore, participants thought that the leaflet had a good structure 'the leaflet is as you would expect it to be and easy to understand'. But the main heading 'Contents of the pack and other information' should placed more at the beginning of the leaflet. Participants preferred the main heading 'Possible side effects' to come before the main heading 'How to take Pharmazine'.

Participants that received the revised PIL with the real text thought that the leaflet was clear and the topics in the PIL made sense 'the main headings in the revised PIL are clear and it is easy to find the correct information'. Other participants thought that the revised PIL in real text consisted of too much information 'it does not have a natural appearance like the current PIL'. They preferred that the main- and subheadings in the revised PIL mentioned every subject that a PIL should cover. But some participants thought that the information about the active ingredients should be both under the main heading 'About this medicine and what it is used for' and the subheading 'ingredients'. The main- and subheadings in the revised leaflet were much more explicit. Participants thought that the revised text structure had a logical order but the information in the revised PIL is a little bit jumbled up compared to the current PIL. Some participants suggested that the information about possible side effects should be placed more in the beginning of the PIL because they think it is more important then how to take the medicine.

Participants that received the revised PIL with the bogus text thought that the leaflet was quite detailed and well-organized because of its subheadings 'more subheadings are useful and the order under the main heading 'Taking the medicine' is good'. The headings functioned as a guideline to get the correct information out of the leaflet. A few participants also had some negative comments, for example the organization of the main headings and under which subheading particular information could be found, was hard to understand. 'There are a few different sections where the same information could be found.' Participants also thought that the wording of the headings and subheadings were better than in the current PIL 'the titles were much easier to read and the wording was more in plain language'. They preferred to read the revised leaflet because the content is broken down into more subcategories. Also the subheadings are more concise and easier to understand than in the current PIL, although some subheadings might be confusing because they seem similar like 'Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you.' and 'Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice:' Furthermore, there should be a subheading about the use of the medicine by children and adolescents. Participants thought that the order of the information and the overall structure in the revised PIL is more logical. 'The structure takes you step by step through the leaflet.' 'Seems pretty well layout, quite clear, step by step'. Some criticism was that the main heading 'Taking the medicine' should come after the main heading 'Possible problems with this medicine'.

The participant's general impression about the current and revised PIL is sometimes in favour of the revised text structure and sometimes more positive about the current text structure. It seems that more subheadings can make a PIL easier to understand but on the other hand the subheadings should be clear so they will not confuse the reader. For example the information under the main heading 'Possible side effects' in the current PIL should be placed under more subheadings. But these subheadings should be compact and comprehensible because the subheadings 'Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you.' and 'Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice:' in the revised PIL are perceived as confusing. The same applies for the subheadings 'what this medicine is', 'what it is used for' and 'how it works' under the main heading 'About this medicine and what it is used for' in the revised PIL. These subheadings seem to confuse participants. Some participants thought that the headings and subheadings were understandable in the current PIL and some participants said that about the revised PIL, although some participants missed the subheading 'Disposal' in the current PIL and the subheading 'Children and adolescents' in the revised PIL.

4.3.2 Difficulty of the patient information leaflet

To measure the participant's evaluation and the comprehension of the current and revised PIL, five questions have been used that are based on the CIRF (Consumer Information Rating Form) of Koo et al. (2007). With these questions it is possible to measure the consumers' perception of the comprehensibility (5 items). The perceived comprehensibility of the information in a PIL was determined on a five point scale from '1' (very easy) to '5' (very difficult). The five items addressed the question 'how easy or hard would you say the information in the leaflet is to': read, understand, remember, locate information in and keep for future reference. Before we can discuss the results on the perceived difficulty of the leaflets we will have to examine by means of the Cronbach's alpha ($\alpha \geq .60$) if the comprehension group is reliable as a construct. The comprehension group for the current PIL has a Cronbach's alpha of .88 and a Cronbach's alpha of .82 for the revised PIL. This means the consistency of the items within the comprehension groups for the results of both current and revised PIL. The results of the comprehension questions about the current PIL have an average of 11,21 (sd = 3,37) and for the revised PIL of 11,07 (sd = 2,95). The difference in averages is not significant ($t = 0.42$, $df = 120$, $p > .05$). We looked at each individual comprehension question and came to the conclusion that none of the questions were statistically significant. This means that the averages between the current and revised PIL of each comprehension question did not differ to a great extent.

4.3.3 Design, layout and tone

The reader's evaluation and appreciation regarding the layout, design and tone of both current and revised PIL was measured with 15 items based on the CIRF of Koo et al. (2007) related to the perception of the quality of the PILs design. This was measured on a semantic differential with positive and negative statements. In general the negative adjective is positioned on the left and the positive on the right but to prevent a certain automatism in answering questions we mirrored some items. For the results we corrected these mirrored items in SPSS. Therefore the scores are presented as follows: 1 is the positive adjective score and 5 is the negative adjective score. Not all evaluation and appreciation results are from 128 participants because some participants did not fill in some items on the form. The items measuring the current PIL have a cronbachs alpha of .86 ($\alpha \geq .60$). The same items measured the revised PIL have a cronbachs alpha of .84. This means that the consistency of the items within these groups are reliable. To organize all 15 items we divided them into three main groups, clarity, attractiveness and visuality, for both the revised and current text structure. These groups consist of the following items:

1. The clarity group: easy, logical structured, concise, clarifying, organized and clear.

2. The attractiveness group: appealing, interesting, personal, encouraging in tone, inviting and attractive.
3. The visuality group: ideal print size and ideal spacing between the lines.
The item 'biased' will not be part of these results because we found that this item does not fit in any of the three groups. Furthermore, participants had many difficulties in deciding if the current or revised PIL was biased or unbiased. Maybe this item is not suitable to measure the reader's evaluation and appreciation concerning the layout, design and tone of the PILs.

Before we can discuss the results on the appreciation of the leaflets in these groups we have to examine, by means of the Cronbach's alpha ($\alpha \geq .60$), if these groups are reliable as a construct. The clarity group measuring the current PIL has a cronbachs alpha of .70. The clarity group measuring the revised PIL has a cronbachs alpha of .79. The attractiveness group measuring the current PIL has a cronbachs alpha of .85. The attractiveness group measuring the revised PIL has a cronbachs alpha of .82. The visuality group measuring the current PIL has a cronbachs alpha of .77. The visuality group measuring the revised PIL has a cronbachs alpha of .73. This means that the consistency of the items within the clarity, attractiveness and visuality group for the results of both current and revised PIL are reliable.

<u>The clarity group</u>

The results of the clarity group had an average of 2,49 (sd = 0,61) for the current PIL and an average of 2,48 (sd = 0,53) for the revised PIL. The difference in averages is not significant ($t = 0.10$, $df = 122$, $p > .05$).

First we examined with an ANOVA if the first group, clarity, has an interaction effect between text structure (revised or current) and which text structure the participants received first, the revised or current. The participants rated the items in the clarity group different depending on which text structure they received first (,032 sig.). If participants received the revised PIL in the first test and the current PIL in the second test they have a more positive opinion about the clarity of the revised PIL (2.41(0,67)) than the current PIL (2,56 (0,76)). If participants started with the current PIL they had a more positive opinion about the clarity of the current PIL (2,42 (0,75)) instead of the revised PIL (2,55 (0,66). There is no interaction effect of structure and presentation order on another factor. We looked at each individual appreciation question in the clarity group and came to the conclusion that none of the questions were significant. This means that the averages between the current and revised PIL of each appreciation question in this group did not differ much.

The attractiveness group

The results of the attractiveness group had an average of 2,75 (sd = 0,56) for the current PIL and an average of 2,77 (sd = 0,61) for the revised PIL. The difference in averages is not significant (t = 0.28, df = 123, p > .05).

We measured with an ANOVA if the group attractiveness has an interaction effect between text structure (revised or current), text version (bogus or real text) and question set combination (QS1 and QS2). The participants rated the items in the attractive group different depending on the text structure (current or revised PIL), the text version (current bogus – revised real or current real – revised bogus) and which question set (QS1 or QS2) the participants received (,046 sig.). As a reminder, the scores are presented as follows: 1 is the positive adjective score and 5 is the negative adjective score. If participants received the current PIL in the real version with QS1 and the revised PIL in the bogus version with QS2 they had a more positive opinion relating to attractiveness of the current PIL (2,75 (0,10)) than the revised PIL (2,98 (0,11)). If participants receive the current PIL in the real version with QS2 and the revised PIL in the bogus version with QS1 they had a more positive opinion regarding the attractiveness of the revised PIL (2,51 (0,11)) than the current PIL (2,68 (0,10)). It makes a difference in the attractiveness of the current or revised PIL if question set 1 or 2 is presented. Participants thought that question set 1 was more attractive in spite of which text structure (current and revised) and text version (bogus and real text) they received. There is no interaction effect of structure and presentation order on another factor. Table 4.22 gives an overview of the averages of the interaction effect between text structure, text version and question set combination.

Table 4.22 Attractiveness group and interaction with factor (mean (sd))

Text version and question set	Current PIL	Revised PIL
Current real with QS1 and revised bogus with QS2	**2,75 (0,10)**	2,98 (0,11)
Current real with QS2 and revised bogus with QS1	2,68 (0,10)	**2,51 (0,11)**

Which text structure the participants received first, the revised or current and the order of the question sets (order 1 till 4) also had an interaction effect within the group attractiveness (,010 sig.). Refer to paragraph 3.3.2 for an explanation of the questionset order. When participants received questionset order 1 they had a more positive opinion with regard to attractiveness of the current PIL (2,89 (0,10)) than the revised PIL (2,96 (0,11)). When participants received order 2 they had a more positive opinion with regard to attractiveness of the current PIL (2,79 (0,10)) than the revised PIL (2,94 (0,11)). When participants received order 3 they had a bit more

positive opinion with regard to attractiveness of the current PIL (2,565 (0,10)) than the revised PIL (2,570 (0,11)). When participants received order 4 they had a positive opinion with regard to attractiveness of the revised PIL (2,62 (0,10)) than the current PIL (2,78 (0,10)). Participants liked the attractiveness of the current PIL with reference to the question set orders 1 till 3 but when they received order 4, the revised PIL was more positively rated. We looked at each individual appreciation question in the attractiveness group and came to the conclusion that none of the questions were significant. This means that the averages between the current and revised PIL of each appreciation question in this group did not differ to a great extent.

The visuality group

The results of the visuality group had an average of 2,30 (sd = 1,01) for the current PIL and an average of 2,33 (sd = 1,02) for the revised PIL. The difference in averages is not significant ($t = 0.50$, $df = 127$, $p > .05$).

There is no interaction effect of the visuality group on any factor like text structure (revised or current), text version (bogus or real text), which text structure the participants received first (revised or current) and question set combination (QS1 and QS2). We looked at each individual appreciation question in the visuality group and came to the conclusion that none of the questions were significant. This means that the averages between the current and revised PIL of each appreciation question in this group did not differ a lot.

4.3.4 Split run test

The interview was concluded with a 'split run test'. The interviewer presented both versions (the current and revised PIL) to the participants on a board. The participants chose a preferred version. The following question was asked: '*Which version of the medicine leaflet do you prefer?*'. The participants wrote their answer on a five point scale on a paper version of the questionnaire: 'I prefer version: A or B'. Version A and B were not for every participant presented on the left or right side of the board. For the results we corrected this in SPSS. Therefore the scores are presented as follows: Version A is current and version B is revised. Afterwards the participants were asked to explain their choice. Table 4.23 gives an overview of the preferred PIL.

Table 4.23 Results 'split run test' (*N = 128*)

Preference	**Number of participants** (%)	**Total number of participants per revised and current PIL** (%)
Completely prefer the current PIL (1)	32 (25,0%)	
Prefer a bit more current than revised PIL (2)	14 (10,9%)	46 (35,9%)
Neutral, not current or revised PIL (3)	3 (2,3%)	3 (2,3%)
Prefer a bit more revised than current PIL (4)	17 (13,3%)	79 (61,7%)
Completely prefer the revised PIL (5)	62 (48,4%)	

The results presented in table 4.27 show that 61,7% of the participants preferred the revised PIL above the current PIL (35,9%). This is the majority of all participants. If we look at the separate results of the United Kingdom and The Netherlands the revised PIL was in favour. 46,9% of the participants from NL and 50% from the UK preferred the revised PIL. Both 25,0% of the participants from NL and the UK preferred the current PIL. The factors like text structure (revised or current), text version (bogus or real text), which text structure the participants received first (revised or current) and question set combination (QS1 and QS2) did not have an effect on these results.

The participants that completely preferred the current PIL said that they thought the current PIL had a logical order of the (sub) headings especially between the main heading 'What you need to know before you take Pharmazine' and 'How to take Pharmazine'. The current PIL was according to these participants clearer and they were more familiar with the structure. Also the information in the current PIL was easier to find, better balanced and ordened because the vital information was mentioned on the first page. It was easier to locate relevant headings.The current PIL looks simpler and the spacing was better. The appearance, with regard to the layout, is also better. The participants that preferred the current PIL somewhat more than the revised PIL said that they appreciated that the current PIL has less subheadings which seem to make it clearer. The layout is less unorganized (busy) and the current PIL has one chapter more, which is better for the overview.

The participants that were neutral and did not prefer the current or revised PIL said that the revised PIL has more subheadings and the information was therefore easier to locate. But the current PIL has a better order of the subheadings. Especially that the main heading 'What you

need to know before you take Pharmazine' is presented before 'How to take Pharmazine'. The organisation of the information in both leaflets was fine according to these participants.

The participants that preferred the revised PIL somewhat more than the current PIL said that the revised PIL is clearer because the information about 'Taking the medicine' is presented earlier than in the current PIL. The text is shorter in the revised PIL and the headings and subheadings are clearer and compact. The revised PIL was easier to read because it has more sub-headings. It is also better organized and clearer to find information. These participants also slightly prefer the revised PIL because of the layout, however the information in the current PIL was better because it consists of more main headings. The participants that completely preferred the revised PIL said that the information was broken down into smaller, more manageable, sections and has a better order of importance. It seems more concise. More sub-headings makes the information clearer and easier to locate because of the smaller chunks of information. The revised PIL appeared to be more concise and it has a better layout (the current PIL has often long lists under one section). It was better that the revised PIL first mentioned what the medicine is used for and then when should you not use this medicine. The revised PIL is well organized, phrasing is clear for everyone and logical order. The chapters in this PIL are positioned more closely together and the titles are better.

4.3.5 Conclusions on the perception of a leaflet

The conclusion about the participant's general impressions of the PIL is that the opinions were very much divided regarding several topics like structure, logical order, wording of the headings and clearness. In general the revised PIL is perceived as complete, clear and logically structured because of the subheadings. The headings in the current PIL were perceived as solid, broad and direct. Important within the overall comments was that the revised PIL should have a subheading Children and adolescents' and the current PIL should have a subheading 'Disposal'.

If we look at the consumers' perception on the comprehensibility of both PILs we can conclude that there is not a lot of difference in the perceived comprehension between both current and revised PIL. The scores of each PIL were average.

Next we will discuss the reader's evaluation and appreciation regarding the layout, design and tone of the PIL. From these results we can conclude that there is not much difference between the appreciation scores in each group (clarity, attractiveness and visuality). The scores of each PIL were again average. However, there appear to be a difference the appreciation of the questionsets and questionset order. Questionset 1 is perceived as more attractive than questionset 2 in spite of which text structure (current and revised) and text version (bogus and real text) the

participants received. Furthermore, participants liked the attractiveness of the current PIL relating to the question set orders 1 till 3 but when they received order 4, the revised PIL is better evaluated.

The results of the 'split run test' showed that most participants preferred the revised PIL above the current PIL. The main reasons for this choice is that the revised PIL has more subheadings, which makes it better organized and manageable. The information appears to be more concise, easier to locate and better phrased.

5. Conclusion and discussion

This research is conducted to compare the revised text structure, as proposed by Pander Maat and Lentz (2011), with a current text structure of a patient information leaflet (PIL). The study could make clear whether the revised text structure indeed improved the findability of information about the medicine and its usage. We focused mainly on the grouping of topics, the presentation of the information and the phrasing of the headings. The outcome of this study has demonstrated the strengths and weaknesses of both the revised and current PIL.

5.1 Conclusion

First we looked at the influence of the text structure (current and revised) on the findability of the information in a PIL. Secondly we examined the participant's perception of the current and revised PIL. This study can contribute in improving the text structure in a patient information leaflet so that it is easier for patients to locate correct information in a PIL. We expected that the revised text structure could help to improve the findability and appreciation of the leaflet but also the compatibility between the PILs structure and the readers' medication schema. We will first draw the most important conclusions on the findability of information in a PIL and then the readers' perception of both current and revised text structure.

Findability

The localization scores of the main- and subheadings in both current and revised PIL have been compared so we could see in which text structure the grouping of topics, the presentation of the information and the phrasing of the headings is better. The grouping of topics and the presentation of the information have been evaluated by examining the location scores of the main headings. The phrasing of the subheadings (quality of the subheadings) have been evaluated by looking at the location scores of the specific main- and subheadings. We used the structure of Morrow et al. (1998) to divide the main- and subheadings into three groups: identifying the medication, instructions on how to take the medicine and information about side effects.

The main structure (main headings) is better in the revised PIL for the group 'Identifying the medication' and 'Information about side effects'. Relating to the group 'Identifying the medication' the following conclusions can be drawn: the main heading 'About this medicine and what it is used for' from the revised PIL has a more positive effect on findability of information than the main heading 'What Pharmazine is and what it is used for' from the current PIL. It is still unclear if the main heading 'Ingredients and registration' from the revised PIL is better than the main heading 'Contents of the pack and other information' from the current PIL. With

respect to the group 'Instructions on how to take the medicine' the following conclusions can be drawn: it is not clear if the main headings 'Taking the medicine' and 'Package, storage and disposal' from the revised PIL are better than the main headings 'How to take Pharmazine' and 'How to store Pharmazine' from the current PIL. With respect to the group 'Information about side effects' we can conclude that it is better for the findability to have one main heading 'possible problems with the medicine' that includes the information about possible side effects and possible problems with the medicine.

The quality of the subheadings (substructure) is mostly better in the current PIL. Relating to the group 'Identifying the medication' the following conclusions can be drawn: The subheadings 'What this medicine is', 'What it is used for' and 'How it works' under the main heading 'About this medicine and what it is used for' in the revised PIL do not make the information under this main heading clearer. With respect to the group 'Instructions on how to take the medicine' we can conclude that a subheading about children and adolescents is preferred. The subheading 'Tell your doctor if your are taking' under the subheading 'Taking Pharmazine with other medicine' does not necessarily make the information clearer. Whether the subheadings under the main heading 'Taking the medicine' will lead to a better findability is still unclear because only the subheadings 'How long to take' was better in the revised PIL. It appears that the information about how to take and when to take is better to find in the current PIL and how much to take is better to find in the revised PIL. But not all results were significant so these subheadings should be further tested in a follow-up study. Furthermore, including a subheading 'Disposal' leads to better findability than placing the information about disposal under the main heading 'How to store'. With respect to the group 'Information about side effects' we can conclude that instead of dividing the information amongst the subheadings 'People who cannot take this medicine' and 'People who should check with their doctor before taking the medicine' it seem to be better to place all information under one subheading (for example, 'Do not take Pharmazine if:' from the current PIL.) The results on the subheadings 'Pregnancy and breast-feeding' and 'If you want to stop taking this medicine' from the revised PIL or 'if you stop taking pharmazine' from the current PIL are uncertain because there is no cause why one is better than the other. Furthermore, if a heading 'Possible side effects' is going to be subdivided the subheadings should be clear and compact. The subheadings 'Tests', 'Allergies' and 'Driving and using tools or machines' seem to be better in the revised PIL. But they should only be included if the information about tests and allergies should be explicitly mentioned.

Perception

The participant's perception on the current and the revised PIL measures the appreciation and comprehensibility of both current and revised text structure. The effect of the revised text structure as opposed to the current text structure on the user's appreciation of the leaflet is as follows: although the overall results on the perception were inconsistent and the general impression of the participants was quite positive for both text structures most participants preferred the revised PIL above the current PIL. The main reasons given for this choice were that the revised PIL had more subheadings, which makes it better organized and manageable. The information was seen as more concise, easier to locate and better phrased. According to these results we can say the effect of the revised text structure as opposed to a current text structure on the user's appreciation of the leaflet is positive. Despite the rather positive impression on both text structures, with a slight advantage for the revised text structure, participants' comments are sometimes contradictory. Furthermore, the scores of the questions on consumers' perception on the comprehensibility and the reader's evaluation and appreciation regarding the layout, design and tone of both PILs did not show great differences. As a result these comments and scores have only a limited value for this research.

The effect of a PIL with the revised text structure as opposed to a current text structure on the user's ability to find the information is as follows: the main structure of the revised text structure and the quality of most subheadings of the current text structure are better for the findability of information in a PIL. The expectation that a PIL with a revised text structure results in better findability of information in a patient information leaflet than a PIL with a current text structure is only partly confirmed because the manipulation of the main headings is successful but the quality of subheadings is less profitable. The appreciation of the organisation of the information, wording and overall design was slightly higher for the revised PIL. The expectation that a PIL with the revised text structure is perceived in a more positive way than a PIL with a current text structure can be tentatively confirmed.

5.2 Discussion

We used several methods to find out what the positive and negative aspects relating to the grouping of topics, the presentation of the information and the phrasing of the headings of the current and revised PIL are. To examine which text structure, current or revised, has a positive effect on the findability and perception of the PIL we used scenario questions, open questions, the Consumer Information Rating Form and the 'split run test'. The combination of these

instruments appeared to be adequate tools to examine the findability and perception of PILs. However, scenario questions give most valuable results. Through working with PILs and not only asking opinions about those PILs you are able to discover possible differences, comprehension problems and positive or negative aspects. By means of scenario questions you are able to look at specific aspects of PILs.

Neither the current text structure nor the revised text structure have been experienced as an ideal basis for a patient information leaflet. However a combination of both can be a interesting option.

5.2.1 Research limitations

It is a challenge to do a research in the field of PILs because it is difficult to simulate a natural environment where participants have to read a PIL. Participants did not have the time to read the whole PIL from cover to cover because the assignment was to scan the leaflet. This interview technique was fairly new to the participants from the United Kingdom and The Netherlands because of its time limitation and unreadable text, although the time limitation to read the PIL was better to simulate a natural environment in which participants had to read the whole PIL. It is more natural to scan a PIL and pick out the parts that are of interest than read the entire PIL.

Furthermore, the usage of PILs in real and bogus text seemed to be misleading, although the overall results were not influenced by these circumstances but in a follow-up study about the order and quality of main- and subheadings it should be considered that PIL readers look at the text under the main- and subheadings.

In addition participants were honest and it seemed that they did not give socially desirable answers. It is very difficult to track if participants give socially desirable answers but because they were critical towards both current and revised PIL it was unlikely. A possible limitation could be that participants from LUTO and Medilingua had experiences in answering questions about PILs. This could have made it easier for them to answer questions about medicine usage but since the interview was slightly different from what they were used to, this appeared not to be a problem. Besides experiences with medication leaflets have not been taken separately into account because the overall results did not show big differences between participants.

Finally these results do not include how long participants needed to answer the scenario questions. The interviews were recorded but because of time limitation the answering times per scenario question could not be included. This is a topic for futher study.

5.2.2 Recommendations

These results can be a guideline for future research intended to improve the readability of patient information leaflets. However, further research is essential to explore the positive aspects of both current and revised PIL to optimize the text structure in a patient information leaflet. Special attention should be paid to the middle section of the PIL structure namely 'Instructions on how to take the medicine' because these results are still obscure. Furthermore, it is important to carefully formulate scenario questions and examine these in a pre-test since the results can be evaluated per question instead of per current or revised PIL.

It could be an option to use the positive findings from both current and revised text structure to design a new text structure, which can be tested in a follow-up research. Furthermore, if an investigation such as this should be more representative for the whole of Europe then a study should be done in more countries throughout Europe.

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Appendices

Appendices in separate document

Appendix 1 Participant information and consent forms

Information form UK:

Participant Information Sheet

User testing of a Patient Information Leaflet

We would like to invite you to take part in the user testing of a Patient Information Leaflet study but before you decide, please read the following information.

What is the purpose of this study?

We are conducting research on the most effective way to present information in Patient Information Leaflets.

Who is doing the study?

The study is being conducted by Ms. Noortje Arts and will be managed by the University of Leeds and the University of Utrecht. It is being conducted on the premises of Luto Research.
This study is being conducted as part of an educational qualification. The supervisor will be Professor DK Theo Raynor.

Who is being asked to participate?

We are interviewing participants from a wide range of backgrounds who can imagine they are taking a particular medication.

What will be involved if I take part in this study?

This study consists of two tests. During each test you will be asked to read through a medicine leaflet about taking a certain medication. You have approximately 1 minute to look through the leaflet. You will then be asked to find information according to 25 questions we have already prepared. Please refer to the leaflet as you answer the questions. After this you will be asked a few questions to evaluate this leaflet. Then you will be asked to fill in a short questionnaire to evaluate the leaflet: how hard or easy was the leaflet, evaluate the tone of voice and layout of the leaflet. In order that we have the best possible record of what you say with regard to the information leaflet we would like to record the interview.

This is not a test of you or your knowledge. It is a test of how understandable the information is. The interview should last no longer than 1 hour.

What are the advantages and disadvantages of taking part?

The advantages are that you will be helping us to improve the quality of medical information provided to patients. There should be no disadvantages to taking part in this study. There is however a time commitment required. This study may last up to one hour.

Can I withdraw from the study at any time?

You do not have to take part in this research and may withdraw at any time without giving a reason. If you withdraw from the study, the information held on you will be destroyed.

Will the information obtained in the study be confidential?

Your personal details (name, date of birth, job title and contact details) will be kept on the Luto database for at least six months. This is to enable us to possibly contact you to participate again. Your details will be kept confidential and secure and will not be shared with a third party, in accordance with the Data Protection Act. At the moment you decide not to participate any longer in the User Testing of Patient Information Leaflets, we will delete your personal details from this research immediately.

The data you provide during the interview will be converted into anonymous data. These data will be used to investigate the most effective way to present information in a Patient Information Sheet.

What will happen to the results of the study?

The data you provide will be used in a study of different ways of presenting information to patients about their medicines. This research is being conducted by the University of Leeds and the University of Utrecht, the Netherlands. We will present the information to the European Medicines Agency to help them improve the regulations about patient information leaflets. We will also write a paper for publication in a medical journal.

Who has reviewed this study?

The study has been reviewed and approved by the University of Leeds, School of Healthcare Research Ethics Committee.

If you agree to take part, would like more information or have any questions or concerns about the study please contact the person conducting the interview. If you have questions once you have left the research interview please send an email to Noortje at N.Arts@students.uu.nl or call her at 0031 616164149 she will be happy to answer any queries you might have. You can also contact Professor DK Theo Raynor on 0113 343 1228 or at d.k.raynor@leeds.ac.uk

Thank you for taking the time to read this information sheet.

Information form NL:

Informatieformulier voor participanten

Gebruikers test van een medische bijsluiter

Hierbij nodigen wij u uit deel te nemen aan een gebruikerstest van een medische bijsluiter. Voordat u begint met de test willen wij u graag nog wat meer informatie geven.

Wat is het doel van dit onderzoek?

Wij doen onderzoek naar de meest effectieve manier om informatie in een medische bijsluiter te presenteren.

Wie doet dit onderzoek?

Dit onderzoek wordt gedaan door Noortje Arts en wordt geleid door de Universiteit Utrecht en de Universiteit van Leeds. Dit onderzoek wordt uitgevoerd op het terrein van MediLingua in Leiden *(Dit onderzoek wordt uitgevoerd op het terrein van de Universiteit Utrecht in Utrecht).*

Dit onderzoek wordt uitgevoerd als onderdeel van academische kwalificatie. De supervisors zijn professor Leo Lentz en professor Henk Pander Maat.

Wie wordt gevraagd om deel te nemen?

Wij interviewen participanten met verschillende demografische kenmerken die zich voor kunnen stellen dat ze een bepaald geneesmiddel in moeten nemen.

Wat moet ik doen als ik meewerk aan dit onderzoek?

Dit onderzoek bevat twee testen. Tijdens iedere test wordt u gevraagd een bijsluiter over een bepaald geneesmiddel te lezen. U hebt ongeveer 1 minuut om deze bijsluiter te bekijken. Dan zal aan u gevraagd worden de informatie met betrekking tot de 25 vragen, die we hebben voorbereid, op te zoeken in de bijsluiter. Gebruik alstublieft de bijsluiter om de vragen te beantwoorden. Hierna wordt u gevraagd een paar evaluatievragen over de bijsluiter te beantwoorden. Vervolgens zal aan u gevraagd worden een korte vragenlijst met beoordeling en waarderingsvragen in te vullen, bijvoorbeeld; ‘Hoe moeilijk of makkelijk vindt u de bijsluiter?’ en ‘Wat vindt u van de toon en opmaak van de bijsluiter?’. Om ervoor te zorgen dat we alles wat u zegt met betrekking tot de bijsluiter opslaan, willen we graag het interview opnemen.

Wij testen niet u of uw kennis. Deze test gaat over of u de informatie begrijpelijk vindt. Dit interview zal zeker niet langer duren dan 1 uur.

Wat zijn de voor- en nadelen van deze deelname?

De voordelen zijn dat u meehelpt aan het verbeteren van de kwaliteit van medische informatie voor patiënten. Er zijn voor u geen nadelen wanneer u meedoet aan dit onderzoek. We vragen echter enige tijd van u. Dit onderzoek neemt ongeveer 1 uur in beslag.

Kan ik op elk moment terugtrekken van het onderzoek?

U hoeft niet deel te nemen aan dit onderzoek en u mag uzelf op elk moment terugtrekken zonder een reden te geven. Als u niet meer deelneemt aan dit onderzoek zal de informatie die u ons gegeven heeft vernietigd worden.

Is de informatie, die verkregen wordt tijdens dit onderzoek, vertrouwelijk?

Uw persoonlijke gegevens (naam, geboortedatum, beroep en contact gegevens) zullen bewaard worden in de MediLingua database (*CG Selecties database*). Dan kunnen we in de toekomst contact met u opnemen met de vraag of u deel wilt nemen aan een ander onderzoek. Op het moment dat u besluit niet meer deel te nemen aan dit onderzoek zullen we uw persoonlijke gegevens die gebruikt worden voor dit onderzoek onmiddellijk verwijderen.

Het onderzoek wordt geanonimiseerd. Dit houdt in dat uw persoonlijke gegevens gescheiden worden van uw antwoorden en niet worden doorgegeven aan derden of worden vermeld in het onderzoek. Deze data zal gebruikt worden om te onderzoeken wat de meest effectieve manier is om informatie in een medische bijsluiter te presenteren. Uw persoonlijke gegevens zullen als vertrouwelijk worden beschouwd en veilig worden bewaard.

Wat zal er gebeuren met de resultaten van dit onderzoek?

Uw gegevens zullen gebruikt worden in dit onderzoek met als doel het op verschillende manieren presenteren van informatie voor patiënten wanneer deze medicijnen krijgen voorgeschreven. Dit onderzoek wordt gedaan door de Universiteit Utrecht en de Universiteit van Leeds (Groot Brittannië). Wij zullen de informatie uit dit onderzoek presenteren aan het Europese Medische bureau om ze te ondersteunen met het verbeteren van het huidige reglement over medische bijsluiters. We zullen ook een paper schrijven dat gepubliceerd zal worden in een medisch wetenschappelijk tijdschrift.

Wie heeft dit onderzoek beoordeeld?

Dit onderzoek is beoordeeld en goedgekeurd door de Universiteit Utrecht en de Universiteit van Leeds, *School of Healthcare Research* Ethisch Comité.

Als u besluit deel te nemen, meer informatie wilt, vragen heeft en/of bezorgd bent over dit onderzoek neemt u dan alstublieft contact op met degene die dit onderzoek uitvoert. Als u meer vragen heeft nadat u dit interview hebt verlaten kunt u een e-mail sturen naar Noortje Arts op N.Arts@students.uu.nl of telefonisch contact opnemen op 06 - 16164149. Zij zal met plezier al uw vragen beantwoorden.

Hartelijk dank dat u de tijd heeft genomen om dit informatieformulier door te lezen.

Participant Consent Form (only used in UK)

Name of Centre: School of Healthcare, University of Leeds

Title of Study: User testing of a Patient Information Leaflet

Please read each of the following statements **- then place your initials in each box if you agree with the statement:**	**Please confirm agreement to the statements by putting your initials in the box below**
I have read and understood the participant information sheet.	
I have had the opportunity to ask questions and discuss this study.	
I have received satisfactory answers to all of my questions.	
I do not need any more information now but can request it at any time.	
I understand the purpose of the research and know what my involvement will be.	
I understand that I am free to withdraw from the study at any time and without having to give a reason.	
I understand that my interview will be audio-recorded.	
I understand that any information I provide, including personal details, will be confidential, stored securely and only accessed by those carrying out the study.	
I understand that any information I give may be included in published documents but all information will be anonymised.	
I agree to take part in this study.	
Participant Signature …… Date	
Name of Participant	
Researcher Signature …….. Date	
Name of Researcher	

Thank you for agreeing to take part in this study.

Appendix 2 Questionnaires

Scenario questions, question set 1:

Question	**Question Set 1** (questions in English and Dutch and the headings where the correct location is found)					
	English Question	**Dutch Question**	**Revised heading English**	**Revised heading Dutch**	**Current heading English**	**Current heading Dutch**
1	Suppose you want to know what the active component in this drug does for you. Where can you find this information in this leaflet?	Stel, u wilt weten wat de werking is van het actieve bestanddeel in dit geneesmiddel. Waar kunt u deze informatie in deze bijsluiter vinden?	What this medicine is *(subheading)*	Wat is dit voor geneesmiddel? *(subheading)*	What Pharmazine is and what it is used for *(main heading)*	Waarvoor wordt dit middel gebruikt ? *(main heading)*
2	Imagine you have epilepsy. Did the doctor prescribe the right medicine for you?	Stel, u hebt epilepsie. Heeft de arts het juiste geneesmiddel voorgeschreven?	What it is used for *(subheading)*	Waar dient het voor? *(subheading)*	What Pharmazine is and what it is used for *(main heading)*	Waarvoor wordt dit middel gebruikt ? *(main heading)*
3	Suppose you have mood swings and you want to know how this medicine affects your mood swings. Where can you find this information in this leaflet?	Stel, u gebruikt dit middel tegen stemmings-wisselingen en u wilt weten hoe dit geneesmiddel uw stemmingswisselingen zal beïnvloeden. Waar kunt u deze informatie vinden in de bijsluiter?	How it works *(subheading)*	Hoe werkt het? *(subheading)*	What Pharmazine is and what it is used for *(main heading)*	Waarvoor wordt dit middel gebruikt ? *(main heading)*
4	Suppose you have heart problems. Are you allowed to use this medicine?	Stel, u hebt hartproblemen. Mag u dit geneesmiddel gebruiken?	People who cannot take this medicine *(subheading)*	Wie kan dit middel niet gebruiken *(subheading)*	Do not take Pharmazine if: *(subheading)*	Wanneer mag u dit middel niet gebruiken? *(subheading)*
5	If you have liver problems and have been prescribed this medicine. What should you do?	Stel, u hebt leverproblemen en de arts heeft u dit geneesmiddel voorgeschreven. Wat moet u doen?	People who should check with their doctor before taking this medicine *(subheading)*	Wie kan dit middel pas gebruiken na toestemming van de arts *(subheading)*	Warnings and precautions *(subheading)*	Wanneer moet u extra voorzichtig zijn met dit middel *(subheading)*
6	Is it likely for your doctor to examine you before and during the treatment?	Is er een kans dat uw arts u voor en tijdens de behandeling zal onderzoeken?	Tests *(subheading)*	Medische controles *(subheading)*	Warnings and precautions *(subheading)*	Wanneer moet u extra voorzichtig zijn met dit middel *(subheading)*
7	Suppose your four year old son has mood swings. Can he have this medicine?	Stel, uw zoon van vier heeft last van stemmingswisselingen. Kan hij dit geneesmiddel daartegen gebruiken?	How much to take *(subheading)* and people who cannot take this medicine *(subheading)*	Hoeveel neemt u in *(subheading)* en Wie kan dit middel niet gebruiken *(subheading)*	Children and adolescents *(subheading)*	Kinderen en jongeren tot 18 jaar *(subheading)*
8	Imagine you are already taking another medicine to treat a skin infection, as well as the medicine described in this leaflet. What should you do?	Stel, u gebruikt al een geneesmiddel tegen huidinfecties, en gaat nu het middel uit deze bijsluiter gebruiken. Wat moet u doen?	Taking Pharmazine with other medicines *(subheading)*	Als u Pharmazine gebruikt in combinatie met andere middelen *(subheading)*	Other medicines and Pharmazine *(subheading)*	Gebruikt u nog andere geneesmiddelen *(subheading)*
9	Can you have grapefruit and grapefruit juice if you are taking this medicine?	Mag u grapefruit en grapefruitsap hebben als u dit geneesmiddel gebruikt?	How food, drinks and alcohol affect this medicine *(subheading)*	Eten, drinken, alcoholgebruik en de werking van dit middel *(subheading)*	Pharmazine with food, drink and alcohol *(subheading)*	Waarop moet u letten met eten, drinken en alcohol *(subheading)*

	English Question	Dutch Question	Revised heading English	Revised heading Dutch	Current heading English	Current heading Dutch
10	Suppose you think you might be sensitive to medicines like Pharmazine. What should you do?	Stel, u denkt dat u overgevoelig bent voor geneesmiddelen zoals Pharmazine. Wat moet u doen?	Allergies *(subheading)*	Allergieën *(subheading)*	Do not take Pharmazine if: *(subheading)*	Wanneer mag u dit middel niet gebruiken *(subheading)*
11	What is the advice in this leaflet for women who are trying to have a baby?	Wat is het advies in deze bijsluiter voor vrouwen die een baby willen krijgen?	Pregnancy and breast-feeding *(subheading)*	Zwangerschap en borstvoeding *(subheading)*	Pregnancy and breast-feeding *(subheading)*	Zwangerschap en borstvoeding *(subheading)*
12	Suppose you want to go to the shop with the car. Are you able to do this while taking this medicine?	Stel, u wilt met de auto naar de winkel. Bent u in staat om dit te doen terwijl u dit geneesmiddel gebruikt?	Driving and using tools or machines *(subheading)*	Rijvaardigheid en het gebruik van gereedschap of machines *(subheading)*	Driving and using machines *(subheading)*	Rijvaardigheid en het gebruik van machines *(subheading)*
13	Suppose you have difficulties swallowing a whole tablet. What should you do?	Stel, u hebt moeite met het doorslikken van een hele tablet. Wat moet u doen?	How to take *(subheading)*	Hoe neemt u dit middel in *(subheading)*	How to take Pharmazine *(main heading)*	Hoe gebruikt u dit middel *(main heading)*
14	Suppose you are 40 years old and you are taking the medicine presented in this leaflet for epilepsy. What is the lowest dose you can take?	Stel, u bent 40 jaar en u gebruikt het geneesmiddel uit deze bijsluiter tegen epilepsie. Wat is de laagste dosering die u kunt innemen?	How much to take *(subheading)*	Hoeveel neemt u in *(subheading)*	How to take Pharmazine *(main heading)*	Hoe gebruikt u dit middel *(main heading)*
15	How many times a day should you take a dose of this medicine?	Hoeveel keer per dag moet u een dosis van dit geneesmiddel innemen?	When to take *(subheading)*	Wanneer neemt u dit middel in *(subheading)*	How to take Pharmazine *(main heading)*	Hoe gebruikt u dit middel *(main heading)*
16	Over what period of time should you take this medication?	Hoe lang zou u dit geneesmiddel moeten gebruiken?	How long to take *(subheading)*	Hoe lang gebruikt u het *(subheading)*	If you stop taking Pharmazine *(subheading)*	Als u stopt met het gebruik van dit middel *(subheading)*
17	Suppose someone you know has taken some of your medicine. What should they do when he or she accidentally took an overdose of the medicine?	Stel, iemand die u kent heeft wat van uw geneesmiddel genomen. Wat moeten zij doen wanneer hij of zij per ongeluk een overdosis van dit geneesmiddel heeft genomen?	If you take too much *(subheading)*	Als u te veel ingenomen heeft *(subheading)*	If you take more Pharmazine that you should *(subheading)*	Heeft u te veel van dit middel ingenomen *(subheading)*
18	Suppose you did not remember to take the medicine this morning. What should you do?	Stel, u bent vanmorgen vergeten om het geneesmiddel in te nemen. Wat moet u doen?	If you forget to take *(subheading)*	Als u een dosis vergeten bent *(subheading)*	If you forget to take Pharmazine *(subheading)*	Bent u vergeten dit middel in te nemen *(subheading)*
19	You want to know if you can end the treatment without first discussing it with your doctor. Where can you find this information in this leaflet?	U wilt weten of u de behandeling kunt beëindigen zonder dit eerst met uw arts te bespreken. Waar kunt u deze informatie vinden in de bijsluiter?	If you want to stop taking this medicine *(subheading)*	Als u wilt stoppen *(subheading)*	If you stop taking Pharmazine *(subheading)*	Als u stopt met het gebruik van dit middel *(subheading)*
20	Suppose you get blistering of the lips while using this medicine. What should you do?	Stel, u krijgt blaren op de lippen terwijl u dit geneesmiddel gebruikt. Wat moet u doen?	Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice: *(subheading)*	Mogelijke bijwerkingen; stop met dit middel en neem direct contact op met uw arts als u het volgende merkt: *(subheading)*	Possible side effects *(main heading)*	Mogelijke bijwerkingen *(main heading)*

	English Question	Dutch Question	Revised heading English	Revised heading Dutch	Current heading English	Current heading Dutch
21	How likely is getting high blood pressure as a side effect after taking this medicine?	Hoe groot is de kans dat u last krijgt van een hoge bloeddruk als een bijwerking bij het gebruik van dit geneesmiddel?	Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you. *(subheading)*	Mogelijke bijwerkingen; Overleg met uw arts als u last heeft van een van de volgende bijwerkingen. *(subheading)*	Possible side effects *(main heading)*	Mogelijke bijwerkingen *(main heading)*
22	Suppose the doctor recently prescribed you this medicine, but you forgot to ask where to keep them. Can you keep this medicine in the refrigerator?	Stel, de arts heeft u onlangs dit geneesmiddel voorgeschreven, maar u bent vergeten te vragen waar u dit geneesmiddel moet opbergen. Kunt u dit geneesmiddel in de koelkast bewaren?	Storage *(subheading)*	Hoe bewaart u dit middel *(subheading)*	How to store Pharmazine *(main heading)*	Hoe bewaart u dit middel *(main heading)*
23	Suppose the doctor tells you to stop taking the tablets. What should you do with the rest of the tablets?	Stel, uw arts geeft aan dat u mag stoppen met het innemen van de tabletten. Wat moet u doen met de tabletten die over zijn?	Disposal *(subheading)*	Hoe gooit u het weg *(subheading)*	How to store Pharmazine *(main heading)*	Hoe bewaart u dit middel *(main heading)*
24	What is the active element of this medicine?	Wat is het actieve bestanddeel in dit geneesmiddel?	Ingredients *(subheading)*	Ingrediënten *(subheading)*	What Pharmazine contains *(subheading)*	Welke stoffen zitten er in dit middel *(subheading)*
25	The 100 mg tablets come in blister packs. How many tablets does a pack contain?	De 100 mg tabletten zitten in een doordrukstrip. Hoeveel tabletten zitten er in een strip?	Contents of the pack and appearance *(subheading)*	Hoeveel zit er in de verpakking en hoe ziet het middel eruit *(subheading)*	What Pharmazine looks like and contents of the pack *(subheading)*	Hoe ziet Pharmazine eruit en hoeveel zit er in een verpakking *(subheading)*

Scenario questions, question set 2:

Question	Question Set 2 (questions in English and Dutch and the headings where the correct location is found)					
	English Question	**Dutch Question**	**Revised heading English**	**Revised heading Dutch**	**Current heading English**	**Current heading Dutch**
1	Suppose you would like to know how this medicine affects your illness. Where can you find this information in this leaflet?	Stel, u wilt weten wat voor effect dit geneesmiddel op uw ziekte heeft. Waar kunt u deze informatie in deze bijsluiter vinden?	What this medicine is *(subheading)*	Wat is dit voor geneesmiddel? *(subheading)*	What Pharmazine is and what it is used for *(main heading)*	Waarvoor wordt dit middel gebruikt ? *(main heading)*
2	Imagine you have mood swings. Is this the right medicine for you?	Stel, u hebt last van stemmingswisselingen. Is dit geneesmiddel daarvoor geschikt?	What it is used for *(subheading)*	Waar dient het voor? *(subheading)*	What Pharmazine is and what it is used for *(main heading)*	Waarvoor wordt dit middel gebruikt? *(main heading)*
3	Suppose you have epilepsy and you want to know what this medicine will do for your illness. Where can you find this information in this leaflet?	Stel, u hebt epilepsie en u wilt weten hoe dit geneesmiddel uitwerkt op uw ziekte. Waar kunt u deze informatie vinden in deze bijsluiter?	How it works *(subheading)*	Hoe werkt het? *(subheading)*	What Pharmazine is and what it is used for *(main heading)*	Waarvoor wordt dit middel gebruikt? *(main heading)*
4	Suppose you have had blood problems. Are you allowed to use this medicine?	Stel, u hebt bloedproblemen gehad. Mag u dit geneesmiddel gebruiken?	People who cannot take this medicine *(subheading)*	Wie kan dit middel niet gebruiken *(subheading)*	Do not take Pharmazine if: *(subheading)*	Wanneer mag u dit middel niet gebruiken? *(subheading)*
5	Suppose you already have a type of epilepsy called mixed seizures which include absences. What should you do?	Stel, u lijdt al aan een vorm van epilepsie waarbij u last heeft van aanvallen en absenties. Wat moet u doen?	People who should check with their doctor before taking this medicine *(subheading)*	Wie kan dit middel pas gebruiken na toestemming van de arts *(subheading)*	Warnings and precautions *(subheading)*	Wanneer moet u extra voorzichtig zijn met dit middel *(subheading)*
6	What type of check-up do you have if taking this medicine?	Wat voor soort testen worden er gedaan als u dit geneesmiddel gebruikt?	Tests *(subheading)*	Medische controles *(subheading)*	Warnings and precautions *(subheading)*	Wanneer moet u extra voorzichtig zijn met dit middel *(subheading)*
7	Suppose your two year old daughter suffers from seizures and you wonder if she can have this medicine. What should you do?	Stel, uw dochter van twee lijdt aan epileptische aanvallen en u vraagt zich af of zij dit geneesmiddel daartegen mag gebruiken. Wat moet u doen?	How much to take *(subheading)* and people who cannot take this medicine *(subheading)*	Hoeveel neemt u in *(subheading)* en Wie kan dit middel niet gebruiken *(subheading)*	Children and adolescents *(subheading)*	Kinderen en jongeren tot 18 jaar *(subheading)*
8	Suppose you are already taking a medicine for asthma, as well as the medicine described in this leaflet. What should you do?	Stel, u gebruikt al een geneesmiddel tegen astma, en u gaat nu het middel uit deze bijsluiter gebruiken. Wat moet u doen?	Taking Pharmazine with other medicines *(subheading)*	Als u Pharmazine gebruikt in combinatie met andere middelen *(subheading)*	Other medicines and Pharmazine *(subheading)*	Gebruikt u nog andere geneesmiddelen *(subheading)*
9	Imagine you would like to go to a party. Are you allowed to drink beer or wine?	Stel, u wilt naar een feest gaan. Mag u bier of wijn drinken?	How food, drinks and alcohol affect this medicine *(subheading)*	Eten, drinken, alcoholgebruik en de werking van dit middel *(subheading)*	Pharmazinie with food, drink and alcohol *(subheading)*	Waarop moet u letten met eten, drinken en alcohol *(subheading)*
10	Suppose you cannot have some types of food and you are unsure if you can use this medicine. What should you do?	Stel, u mag bepaalde soorten voedingsmiddelen niet hebben en u bent niet zeker of u dit geneesmiddel wel mag gebruiken. Wat moet u doen?	Allergies *(subheading)*	Allergieën *(subheading)*	Do not take Pharmazine if: *(subheading)*	Wanneer mag u dit middel niet gebruiken *(subheading)*

	English Question	Dutch Question	Revised heading English	Revised heading Dutch	Current heading English	Current heading Dutch
11	Suppose a woman wants to give mothers milk to her baby. Is she allowed to use this medicine?	Stel, een vrouw wil haar baby moedermelk geven. Mag zij dit geneesmiddel gebruiken?	Pregnancy and breast-feeding *(subheading)*	Zwangerschap en borstvoeding *(subheading)*	Pregnancy and breast-feeding *(subheading)*	Zwangerschap en borstvoeding *(subheading)*
12	Suppose you want to mow the lawn. What does this leaflet tell you about this?	Stel, u wilt het gras maaien. Wat zegt de bijsluiter daarover?	Driving and using tools or machines *(subheading)*	Rijvaardigheid en het gebruik van gereedschap of machines *(subheading)*	Driving and using machines *(subheading)*	Rijvaardigheid en het gebruik van machines *(subheading)*
13	Suppose you are not sure in which way to swallow this medicine. What should you do?	Stel, u weet niet zeker hoe u dit geneesmiddel door moet slikken. Wat moet u doen?	How to take *(subheading)*	Hoe neemt u dit middel in *(subheading)*	How to take Pharmazine *(main heading)*	Hoe gebruikt u dit middel *(main heading)*
14	Suppose you are 74 years old and you have epilepsy. What does the leaflet tell you about the recommended dose?	Stel, u bent 74 jaar en u hebt epilepsie. Wat zegt de bijsluiter over de aanbevolen dosering?	How much to take *(subheading)*	Hoeveel neemt u in *(subheading)*	How to take Pharmazine *(main heading)*	Hoe gebruikt u dit middel *(main heading)*
15	At which times during the day should you take a dose of this medicine?	Op welke momenten van de dag moet u een dosering van dit geneesmiddel nemen?	When to take *(subheading)*	Wanneer neemt u dit middel in *(subheading)*	How to take Pharmazine *(main heading)*	Hoe gebruikt u dit middel *(main heading)*
16	Suppose you have doubts about keeping on with this medicine. What should you do?	Stel, u weet niet zeker of u door wilt gaan met het geneesmiddel. Wat moet u doen?	How long to take *(subheading)*	Hoe lang gebruikt u het *(subheading)*	If you stop taking Pharmazine *(subheading)*	Als u stopt met het gebruik van dit middel *(subheading)*
17	Suppose you have accidentally taken too much of this medicine and you decide go to the hospital. What should you take with you to the hospital?	Stel, u hebt per ongeluk te veel van het geneesmiddel genomen en u besluit naar het ziekenhuis te gaan. Wat moet u meenemen naar het ziekenhuis?	If you take too much *(subheading)*	Als u te veel ingenomen heeft *(subheading)*	If you take more Pharmazine that you should *(subheading)*	Heeft u te veel van dit middel ingenomen *(subheading)*
18	Suppose you have not taken a dose earlier in the day and it is now time for your next dose. When should you take the medicine?	Stel, u hebt eerder op de dag nog geen dosis gehad en het is nu tijd voor de volgende dosis. Wanneer moet u het geneesmiddel innemen?	If you forget to take *(subheading)*	Als u een dosis vergeten bent *(subheading)*	If you forget to take Pharmazine *(subheading)*	Bent u vergeten dit middel in te nemen *(subheading)*
19	Suppose you have problems with this medicine and you do not want to take this medicine any longer. What should you do?	Stel, u hebt problemen met dit geneesmiddel en u wilt het geneesmiddel niet meer gebruiken. Wat moet u doen?	If you want to stop taking this medicine *(subheading)*	Als u wilt stoppen *(subheading)*	If you stop taking Pharmazine *(subheading)*	Als u stopt met het gebruik van dit middel *(subheading)*
20	Suppose you get a sore throat and a high temperature while using this medicine and are worried about this. What should you do?	Stel, u hebt last van een zere keel en hoge koorts terwijl u dit geneesmiddel gebruikt en u maakt zich daarover zorgen. Wat moet u doen?	Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice: *(subheading)*	Mogelijke bijwerkingen; stop met dit middel en neem direct contact op met uw arts als u het volgende merkt: *(subheading)*	Possible side effects *(main heading)*	Mogelijke bijwerkingen *(main heading)*
21	How likely are you to have hearing problems as a side effect after using this medicine?	Hoe groot is de kans dat u last krijgt van gehoorproblemen als bijwerking nadat u dit geneesmiddel hebt gebruikt?	Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you. *(subheading)*	Mogelijke bijwerkingen; Overleg met uw arts als u last heeft van een van de volgende bijwerkingen. *(subheading)*	Possible side effects *(main heading)*	Mogelijke bijwerkingen *(main heading)*

	English Question	Dutch Question	Revised heading English	Revised heading Dutch	Current heading English	Current heading Dutch
22	Are there any recommendations on how to keep this medication?	Geeft de bijsluiter adviezen over hoe u dit geneesmiddel het beste kunt bewaren?	Storage *(subheading)*	Hoe bewaart u dit middel *(subheading)*	How to store Pharmazine *(main heading)*	Hoe bewaart u dit middel *(main heading)*
23	Can you flush the unused medicine down the toilet?	Kunt u de ongebruikte medicijnen door het toilet spoelen?	Disposal *(subheading)*	Hoe gooit u het weg *(subheading)*	How to store Pharmazine *(main heading)*	Hoe bewaart u dit middel *(main heading)*
24	Suppose you would like to know what inactive elements this medicine contains. What does this leaflet tell you about this?	Stel, u wilt weten welke inactieve bestanddelen dit geneesmiddel bevat. Wat zegt de bijsluiter daarover?	Ingredients *(subheading)*	Ingrediënten *(subheading)*	What Pharmazine contains *(subheading)*	Welke stoffen zitten er in dit middel *(subheading)*
25	Imagine you have three tablets in front of you but you do not know which one is the medicine of this leaflet. What kind of shape do these tablets have?	Stel, u hebt drie tabletten voor u liggen maar u weet niet zeker welke tablet bij het geneesmiddel uit deze bijsluiter hoort. Welke vorm hebben deze tabletten?	Contents of the pack and appearance *(subheading)*	Hoeveel zit er in de verpakking en hoe ziet het middel eruit *(subheading)*	What Pharmazine looks like and contents of the pack *(subheading)*	Hoe ziet Pharmazine eruit en hoeveel zit er in een verpakking *(subheading)*

The used literature for the scenario questions:

- Dolk (2009, pp 23) In version 1 questions: 2, 4, 5, 7, 12, 18 and 20 and in version 2 - questions: 2, 3, 5, 7 and 20.
- Dickinson et al. (2001, pp. 155) In version 1 questions: 8, 13 and 17 and in version 2 - questions: 13 and 17.
- Pander Maat (2008, pp. 40-45) In version 2 questions 6, 8 and 9.
- Gustafsson et al. (2005, pp. 36) In version 2 question 21.

The appreciation questionnaires

Participant's impression and comments on the medicine leaflet no. 1 / Impressie en toelichting van de participant op de bijsluiter nr. 1:

1. Overall, what do you think of the leaflet? / 1. Wat is uw algemene indruk van de bijsluiter? *(Dickinson 2001: 158)*

Any particular good points? / Zijn er bepaalde positieve punten?

Any particular bad points? / Zijn er bepaalde negatieve punten?

2. In particular, what did you think about the headings and subheadings? / 2. Wat vindt u van de kopjes en subkopjes? *(Dolk 2009: 24)*

Any particular good points? / Zijn er bepaalde positieve punten?

Any particular bad points? / Zijn er bepaalde negatieve punten?

3. In particular, what did you think about the order of the information in the leaflet? /3. Wat vindt u van de volgorde van de informatie in deze bijsluiter?

Any particular good points? / Zijn er bepaalde positieve punten?

Any particular bad points? / Zijn er bepaalde negatieve punten?

4. Is there anything else about this leaflet that we have not talked about which you would like to mention? / 4. Zijn er nog andere punten die u graag wilt vermelden over deze bijsluiter waar we het nog niet over hebben gehad? *(Dickinson 2001: 158)*

Reviewed both appreciation forms by interviewer (Rev'd) by means of data/corrections/additions/deletions and correct as marked.

Interviewer signature: Date:

Impression and comments on the medicine leaflet no. 2 / Algemene indruk en opmerkingen over de bijsluiter nr. 2:

1. How hard or easy would you say the information in the leaflet is to…../ Hoe makkelijk of moeilijk vindt u de bijsluiter om te…… *(Pander Maat 2008:50 en Dolk 2009: 21)*

	very easy/erg makkelijk	*Easy/makkelijk*	*not easy not difficult/niet makkelijk niet moeilijk*	*Difficult/moeilijk*	*very difficult/erg moeilijk*
Read/ Lezen	○	○	○	○	○
Understand/Begrijpen	○	○	○	○	○
Remember/Onthouden	○	○	○	○	○
Locate information/ Informatie in te vinden	○	○	○	○	○
Keep for future reference/ Vaker te gebruiken	○	○	○	○	○

2. Below is a list of words on a scale describing the design, layout and tone of the leaflet. Which best describes your opinion? / 2. Hieronder staan een aantal woorden die het ontwerp, opmaak en toon van de bijsluiter beschrijven. Welke beschrijft uw mening het beste? *(Dolk 2009: 21)*

I find the leaflet: / Ik vind de bijsluiter:

Easy/Makkelijk	○	○	○	○	○	Difficult/Moeilijk
Unclear/Onduidelijk	○	○	○	○	○	Clear/Duidelijk
Logically structured/Logisch gestructureerd	○	○	○	○	○	Illogically structured/Onlogisch gestructureerd
Concise/Beknopt	○	○	○	○	○	Long-winded/Langdradig
Appealing/Aantrekkelijk	○	○	○	○	○	Unappealing/Onaantrekkelijk
Interesting/Interessant	○	○	○	○	○	Not interesting/Oninteressant
Uninviting/Niet uitnodigend	○	○	○	○	○	Inviting/Uitnodigend
Clarifying/Helder	○	○	○	○	○	Not Clarifying/Niet helder
Personal/Persoonlijk	○	○	○	○	○	Impersonal/Onpersoonlijk
Poorly organized/Slecht georganiseerd	○	○	○	○	○	Well organized/Goed georganiseerd
Ideal print size/Goede grootte van letters	○	○	○	○	○	Poor print size/Slechte grootte van letters
Encouraging in tone/Aanmoedigende toon	○	○	○	○	○	Alarming in tone/ Alarmerende toon
Biased/Bevooroordeeld	○	○	○	○	○	Unbiased/Niet bevooroordeeld
Unattractive/Niet boeiend	○	○	○	○	○	Attractive/Boeiend
Ideal spacing between lines/Ideale ruimte tussen de regels	○	○	○	○	○	Poor spacing between lines/ te weinig ruimte tussen de regels

Impression and comments on the medicine leaflet no. 3 / Algemene indruk en opmerkingen over de bijsluiter nr. 3:

2. How hard or easy would you say the information in the leaflet is to…../ Hoe makkelijk of moeilijk vindt u de bijsluiter om te……*(Pander Maat 2008:50 en Dolk 2009: 21)*

	very easy/erg makkelijk	*Easy/makkelijk*	*not easy not difficult/niet makkelijk niet moeilijk*	*Difficult/moeilijk*	*very difficult/erg moeilijk*
Read/ Lezen	○	○	○	○	○
Understand/Begrijpen	○	○	○	○	○
Remember/Onthouden	○	○	○	○	○
Locate information/ Informatie in te vinden	○	○	○	○	○
Keep for future reference/ Vaker te gebruiken	○	○	○	○	○

2. Below is a list of words on a scale describing the design, layout and tone of the leaflet. Which best describes your opinion? / 2. Hieronder staan een aantal woorden die het ontwerp, opmaak en toon van de bijsluiter beschrijven. Welke beschrijft uw mening het beste? *(Dolk 2009: 21)*

I find the leaflet: / Ik vind de bijsluiter:

Easy/Makkelijk	○	○	○	○	○	Difficult/Moeilijk
Unclear/Onduidelijk	○	○	○	○	○	Clear/Duidelijk
Logically structured/Logisch gestructureerd	○	○	○	○	○	Illogically structured/Onlogisch gestructureerd
Concise/Beknopt	○	○	○	○	○	Long-winded/Langdradig
Appealing/Aantrekkelijk	○	○	○	○	○	Unappealing/Onaantrekkelijk
Interesting/Interessant	○	○	○	○	○	Not interesting/Oninteressant
Uninviting/Niet uitnodigend	○	○	○	○	○	Inviting/Uitnodigend
Clarifying/Helder	○	○	○	○	○	Not Clarifying/Niet helder
Personal/Persoonlijk	○	○	○	○	○	Impersonal/Onpersoonlijk
Poorly organized/Slecht georganiseerd	○	○	○	○	○	Well organized/Goed georganiseerd
Ideal print size/Goede grootte van letters	○	○	○	○	○	Poor print size/Slechte grootte van letters
Encouraging in tone/Aanmoedigende toon	○	○	○	○	○	Alarming in tone/ Alarmerende toon
Biased/Bevooroordeeld	○	○	○	○	○	Unbiased/Niet bevooroordeeld
Unattractive/Niet boeiend	○	○	○	○	○	Attractive/Boeiend
Ideal spacing between lines/Ideale ruimte tussen de regels	○	○	○	○	○	Poor spacing between lines/ te weinig ruimte tussen de regels

3. Which version of the medicine leaflet do you prefer? / Welke versie van de bijsluiter heeft uw voorkeur?
Ik geef de voorkeur aan versie:

I prefer version:

A ○ ○ ○ ○ ○ **B**

The main reason is: / De belangrijkste reden daarvoor is:

Appendix 3 Data

A. Localization scores
B. Chosen incorrect headings and subheadings

A. Localization scores

Differences of correct localization scores between current and revised text structure *(N=128)*								
Q. Nr.	Diff. score **Level 1**	Percentage level 1 scores	Diff. score **Level 2**	Percentage level 2 scores	**Revised heading English**	**Revised heading Dutch**	**Current heading English**	**Current heading Dutch**
1	C > R	41,4% > 7,8%	R > C	67,2% > 41,4%	What this medicine is *(subheading)*	Wat is dit voor geneesmiddel? *(subheading)*	What Pharmazine is and what it is used for *(main heading)*	Waarvoor wordt dit middel gebruikt ? *(main heading)*
2	C > R	61,7% > 42,2%	-		What it is used for *(subheading)*	Waar dient het voor? *(subheading)*	What Pharmazine is and what it is used for *(main heading)*	Waarvoor wordt dit middel gebruikt? *(main heading)*
3	-		R > C	50,0% > 35,9%	How it works *(subheading)*	Hoe werkt het? *(subheading)*	What Pharmazine is and what it is used for *(main heading)*	Waarvoor wordt dit middel gebruikt? *(main heading)*
4	C > R	70,3% > 56,3%	-		People who cannot take this medicine *(subheading)*	Wie kan dit middel niet gebruiken *(subheading)*	Do not take Pharmazine if: *(subheading)*	Wanneer mag u dit middel niet gebruiken? *(subheading)*
5	-		-		People who should check with their doctor before taking this medicine *(subheading)*	Wie kan dit middel pas gebruiken na toestemming van de arts *(subheading)*	Warnings and precautions *(subheading)*	Wanneer moet u extra voorzichtig zijn met dit middel *(subheading)*
6	R > C	58,6% > 20,3%	R > C	77,3% > 32,0%	Tests *(subheading)*	Medische controles *(subheading)*	Warnings and precautions *(subheading)*	Wanneer moet u extra voorzichtig zijn met dit middel *(subheading)*
7	C > R	59,4% > 16,4%	C > R	62,5% > 18,0%	How much to take *(subheading)* and people who cannot take this medicine *(subheading)*	Hoeveel neemt u in *(subheading)* en Wie kan dit middel niet gebruiken *(subheading)*	Children and adolescents *(subheading)*	Kinderen en jongeren tot 18 jaar *(subheading)*
8	C > R	84,4% > 46,1%	-		Taking Pharmazine with other medicines *(subheading)*	Als u Pharmazine gebruikt in combinatie met andere middelen *(subheading)*	Other medicines and Pharmazine *(subheading)*	Gebruikt u nog andere geneesmiddelen *(subheading)*
9	-		-		How food, drinks and alcohol affect this medicine *(subheading)*	Eten, drinken, alcoholgebruik en de werking van dit middel *(subheading)*	Pharmazinie with food, drink and alcohol *(subheading)*	Waarop moet u letten met eten, drinken en alcohol *(subheading)*
10	R > C	35,9% >18,8%	R > C	96,1% > 81,3%	Allergies *(subheading)*	Allergieën *(subheading)*	Do not take Pharmazine if: *(subheading)*	Wanneer mag u dit middel niet gebruiken *(subheading)*
11	C > R	80,5% > 64,8%	-		Pregnancy and breast-feeding *(subheading)*	Zwangerschap en borstvoeding *(subheading)*	Pregnancy and breast-feeding *(subheading)*	Zwangerschap en borstvoeding *(subheading)*
12	R > C	87,5% >76,6%	R > C	97,7% > 85,9%	Driving and using tools or machines *(subheading)*	Rijvaardigheid en het gebruik van gereedschap of machines *(subheading)*	Driving and using machines *(subheading)*	Rijvaardigheid en het gebruik van machines *(subheading)*
13	-		-		How to take *(subheading)*	Hoe neemt u dit middel in *(subheading)*	How to take Pharmazine *(main heading)*	Hoe gebruikt u dit middel *(main heading)*

Q. Nr.	Diff. score **Level 1**	Percentage level 1 scores	Diff. score **Level 2**	Percentage level 2 scores	**Revised heading English**	**Revised heading Dutch**	**Current heading English**	**Current heading Dutch**
14	-		R > C	83,6% > 73,4%	How much to take *(subheading)*	Hoeveel neemt u in *(subheading)*	How to take Pharmazine *(main heading)*	Hoe gebruikt u dit middel *(main heading)*
15	C > R	97,7% >63,3%	-		When to take *(subheading)*	Wanneer neemt u dit middel in *(subheading)*	How to take Pharmazine *(main heading)*	Hoe gebruikt u dit middel *(main heading)*
16	R > C	49,2% > 37,5%	-		How long to take *(subheading)*	Hoe lang gebruikt u het *(subheading)*	If you stop taking Pharmazine *(subheading)*	Als u stopt met het gebruik van dit middel *(subheading)*
17	-		-		If you take too much *(subheading)*	Als u te veel ingenomen heeft *(subheading)*	If you take more Pharmazine that you should *(subheading)*	Heeft u te veel van dit middel ingenomen *(subheading)*
18	-		-		If you forget to take *(subheading)*	Als u een dosis vergeten bent *(subheading)*	If you forget to take Pharmazine *(subheading)*	Bent u vergeten dit middel in te nemen *(subheading)*
19	C > R	83,6% > 68,8%	C > R	85,2% > 73,4%	If you want to stop taking this medicine *(subheading)*	Als u wilt stoppen *(subheading)*	If you stop taking Pharmazine *(subheading)*	Als u stopt met het gebruik van dit middel *(subheading)*
20	C > R	85,9% > 53,9%	R > C	98,4% > 85,9%	Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice: *(subheading)*	Mogelijke bijwerkingen; stop met dit middel en neem direct contact op met uw arts als u het volgende merkt: *(subheading)*	Possible side effects *(main heading)*	Mogelijke bijwerkingen *(main heading)*
21	C > R	94,5% > 35,9%	-		Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you. *(subheading)*	Mogelijke bijwerkingen; Overleg met uw arts als u last heeft van een van de volgende bijwerkingen. *(subheading)*	Possible side effects *(main heading)*	Mogelijke bijwerkingen *(main heading)*
22	-		-		Storage *(subheading)*	Hoe bewaart u dit middel *(subheading)*	How to store Pharmazine *(main heading)*	Hoe bewaart u dit middel *(main heading)*
23	R > C	94,5% > 73,4%	R > C	94,5% > 73,4%	Disposal *(subheading)*	Hoe gooit u het weg *(subheading)*	How to store Pharmazine *(main heading)*	Hoe bewaart u dit middel *(main heading)*
24	-		-		Ingredients *(subheading)*	Ingrediënten *(subheading)*	What Pharmazine contains *(subheading)*	Welke stoffen zitten er in dit middel *(subheading)*
25	-		-		Contents of the pack and appearance *(subheading)*	Hoeveel zit er in de verpakking en hoe ziet het middel eruit *(subheading)*	What Pharmazine looks like and contents of the pack *(subheading)*	Hoe ziet Pharmazine eruit en hoeveel zit er in een verpakking *(subheading)*
Total score **level 1**: C = 10 R = 5. Total score **level 2**: C = 7 R = 5								

Legend:
C > R: Current text structure has more correct locations than Revised text structure
R > C: Revised text structure has more correct locations than Current text structure
Level 1 scores: Correct if: location is correct. Else: incorrect.
Level 2 scores: Correct if: Main heading correct and subheading incorrect. Else: incorrect.

Q Nr.: Question number / **Diff.:** Difference

B. Chosen incorrect headings and subheadings

The correct and incorrect headings and subheadings per question (*N = 128)*					
Questions	**Correct main heading or subheading** (English/*Dutch*)	**Number of participants who found the correct heading or subheading**	**Number of participants who did not found the correct heading or subheading**	**The majority of the participants chose the following incorrect main heading or subheading** (English/*Dutch*)	**The number of participants who gave this incorrect heading or subheading**
Current 1	What Pharmazine is and what it is used for/*Waarvoor wordt dit middel gebruikt ?* **(main heading)**	53 (41,4%)	75 (58,6%)	- What Pharmazine contains/*Welke stoffen zitten er in dit middel* **(subheading)** - Possible side effects/*Mogelijke bijwerkingen* **(main heading)**	38 (29,7%) 23 (18%)
Revised 1	What this medicine is/*Wat is dit voor geneesmiddel?* **(subheading)**	10 (7,8%)	118 (92,2%)	- How it works/*Hoe werkt het?* **(subheading)** **-** Ingredients/*Ingrediënten* **(subheading)**	63 (49,2%) 17 (13,3%)
Current 2	What Pharmazine is and what it is used for/*Waarvoor wordt dit middel gebruikt?* **(main heading)**	79 (61,7%)	49 (38,3%)	- Do not take Pharmazine if:/*Wanneer mag u dit middel niet gebruiken (subheading)* - Warning and precautions/*Wanneer moet u extra voorzichtig zijn met dit middel?* **(subheading)**	21 (16,4%) 21 (16,4%)
Revised 2	What it is used for/*Waar dient het voor?* **(subheading)**	54 (42,2%)	74 (57,8%)	- People who should check with their doctor before taking this medicine/*Wie kan dit middel pas gebruiken na toestemming van de arts?* **(subheading)** **-** People who cannot take this medicine/*Wie kan dit middel niet gebruiken* **(subheading)**	23 (18%) 13 (10,2%)
Current 3	What Pharmazine is and what it is used for/*Waarvoor wordt dit middel gebruikt ?* **(main heading)**	46 (35,9%)	82 (64,1%)	- Possible side effects/*Mogelijke bijwerkingen* **(main heading)** - Warning and precautions/*Wanneer moet u extra voorzichtig zijn met dit middel?* **(subheading)**	28 (21,9%) 25 (19,5%)
Revised 3	How it works/*Hoe werkt het?* **(subheading)**	47 (36,7%)	81 (63,3%)	- Possible side effects/Mogelijke bijwerkingen **(subheading)** **-** What it is used for*/Waar dient het voor?* **(subheading)** - People who should check with their doctor before taking this medicine/*Wie kan dit middel pas gebruiken na toestemming van de arts* **(subheading)** **-** Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you./*Mogelijke bijwerkingen; Overleg met uw arts als u last heeft van een van de volgende bijwerkingen.* **(subheading)**	*17 (13,3%)* *14 (10,9%)* *14 (10,9%)* *14 (10,9%)*
Current 4	Do not take Pharmazine if:/*Wanneer mag u dit middel niet gebruiken?* **(subheading)**	90 (70,3%)	38 (29,7%)	- Warnings and precautions/*Wanneer moet u extra voorzichtig zijn met dit middel* **(subheading)**	24 (18,8%)
Revised 4	People who cannot take this medicine/*Wie kan dit middel niet gebruiken* **(subheading)**	72 (56,3%)	56 (43,8%)	- People who should check with their doctor before taking this medicine/*Wie kan dit middel pas gebruiken na toestemming van de arts* **(subheading)**	40 (31,3%)

Questions	**Correct main heading or subheading** (English/*Dutch*)	**Number of participants who found the correct heading or subheading**	**Number of participants who did not found the correct heading or subheading**	**The majority of the participants chose the following incorrect main heading or subheading** (English/*Dutch*)	**The number of participants who gave this incorrect heading or subheading**
Current 5	Warnings and precautions/*Wanneer moet u extra voorzichtig zijn met dit middel* **(subheading)**	68 (53,1%)	60 (46,9%)	- Do not take Pharmazine if:/*Wanneer mag u dit middel niet gebruiken?* **(subheading)** - Other medicines and Pharmazine/*Gebruikt u nog andere geneesmiddelen* **(subheading)**	29 (22,7%) 16 (12,5%)
Revised 5	People who should check with their doctor before taking this medicine/*Wie kan dit middel pas gebruiken na toestemming van de arts* **(subheading)**	71 (55,5%)	57 (44,5%)	- People who cannot take this medicine/*Wie kan dit middel niet gebruiken* **(subheading)** - Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice:/*Mogelijke bijwerkingen; stop met dit middel en neem direct contact op met uw arts als u het volgende merkt:* **(subheading)** - Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you./*Mogelijke bijwerkingen; Overleg met uw arts als u last heeft van een van de volgende bijwerkingen.* **(subheading)**	14 (10,9%) 10 (7,8%) 10 (7,8%)
Current 6	Warnings and precautions/*Wanneer moet u extra voorzichtig zijn met dit middel* **(subheading)**	26 (20,3%)	102 (79,7%)	- Not found - How to take Pharmazine/*Hoe gebruikt u dit middel* **(main heading)** - Possible side effects/*Mogelijke bijwerkingen* **(main heading)**	38 (29,7%) 22 (17,2%) 15 (11,7%)
Revised 6	Tests/*Medische controles* **(subheading)**	75 (58,6%)	53 (41,4%)	- People who should check with their doctor before taking this medicine/*Wie kan dit middel pas gebruiken na toestemming van de arts* **(subheading)** - Not found	17 (13,3%) 10 (7,8%)
Current 7	Children and adolescents/*kinderen en jongeren tot 18 jaar* **(subheading)**	76 (59,4%)	52 (40,6%)	- Use in children and adolescents/ *Gebruik bij kinderen en jongeren tot 18 jaar* **(subheading)** - Contents of the pack and appearance/*Hoeveel zit er in de verpakking en hoe ziet het middel eruit* **(subheading)**	27 (21,1%) 10 (7,8%)
Revised 7	How much to take and people who cannot take this medicine/*Hoeveel neemt u in en Wie kan dit middel niet gebruiken* **(subheading)**	82 (64,1%) (2.02: 21, 16,4%; 3.01: 61, 47,7%)	46 (35,9%)	- People who should check with their doctor before taking this medicine/*Wie kan dit middel pas gebruiken na toestemming van de arts* **(subheading)**	27 (21,1%)
Current 8	Other medicines and Pharmazine/*Gebruikt u nog andere geneesmiddelen* **(subheading)**	108 (84,4%)	20 (15,6%)	- Do not take Pharmazine if:/*Wanneer mag u dit middel niet gebruiken?* **(subheading)**	9 (7,0%)
Revised 8	Taking Pharmazine with other medicines/*Als u Pharmazine gebruikt in combinatie met andere middelen* **(subheading)**	59 (46,1%)	69 (53,9%)	- Tell your doctor if you are taking:/*Overleg met uw arts als u een van de volgende middelen gebruikt:* **(subheading)**	43 (33,6%)
Current 9	Pharmazine with food, drink and alcohol/*Waarop moet u letten met eten, drinken en alcohol* **(subheading)**	114 (89,1%)	14 (10,9%)	- Do not take Pharmazine if:/*Wanneer mag u dit middel niet gebruiken?* **(subheading)**	6 (4,7%)

Questions	**Correct main heading or subheading** (English/*Dutch*)	**Number of participants who found the correct heading or subheading**	**Number of participants who did not found the correct heading or subheading**	**The majority of the participants chose the following incorrect main heading or subheading** (English/*Dutch*)	**The number of participants who gave this incorrect heading or subheading**
Revised 9	How food, drinks and alcohol affect this medicine/*Eten, drinken, alcoholgebruik en de werking van dit middel* **(subheading)**	118 (92,2%)	10 (7,8%)	- How to take/*Hoe neemt u dit middel in* **(subheading)**	3 (2,3%)
Current 10	Do not take Pharmazine if:/*Wanneer mag u dit middel niet gebruiken* **(subheading)**	24 (18,8%)	104 (81,3%)	- Pharmazine with food, drink and alcohol/*Waarop moet u letten met eten, drinken en alcohol* **(subheading)** - Warnings and precautions/*Wanneer moet u extra voorzichtig zijn met dit middel* **(subheading)** - Possible side effects/*Mogelijke bijwerkingen* **(main heading)**	43 (33,6%) 25 (19,5%) 20 (15,6%)
Revised 10	Allergies/*Allergieën* **(subheading)**	46 (35,9%)	82 (64,1%)	- How food, drinks and alcohol affect this medicine/*Eten, drinken, alcoholgebruik en de werking van dit middel* **(subheading)** - People who should check with their doctor before taking this medicine/*Wie kan dit middel pas gebruiken na toestemming van de arts* **(subheading)** - Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you./*Mogelijke bijwerkingen; Overleg met uw arts als u last heeft van een van de volgende bijwerkingen.* **(subheading)**	26 (20,3%) 19 (14,8%) 11 (8,6%)
Current 11	Pregnancy and breast-feeding/*Zwangerschap en borstvoeding* **(subheading)**	103 (80,5%)	25 (19,5%)	- Warnings and precautions/*Wanneer moet u extra voorzichtig zijn met dit middel* **(subheading)**	14 (10,9%)
Revised 11	Pregnancy and breast-feeding/*Zwangerschap en borstvoeding* **(subheading)**	83 (64,8%)	45 (35,2%)	- People who should check with their doctor before taking this medicine/*Wie kan dit middel pas gebruiken na toestemming van de arts* **(subheading)**	38 (29,7%)
Current 12	Driving and using machines/*Rijvaardigheid en het gebruik van machines* **(subheading)**	98 (76,6%)	30 (23,4%)	- Possible side effects/*Mogelijke bijwerkingen* **(main heading)**	14 (10,9%)
Revised 12	Driving and using tools or machines/*Rijvaardigheid en het gebruik van gereedschap of machines* **(subheading)**	112 (87,5%)	16 (12,5%)	- Allergies/*Allergieën* **(subheading)** - Possible side effects/Mogelijke bijwerkingen **(subheading)**	7 (5,5%) 5 (3,9%)
Current 13	How to take Pharmazine/*Hoe gebruikt u dit middel* **(main heading)**	117 (91,4%)	11 (8,6%)	- Warnings and precautions/*Wanneer moet u extra voorzichtig zijn met dit middel* **(subheading)**	3 (2,3%)
Revised 13	How to take/*Hoe neemt u dit middel in* **(subheading)**	111 (86,7%)	17 (13,3%)	- How much to take /*Hoeveel neemt u in* **(subheading)** - Contents of the pack and appearance/*Hoeveel zit er in de verpakking en hoe ziet het middel eruit* **(subheading)**	3 (2,3%) 3 (2,3%)
Current 14	How to take Pharmazine *Hoe gebruikt u dit middel* **(main heading)**	92 (71,9%)	36 (28,1%)	- Warnings and precautions/*Wanneer moet u extra voorzichtig zijn met dit middel* **(subheading)**	17 (13,3%)

Questions	**Correct main heading or subheading** (English/*Dutch*)	**Number of participants who found the correct heading or subheading**	**Number of participants who did not found the correct heading or subheading**	**The majority of the participants chose the following incorrect main heading or subheading** (English/*Dutch*)	**The number of participants who gave this incorrect heading or subheading**
Revised 14	How much to take*/Hoeveel neemt u in* **(subheading)**	102 (79,7%)	26 (20,3%)	- People who should check with their doctor before taking this medicine/*Wie kan dit middel pas gebruiken na toestemming van de arts* **(subheading)**	7 (5,5%)
Current 15	How to take Pharmazine/*Hoe gebruikt u dit middel* **(main heading)**	125 (97,7%)	3 (2,3%)	-	-
Revised 15	When to take*/Wanneer neemt u dit middel in* **(subheading)**	81 (63,3%)	47 (36.7%)	- How much to take */Hoeveel neemt u in* **(subheading)** - How to take/*Hoe neemt u dit middel in* **(subheading)**	34 (26,6%) 13 (10,2%)
Current 16	If you stop taking Pharmazine/ *Als u stopt met het gebruik van dit middel* **(subheading)**	48 (37,5%)	80 (62,5%)	- How to take Pharmazine/*Hoe gebruikt u dit middel* **(main heading)**	55 (43,0%)
Revised 16	How long to take/*Hoe lang gebruikt u het* **(subheading)**	63 (49,2%)	65 (50,8%)	- If you want to stop taking this medicine */Als u wilt stoppen* **(subheading)**	44 (34,4%)
Current 17	If you take more Pharmazine that you should/*Heeft u te veel van dit middel ingenomen* **(subheading)**	107 (83,6%)	21 (16,4%)	- Not found - Warnings and precautions/*Wanneer moet u extra voorzichtig zijn met dit middel* **(subheading)**	5 (3,9%) 5 (3,9%)
Revised 17	If you take too much/*Als u te veel ingenomen heeft* **(subheading)**	106 (82,8%)	22 (17,2%)	- Not found - People who cannot take this medicine/*Wie kan dit middel niet gebruiken* **(subheading)**	6 (4,7%) 4 (3,1%)
Current 18	If you forget to take Pharmazine/*Bent u vergeten dit middel in te nemen* **(subheading)**	116 (90,6%)	12 (9,4%)	- How to take Pharmazine/*Hoe gebruikt u dit middel* **(main heading)**	9 (7,0%)
Revised 18	If you forget to take/*Als u een dosis vergeten bent* **(subheading)**	117 (91,4%)	11 (8,6%)	- When to take*/Wanneer neemt u dit middel in* **(subheading)** - How to take/*Hoe neemt u dit middel in* **(subheading)**	4 (3,1%) 3 (2,3%)
Current 19	If you stop taking Pharmazine/*Als u stopt met het gebruik van dit middel* **(subheading)**	107 (83,6%)	21 (16,4%)	- Possible side effects/*Mogelijke bijwerkingen* **(main heading)**	8 (6,3%)
Revised 19	If you want to stop taking this medicine */Als u wilt stoppen* **(subheading)**	88 (68,8%)	40 (31,3%)	- Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you./*Mogelijke bijwerkingen; Overleg met uw arts als u last heeft van een van de volgende bijwerkingen.* **(subheading)** - Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice:/*Mogelijke bijwerkingen; stop met dit middel en neem direct contact op met uw arts als u het volgende merkt:* **(subheading)**	10 (7,8%) 9 (7,0%)
Current 20	Possible side effects/*Mogelijke bijwerkingen* **(main heading)**	110 (85,9%)	18 (14,1%)	- Warnings and precautions/*Wanneer moet u extra voorzichtig zijn met dit middel* **(subheading)**	11 (8,6%)

Questions	**Correct main heading or subheading** (English/*Dutch*)	**Number of participants who found the correct heading or subheading**	**Number of participants who did not found the correct heading or subheading**	**The majority of the participants chose the following incorrect main heading or subheading** (English/*Dutch*)	**The number of participants who gave this incorrect heading or subheading**
Revised 20	Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice:/*Mogelijke bijwerkingen; stop met dit middel en neem direct contact op met uw arts als u het volgende merkt:* **(subheading)**	69 (53,9%)	59 (46,1%)	- Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you./*Mogelijke bijwerkingen; Overleg met uw arts als u last heeft van een van de volgende bijwerkingen.* **(subheading)** - Possible side effects/*Mogelijke bijwerkingen* **(subheading)**	26 (20,3%) 21 (16,4%)
Current 21	Possible side effects/*Mogelijke bijwerkingen* **(main heading)**	121 (94,5%)	7 (5,5%)	-	-
Revised 21	Possible side effects; Talk to your doctor if you have any of the side effects listed below, and they trouble you./*Mogelijke bijwerkingen; Overleg met uw arts als u last heeft van een van de volgende bijwerkingen.* **(subheading)**	46 (35,9%)	82 (64,1%)	- Possible side effects/*Mogelijke bijwerkingen* **(subheading)** - Possible side effects; Stop taking this medicine and tell your doctor straight away if you notice:/*Mogelijke bijwerkingen; stop met dit middel en neem direct contact op met uw arts als u het volgende merkt:* **(subheading)**	66 (51,6%) 10 (7,8%)
Current 22	How to store Pharmazine/*Hoe bewaart u dit middel* **(main heading)**	128 (100%)	0 (0%)	-	-
Revised 22	Storage/ *Hoe bewaart u dit middel* **(subheading)**	128 (100%)	0 (0%)	-	-
Current 23	How to store Pharmazine/*Hoe bewaart u dit middel* **(main heading)**	94 (73,4%)	34 (26,6%)	- If you stop taking Pharmazine/ *Als u stopt met het gebruik van dit middel* **(subheading)**	22 (17,2%)
Revised 23	Disposal/*Hoe gooit u het weg* **(subheading)**	121 (94,5%)	7 (5,5%)	- If you want to stop taking this medicine /*Als u wilt stoppen* **(subheading)**	6 (4,7%)
Current 24	What Pharmazine contain /*Welke stoffen zitten er in dit middel* **(subheading)**	96 (75,0%)	32 (25%)	- Pharmazine contains/ *Pharmazine bevat de volgende ingrediënten* **(subheading)** - What Pharmazine is and what it is used for/*Waarvoor wordt dit middel gebruikt ?* **(main heading)**	16 (12,5%) 12 (9,4%)
Revised 24	Ingredients/*Ingrediënten* **(subheading)**	99 (77,3%)	29 (22,7%)	- What this medicine is/*Wat is dit voor geneesmiddel?* **(subheading)**	15 (11,7%)
Current 25	What Pharmazine looks like and contents of the pack/*Hoe ziet Pharmazine eruit en hoeveel zit er in een verpakking* **(subheading)**	116 (90,6%)	12 (9,4%)	- What Pharmazine contain /*Welke stoffen zitten er in dit middel* **(subheading)** **-** How to take Pharmazine/*Hoe gebruikt u dit middel* **(main heading)**	4 (3,1%) 3 (2,3%)
Revised 25	Contents of the pack and appearance/*Hoeveel zit er in de verpakking en hoe ziet het middel eruit* **(subheading)**	113 (88,3%)	15 (11,7%)	- What this medicine is/*Wat is dit voor geneesmiddel?* **(subheading)**	5 (3,9%)

Appendix 4 Current and revised patient information leaflets

Current PIL English (real text)

Package Leaflet: Information for the User

Pharmazine

100, 200 and 400 mg Tablets

Read all of this leaflet carefully before you start taking this medicine – because it contains important information for you.
- Keep the 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 their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1 What Pharmazine is and what it is used for

Pharmazine can affect the body in several different ways. It is an anti-convulsant medicine (prevents fits), it can also modify some types of pain and can control mood swings.

Pharmazine is used
- To treat some forms of epilepsy
- To treat a painful condition of the face called trigeminal neuralgia
- To help control serious mood swings when some other medicines don't work.

2 What you need to know before you take Pharmazine

Do not take Pharmazine if:
- you think you may be hypersensitive (allergic) to Pharmazine or similar drugs such as oxcarbazepine (Trileptal), or to any of a related group of drugs known as tricyclic antidepressants (such as amitriptyline or imipramine). If you are allergic to Pharmazine there is a one in four (25%) chance that you could also have an allergic reaction to oxcarbazepine.
- you are allergic to any of the other ingredients of Pharmazine Tablets (listed in Section 6). Signs of a hypersensitivity reaction include swelling of the face or mouth (angioedema), breathing problems, runny nose, skin rash, blistering or peeling.
- you have any heart problems,
- you have ever had problems with your bone marrow,
- you have a blood disorder called porphyria,
- you have taken drugs called monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days.

A small number of people being treated with anti-epileptics such as Pharmazine have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Serious skin side effects can rarely occur during treatment with Pharmazine. This risk can be predicted with a blood sample in people of Chinese and Thai origin. Discuss this with your doctor before taking Pharmazine if you are of such origin.

Warnings and precautions

Talk to your doctor or pharmacist before taking Pharmazine:
- If you are pregnant or planning to become pregnant
- If you are breastfeeding
- If you suffer from the sort of epilepsy where you get mixed seizures which include absences
- If you have any mental illness
- If you allergic to an epilepsy medicine called phenytoin
- If you have liver problems
- If you are elderly
- If you have any eye problems such as glaucoma (increased pressure in the eye)

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist because Pharmazine might not be the right medicine for you.

Your doctor may want you to have a number of blood tests before you start taking Pharmazine and from time to time during your treatment. This is quite usual and nothing to worry about.

Children and adolescents

Do not give this medicine to children between the ages of 0 and 5 years. This is because it does not work.

Other medicines and Pharmazine

Because of the way that Pharmazine works, it can affect, and be affected by, lots of other things that you might be eating or medicines that you are taking. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is very important to make sure that your doctor knows all about what else you are taking, including anything that you have bought from a chemist or health food shop. It may be necessary to change the dose of some medicines, or stop taking something altogether.

Tell the doctor if you are taking, have recently taken or might take any other medicines. This concerns medicines such as:
- Hormone contraceptives, e.g. pills, patches, injections or implants. Pharmazine affects the way the contraceptive works in your body, and you may get breakthrough bleeding or spotting. It may also make the contraceptive less effective and there will be a risk of getting pregnant. Your doctor will be able to advise you about this, and you should think about using other contraceptives.
- Hormone Replacement Therapy (HRT). Pharmazine can make HRT less effective.
- Any medicines for depression or anxiety.
- Corticosteroids ('steroids'). You might be taking these for inflammatory conditions such as asthma, inflammatory bowel disease, muscle and joint pains.
- Anticoagulants to stop your blood clotting.
- Antibiotics to treat infections including skin infections and TB.
- Antifungals to treat fungal infections.
- Painkillers containing paracetamol, dextropropoxyphene, tramadol, methadone or buprenorphine.
- Other medicines to treat epilepsy.
- Medicines for high blood pressure or heart problems.
- Antihistamines (medicines to treat allergy such as hayfever, itch, etc).
- Diuretics (water tablets).
- Cimetidine or omeprazole (medicines to treat gastric ulcers).
- Isotretinoin (a medicine for the treatment of acne).
- Metoclopramide (an anti-sickness medication).
- Acetazolamide (a medicine to treat glaucoma - increased pressure in the eye).
- Danazol or gestrinone (treatments for endometriosis).
- Theophylline or aminophylline (used in the treatment of asthma).
- Ciclosporin (an immunosuppressant, used after transplant operations, but also sometimes in the treatment of arthritis or psoriasis).
- Drugs to treat schizophrenia.
- Cancer drugs.
- The anti-malarial drug, mefloquine.
- Drugs to treat HIV.
- Levothyroxine (used to treat hypothyroidism).
- Muscle relaxant drugs.
- Bupropion (used to help stop smoking).
- A herbal remedy called St John's Wort or Hypericum.
- Drugs or supplements containing Vitamin B (nicotinamide).

Pharmazine with food, drink and alcohol
- Drinking alcohol may affect you more than usual. Discuss whether you should stop drinking with your doctor.
- Eating grapefruit, or drinking grapefruit juice, may increase your chance of experiencing side effects.

Pregnancy and breast-feeding

You must discuss your epilepsy treatment with your doctor well before you become pregnant. If you do get pregnant while you're taking Pharmazine Tablets you must tell the doctor straightaway. It is important that your epilepsy remains well controlled, but, as with other anti-epilepsy treatments, there is a risk of harm to the foetus. Make sure you are very clear about the risks and the benefits of taking Pharmazine Tablets. Mothers taking Pharmazine Tablets can breastfeed their babies, but you must tell the doctor as soon as possible if you think that the baby is suffering side effects such as excessive sleepiness or skin reactions because you are taking Pharmazine Tablets.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Pharmazine Tablets can make you feel dizzy or drowsy, especially at the start of treatment or when the dose is changed. If you are affected in this way, or if your eyesight is affected, you should not drive or operate machinery.

Pharmazine contains

Pharmazine contains sucrose. If you have diabetes, you need to take this into account. The tablets further contain the inactive ingredient carboxymethylcellulose.

3 How to take Pharmazine

Always take this medicine exactly how your doctor has told you. Check with your doctor or pharmacist if you are not sure. The doctor will tell you how many Pharmazine Tablets to take and when to take them. The dose will be on the pharmacist's label. Check the label carefully. It is important to take the tablets at the right times. If you are not sure, ask your doctor or pharmacist.

Your doctor will usually start Pharmazine at a fairly low dose which can then be increased to suit you individually. The dose needed varies between patients. You can take Pharmazine Tablets during, after or between meals. Swallow the tablets with a drink. You are usually told to take a dose two or three times a day. If necessary you may break the tablets in half along the scored line. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

To treat epilepsy the usual doses are:
Adults: 800-1,200 mg a day, although higher doses may be necessary. If you are elderly you might require a lower dose.
Children: Aged 5-15 years: 400-600 mg a day
Pharmazine Tablets are not recommended for children under 5.

To treat trigeminal neuralgia the usual dose is: 600-800 mg a day.

To treat mood swings the usual dose is: 400-600 mg a day

Use in children and adolescents

Other forms of this medicine may be more suitable for children; ask your doctor or pharmacist.

If you take more Pharmazine than you should

If you accidentally take too many Pharmazine Tablets, tell your doctor or your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.

If you forget to take Pharmazine

If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, though, just take the next dose and forget about the one you missed.

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

If you stop taking Pharmazine

Keep taking your tablets for as long as you have been told, unless you have any problems. Check with your doctor first if you want to stop taking Pharmazine.

4 Possible side effects

Pharmazine Tablets do not usually cause problems. But like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Pharmazine Tablets and tell your doctor straight away if you notice:

- Serious skin reactions such as rash, red skin, blistering of the lips, eyes or mouth, or skin peeling accompanied by fever. These reactions may be more frequent in patients of Chinese or Thai origin
- Mouth ulcers or unexplained bruising or bleeding
- Sore throat or high temperature, or both
- Yellowing of your skin or the whites of your eyes
- Swollen ankles, feet or lower legs
- Any signs of nervous illness or confusion
- Pain in your joints and muscles, a rash across the bridge of the nose and cheeks and problems with breathing (these may be the signs of a rare reaction known as lupus erythematosus)
- Fever, skin rash, joint pain, and abnormalities in blood and liver function tests (these may be the signs of a multi-organ sensitivity disorder)
- Bronchospasm with wheezing and coughing, difficulty in breathing, feeling faint, rash, itching or facial swelling (these may be the signs of a severe allergic reaction)
- Pain in the area near the stomach.

The side effects listed below have also been reported.

More than 1 in 10 people have experienced:
Leucopenia (a reduced number of the cells which fight infection making it easier to catch infections); dizziness and tiredness; feeling unsteady or finding it difficult to control movements; feeling or being sick; changes in liver enzyme levels (usually without any symptoms); skin reactions which may be severe.

Up to 1 in 10 people have experienced:
Changes in the blood including an increased tendency to bruise or bleed; fluid retention and swelling; weight increase; low sodium in the blood which might result in confusion; headache; double or blurred vision; dry mouth.

Up to 1 in 100 people have reported:
Abnormal involuntary movements including tremor or tics; abnormal eye movements; diarrhoea; constipation.

Up to 1 in 1,000 people have reported:
Disease of the lymph glands; folic acid deficiency; a generalised allergic reaction including rash, joint pain, fever, problems with the kidneys and other organs; hallucinations; depression; loss of appetite; restlessness; aggression; agitation; confusion; speech disorders; numbness or tingling in the hands and feet; muscle weakness; high blood pressure (which may make you feel dizzy, with a flushed face, headache, fatigue and nervousness); low blood pressure (the symptoms of which are feeling faint, light headed, dizzy, confused, having blurred vision); changes to heart beat; stomach pain; liver problems including jaundice; symptoms of lupus.

Up to 1 in 10,000 people have reported:
Changes to the composition of the blood including anaemia; porphyria; meningitis; swelling of the breasts and discharge of milk which may occur in both male and females; abnormal thyroid function tests; osteomalacia (which may be noticed as pain on walking and bowing of the long bones in the legs); osteoporosis; increased blood fat levels; taste disturbances; conjunctivitis; glaucoma; cataracts; hearing disorders; heart and circulatory problems including deep vein thrombosis (DVT), the symptoms of which could include tenderness, pain, swelling, warmth, skin discoloration and prominent superficial veins; lung or breathing problems; severe skin reactions including Stevens- Johnson syndrome (These reactions may be more frequent in patients of Chinese or Thai origin); sore mouth or tongue; liver failure; increased sensitivity of the skin to sunlight; alterations in skin pigmentation; acne; excessive sweating; hair loss; increased hair growth on the body and face; muscle pain or spasm; sexual difficulties which may include reduced male fertility, loss of libido or impotence; kidney failure; blood spots in the urine; increased or decreased desire to pass urine or difficulty in passing urine.

Do not be alarmed by this list. Most people take Pharmazine Tablets without any problems.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

Additional side effects in children and adolescents

The following side effects may be more likely to happen in children:
sore throat or high temperature.

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

5 How to store Pharmazine

Pharmazine 400 mg Tablets must be stored in a dry place. There are no special storage requirements for the other strengths.

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

Do not take this medicine after the expiry date which is stated on the outside of the pack. The expiry date refers to the last day of that month.

If your doctor tells you to stop taking the tablets, please take any unused tablets back to your pharmacist to be destroyed. Do not throw away any medicines via waste water. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Pharmazine contains

The active substance is carbamazepine.
The tablets come in 3 strengths containing either 100, 200 or 400mg of carbamazepine.
The other ingredients are silicon dioxide, microcrystalline cellulose, magnesium stearate and sodium carboxymethylcellulose.

What Pharmazine looks like and contents of the pack

Pharmazine 100 Tablets are round, white tablets with one side impressed "zepine", the other "100" and a score line.

Pharmazine 200 Tablets are round, white tablets with one side impressed "zepine", the other "200" and a score line.

The 100 mg and 200 mg tablets come in blister packs of 84.

Pharmazine 400 mg Tablets are rod-shaped, white tablets with zepine on one side and 400 on the other. Both sides have a score line.

The 400 mg tablets come in blister packs of 56.

Marketing Authorization Holder and Manufacturer

The Product licence holder is United Pharmaceuticals UK Limited, England.

The tablets are released onto the market by United Pharmaceuticals UK Limited, England.

This leaflet was revised in September 2010.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at United Pharmaceuticals UK Ltd, telephone number 01234 56789.

Current PIL English (bogus text)

Package Leaflet: Information for the user

Pharmazine

100, 200 owd 400 mj Rodlors

Rood oll ul rhas loollor corolully doluro yuu srorr robawj rhas modacawo – docouso ar cuwroaws amhurrowr awlurmorauw lur yuu.

- Booh rho loollor. Yuu moy wood ru rood ar ojoaw.
- Al yuu hovo owy lurrhor quosrauws, osb yuur ducrur ur hhormocasr.
- Rhas modacawo hos doow hroscradod lur yuu. Du wur hoss ar uw ru urhors. Ar moy horm rhom, ovow rhoar sajws ul allwoss oro rho somo os yuurs.
- Al yuu jor owy sado ollocrs, rolb ru yuur ducrur ur hhormocasr. Rhas awcludos owy Hussadlo sado ollocrs wur lasrod aw rhas.

In this leaflet:

1 What Pharmazine is and what it is used for

Pharmazine cow ollocr rho dudy aw sovorol dallorowr woys. Ar as ow owra-cuwvulsowr modacawo (hrovowrs lars), ar cow olsu mudaly sumo ryhos ul hoaw owd cow cuwrrul muud dasurdors.

Pharmazine as usod

- Ru rroor sumo lurms ul ohalohsy
- Ru rroor o hoawlul cuwdarauw ul rho loco collod rrajomawol wouroljao
- Ru holh cuwrrul sorauus muud dasurdors whow sumo urhor modacawos duw'r wurb.

2 What you need to know before you take Pharmazine

Do not take Pharmazine if:

- yuu rhawb yuu moy do hyhorsowsaravo (ollorjac) ru Pharmazine ur samalor drujs such os uxcordozohawo (Rralohrol), ur ru owy ul o rolorod jruuh ul drujs bwuww os rracyclac owradohrossowrs (such os omarrahrylawo ur amahromawo). Al yuu oro ollorjac ru Pharmazine rhoro as o uwo aw luur (25%) chowco rhor yuu cuuld olsu hovo ow ollorjac roocrauw ru uxcordozohawo.
- yuu oro ollorjac ru owy ul rho urhor awjrodaowrs ul Pharmazine Rodlors (lasrod aw Socrauw 6). Sajws ul o hyhorsowsaravary roocrauw awcludo swolljawj ul rho loco ur muurh (owjauodomo), droorhawj hrudloms, ruwwy wuso, sbaw rosh, dlasrorawj ur hoolawj.
- yuu hovo owy hoorr hrudloms,
- yuu hovo ovor hod hrudloms warh yuur duwo morruw,
- yuu hovo o dluud dasurdor collod hurhhyrao,
- yuu hovo robow drujs collod muwuomawo uxadoso awhadarurs (MOUAs), usod ru rroor dohrossauw, warhaw rho losr 14 doys.

O smoll wumdor ul houhlo doawj rroorod warh owra-ohalohracs such os Pharmazine hovo hod rhuujhrs ul hormawj ur ballawj rhomsolvos. Al or owy ramo yuu hovo rhoso rhuujhrs, ammodaoroly cuwrocr yuur ducrur.

Sorauus sbaw sado ollocrs cow roroly uccur durawj rroormowr warh Pharmazine. Rhas rasb cow do hrodacrod warh o dluud somhlo aw houhlo ul Chawoso owd Rhoa urajaw. Dascuss rhas warh yuur ducrur doluro robawj Pharmazine al yuu oro ul such urajaw.

Warnings and precautions

Rolb ru yuur ducrur ur hhormocasr doluro robawj Pharmazine:

- al yuu oro hrojwowr ur hlowwawj ru documo hrojwowr
- al yuu oro droosrloodawj
- al yuu sullor lrum rho surr ul ohalohsy whoro yuu jor maxod soazuros whach awcludo odsowcos
- al yuu hovo owy mowrol allwoss
- al yuu ollorjac ru ow ohalohsy modacawo collod hhowyruaw
- al yuu hovo lavor hrudloms
- al yuu oro oldorly
- al yuu hovo owy oyo hrudloms such os jloucumo (awcroosod hrossuro aw rho oyo)

Al owy ul rho oduvo ohhly ru yuu (ur yuu oro wur suro), rolb ru yuur ducrur ur hhormocasr docouso Pharmazine majhr wur do rho rajhr modacawo lur yuu.

Yuur ducrur moy wowr yuu ru hovo o wumdor ul dluud rosrs doluro yuu srorr robawj Pharmazine owd lrum ramo ru ramo durawj yuur rroormowr. Rhas as quaro usuol owd wurhawj ru wurry oduur.

Children and adolescents

Du wur javo rhas modacawo ru chaldrow dorwoow rho ojos ul 0 owd 5 yoors. Rhas as docouso ar duos wur wurb.

Other medicines and Pharmazine

Docouso ul rho woy rhor Pharmazine wurbs, ar cow ollocr, owd do ollocrod dy, lurs ul urhor rhawjs rhor yuu majhr do oorawj ur modacawos rhor yuu oro robawj. Roll yuur ducrur ur hhormocasr al yuu oro robawj, hovo rocowrly robow ur majhr robo owy urhor modacawos. Ar as vory amhurrowr ru mobo suro rhor yuur ducrur bwuws oll oduur whor olso yuu oro robawj, awcludawj owyrhawj rhor yuu hovo duujhr lrum o chomasr ur hoolrh luud shuh. Ar moy do wocossory ru chowjo rho duso ul sumo modacawos, ur sruh robawj sumorhawj olrujorhor.

Roll rho ducrur al yuu oro robawj, hovo rocowrly robow ur majhr robo owy urhor modacawos. Rhas cuwcorws modacawos such os:

- Hurmuwo cuwrrocohravos, o.j. halls, horchos, awjocrauws ur amhlowrs. Pharmazine ollocrs rho woy rho cuwrrocohravo wurbs aw yuur dudy, owd yuu moy jor droobrhruujh dloodawj ur shurrawj. Ar moy olsu mobo rho cuwrrocohravo loss ollocravo owd rhoro wall do o rasb ul jorrawj hrojwowr. Yuur ducrur wall do odlo ru odvaso yuu oduur rhas, owd yuu shuuld rhawb oduur usawj urhor cuwrrocohravos.
- Hurmuwo Rohlocomowr Rhorohy (HRR). Pharmazine cow mobo HRR loss ollocravo.
- Owy modacawos lur dohrossauw ur owxaory.
- Curracusroruads ('sroruads'). Yuu majhr do robawj rhoso lur awllommorury cuwdarauws such os osrhmo, awllommorury duwol dasooso, musclo owd juawr hoaws.
- Owracuojulowrs ru sruh yuur dluud clurrawj.
- Owradauracs ru rroor awlocrauws awcludawj sbaw awlocrauws owd RD.
- Owraluwjols ru rroor luwjol awlocrauws.
- Hoawballors cuwroawawj horocoromul, doxrruhruhuxyhhowo, rromodul, morhoduwo ur duhrowurhhawo.
- Urhor modacawos ru rroor ohalohsy.
- Modacawos lur hajh dluud hrossuro ur hoorr hrudloms.
- Owrahasromawos (modacawos ru rroor ollorjy such os hoylovor, arch, orc).
- Dauroracs (woror rodlors).
- Camoradawo ur umohrozulo (modacawos ru rroor josrrac ulcors).
- Asurrorawuaw (o modacawo lur rho rroormowr ul ocwo).
- Moruclurromado (ow owra-sacbwoss modacorauw).
- Ocorozulomado (o modacawo ru rroor jloucumo - awcroosod hrossuro aw rho oyo).
- Dowozul ur josrrawuwo (rroormowrs lur owdumorrausas).
- Rhouhhyllawo ur omawuhhyllawo (usod aw rho rroormowr ul osrhmo).
- Caclushuraw (ow ammuwusuhhrossowr, usod olror rrowshlowr uhororauws, dur olsu sumoramos aw rho rroormowr ul orrhraras ur hsuraosas).
- Drujs ru rroor schazuhhrowao.
- Cowcor drujs.
- Rho owra-moloraol druj, molluquawo.
- Drujs ru rroor HAV.
- Lovurhyruxawo (usod ru rroor hyhurhyruadasm).
- Musclo roloxowr drujs.
- Duhruhauw (usod ru holh sruh smubawj).
- O hordol romody collod Sr Juhw's Wurr ur Hyhoracum.
- Drujs ur suhhlomowrs cuwroawawj Varomaw D ('wacurawomado).

Pharmazine with food, drink and alcohol

- Drawbawj olcuhul moy ollocr yuu muro rhow usuol. Dascuss whorhor yuu shuuld sruh drawbawj warh yuur ducrur.
- Oorawj jroholruar, ur drawbawj jroholruar juaco, moy awcrooso yuur chowco ul oxhoraowcawj sado ollocrs.

Pregnancy and breast-feeding

Yuu musr dascuss yuur ohalohsy rroormowr warh yuur ducrur woll doluro yuu documo hrojwowr. Al yuu du jor hrojwowr whalo yuu'ro robawj Pharmazine Rodlors yuu musr roll rho ducrur srroajhrowoy. Ar as amhurrowr rhor yuur ohalohsy romoaws woll cuwrrullod, dur, os warh urhor owra-ohalohsy rroormowrs, rhoro as o rasb ul horm ru rho luorus. Mobo suro yuu oro vory cloor oduur rho rasbs owd rho dowolars ul robawj Pharmazine Rodlors. Murhors robawj Pharmazine Rodlors cow droosrlood rhoar dodaos, dur yuu musr roll rho ducrur os suuw os hussadlo al yuu rhawb rhor rho dody as sullorawj sado ollocrs such os oxcosssavo sloohawoss ur sbaw roocrauws docouso yuu oro robawj Pharmazine Rodlors.

Al yuu oro hrojwowr ur droosr-loodawj, rhawb yuu moy do hrojwowr ur oro hlowwawj ru hovo o dody, osb yuur ducrur ur hhormocasr lur odvaco doluro robawj rhas modacawo.

Driving and using machines

Pharmazine Rodlors cow mobo yuu lool dazzy ur druwsy, oshocaolly or rho srorr ul rroormowr ur whow rho duso as chowjod. Al yuu oro ollocrod aw rhas woy, ur al yuur oyosajhr as ollocrod, yuu shuuld wur dravo ur uhororo.

Pharmazine contains

Rho rodlors cuwroaw rho awocravo awjrodaowrs salacuw dauxado, oshocaolly or rho srorr ul rroormilawo colluluso, mojwosaum sroororo owd sudaum corduxymorhylcolluluso.

3 How to take Pharmazine

Olwoys robo rhas modacawo oxocrly huw yuur ducrur hos ruld yuu. Chocb warh yuur ducrur ur hhormocasr al yuu oro wur suro. Rho ducrur wall roll yuu huw mowy Pharmazine Rodlors ru robo owd whow ru robo rhom. Rho duso wall do uw rho hhormocasr's lodol. Chocb rho lodol corolully. Ar as amhurrowr ru robo rho rodlors or rho rajhr ramos. Al yuu oro wur suro, osb yuur ducrur ur hhormocasr.

Yuur ducrur wall usuolly srorr Pharmazine or o loarly luw duso whach cow rhow do awcroosod ru suar yuu awdavaduolly. Rho duso woodod voraos dorwoow horaowrs. Yuu cow robo Pharmazine Rodlors durawj, olror ur dorwoow mools. Swolluw rho rodlors warh o drawb. Yuu oro usuolly ruld ru robo o duso rwu ur rhroo ramos o doy. Al wocossory yuu moy droob rho rodlors aw holl oluwj rho scurod lawo. Rho scuro lawo as uwly rhoro ru holh yuu droob rho rodlor al yuu hovo dallaculry swolluwawj ar whulo.

Ru rroor ohalohsy rho usuol dusos oro: Odulrs: 800-1,200 mj o doy, olrhuujh hajhor dusos moy do wocossory. Al yuu oro oldorly yuu majhr roquaro o luwor duso.
Chaldrow: Ojod 5-15 yoors: 400-600 mj o doy Pharmazine Rodlors oro wur rocummowdod lur chaldrow uwdor 5.

Ru rroor rrajomawol wouroljao rho usuol duso as: 600-800 mj o doy.

Ru rroor muud swawjs rho usuol duso as: 400-600 mj o doy

Use in children and adolescents

Urhor lurms ul rhas modacawo moy do muro suarodlo lur chaldrow; osb yuur ducrur ur hhormocasr.

If you take more Pharmazine than you should

Al yuu occadowrolly robo ruu mowy Pharmazine Rodlors, roll yuur ducrur ur yuur woorosr husharol cosuolry dohorrmowr. Robo yuur modacawo hocb warh yuu su rhor houhlo cow soo whor yuu hovo robow.

If you forget to take Pharmazine

Al yuu lurjor ru robo o duso, robo uwo os suuw os yuu romomdor. Al ar as woorly ramo lur yuur woxr duso, rhuujh, jusr robo rho woxr duso owd lurjor oduur rho uwo yuu massod.

Al yuu hovo owy lurrhor quosrauws uw rho uso ul rhas modacawo, osb yuur ducrur ur hhormocasr.

If you stop taking Pharmazine

Booh robawj yuur rodlors lur os luwj os yuu hovo doow ruld, uwloss yuu hovo owy hrudloms. Chocb warh yuur ducrur larsr al yuu wowr ru sruh robawj Pharmazine.

4 Possible side effects

Pharmazine Rodlors du wur usuolly couso hrudloms. Dur labo oil modacawos, rhas modacawo cow couso sado ollocrs, olrhuujh wur ovorydudy jors rhom.

Sruh robawj Pharmazine Rodlors owd roll yuur ducrur srroajhr owoy al yuu wuraco:

- Sorauus sbaw roocrauws such os rosh, rod sbaw, dlasrorawj ul rho lahs, oyos ur miurh, ur sbaw hoolawj occumhowaod dy lovor. Rhoso roocrauws moy do muro lroquowr aw horaowrs ul Chawoso ur Rhoa urajaw
- Muurh ulcors ur uwoxhloawod druasawj ur dloodawj
- Suro rhruor ur hajh romhororuro, ur durh
- Yolluwawj ul yuur sbaw ur rho wharos ul yuur oyos
- Swullow owblos, loor ur luwor lojs
- Owy sajws ul worvuus allwoss ur cuwlusauw
- Hoaw aw yuur juawrs owd musclos, o rosh ocruss rho dradjo ul rho wuso owd choobs owd hrudloms warh droorhawj (rhoso moy do rho sajws ul o roro roocrauw bwuww os luhus oryrhomorusus)
- Lovor, sbaw rosh, juawr hoaw, owd odwurmolaraos aw dluud owd lavor luwcrauw rosrs (rhoso moy do rho sajws ul o mulra-urjow sowsaravary dasurdor)
- Druwchushosm warh whoozawj owd cuujhawj, dallaculry aw droorhawj, loolawj loawr, rosh, archawj ur locaol swollawj (rhoso moy do rho sajws ul o sovoro ollorjac roocrauw)
- Hoaw aw rho oroo woor rho srumoch.

Rho sado ollocrs lasrod doluw hovo olsu doow rohurrod.

Muro rhow 1 aw 10 houhlo hovo oxhoraowcod: Loucuhowao (o roducod wumdor ul rho colls whach lajhr awlocrauw mobawj ar oosaor ru corch awlocrauws); dazzawoss owd rarodwoss; loolawj uwsroody ur lawdawj ar dallaculr ru cuwrrul muvomowrs; loolawj ur doawj sacb; chowjos aw lavor owzymo lovols (usuolly warhuur owy symhrums); sbaw roocrauws whach moy do sovoro.

Uh ru 1 aw 10 houhlo hovo oxhoraowcod: Chowjos aw rho dluud awcludawj ow awcroosod rowdowcy ru druaso ur dlood; lluad rorowrauw owd swollawj; woajhr awcrooso; luw sudaum aw rho dluud whach majhr rosulr aw cuwlusauw; hoodocho; duudlo: dry muurh.

Uh ru 1 aw 100 houhlo hovo rohurrod: Odwurmol awvuluwrory muvomowrs awcludawj rromur ur racs; odwurmol oyo muvomowrs; daorrhuoo; cuwsrahorauw.

Uh ru 1 aw 1,000 houhlo hovo rohurrod: Dasooso ul rho lymhh jlowds; lulac ocad dolacaowcy; o joworolasod ollorjac roocrauw awcludawj rosh, juawr hoaw, lovor, hrudloms warh rho badwoys owd urhor urjows; hollucaworauws; dohrossauw; luss ul ohhoraro; rosrlosswoss; ojjrossauw; ojaroraww; cuwlusauw; shooch dasurdors; wumdwoss ur rawjlawj aw rho howds owd loor; musclo woobwoss; hajh dluud hrossuro (whach moy mobo yuu lool dazzy, warh o llushod loco, hoodocho, lorajuo owd worvuuswoss); luw dluud hrossuro (rho symhrums ul whach oro loolawj loawr, lajhr hoodod, dazzy, cuwlusod, hovawj dlurrod vasauw); chowjos ru hoorr door; srumoch hoaw; lavor hrudloms awcludawj jouwdaco; symhrums ul luhus.

Uh ru 1 aw 10,000 houhlo hovo rohurrod: Chowjos ru rho cumhusarauw ul rho dluud awcludawj owoomao; hurhhyrao; mowawjaras; swollawj ul rho droosrs owd daschorjo ul malb whach moy uccur aw durh molo owd lomolos; odwurmol rhyruad luwcrauw rosrs; usroumolocao (whach moy do wuracod os hoaw uw wolbawj owd duwawj ul rho luwj duwos aw rho lojs); usrouhurusas; awcroosod dluud lor lovols; rosro dasrurdowcos; cuwjuwcravaras; jloucumo; cororocrs; hoorawj dasurdors; hoorr owd carculorury hrudloms awcludawj dooh voaw rhrumdusas (DVR), rho symhrums ul whach cuuld awcludo rowdorwoss, hoaw, swollawj, wormrh, sbaw dasculuroraww owd hrumawowr suhorlacaol voaws; luwj ur droorhawj hrudloms; sovoro sbaw roocrauws awcludawj Srovows- Juhwsuw sywdrumo (Rhoso roocrauws moy do muro lroquowr aw horaowrs ul Chawoso ur Rhoa urajaw); suro muurh ur ruwjuo; lavor loaluro; awcroosod sowsaravary ul rho sbaw ru suwlajhr; olrororauws aw sbaw hajmowrorauw; ocwo; oxcossavo swoorawj; hoar luss; awcroosod hoar jruwrh uw rho dudy owd loco; luss ul ladadu ur amhurowco; badwoy loaluro; dluud shurs aw rho urawo; awcroosod ur docroosod dosaro ru hoss urawo ur dallaculry aw hossawj urawo.

Du wur do olormod dy rhas lasr. Musr houhlo robo Pharmazine Rodlors warhuur owy.

Al owy ul rho symhrums documo rruudlosumo, ur al yuu wuraco owyrhawj olso wur mowrauwod horo, hlooso ju owd soo yuur ducrur. Ho/sho moy wowr ru javo yuu o dallorowr modacawo.

Additional side effects in children and adolescents

Rho lullusawj sado ollocrs moy do muro laboly ru hohhow aw chaldrow:

suro rhruor ur hajh romhororuro.

Al yuu hovo owy lurrhor quosrauws uw rho uso ul rhas modacawo, osb yuur ducrur ur hhormocasr.

5 How to store Pharmazine

Pharmazine 400 mj Rodlors musr do srurod aw o dry hloco. Rhoro oro wu shocaol srurojo roquaromowrs lur rho urhor srrowjrhs.

Booh rhas modacawo uur ul rho sajhr owd rooch ul chaldrow.

Du wur robo rhas modacawo olror rho oxhary doro whach as srorod uw rho uursado ul rho hocb. Rho oxhary doro rolors ru rho losr doy ul rhor muwrh.

Al yuur ducrur rolls yuu ru sruh robawj rho rodlors, hlooso robo owy uwusod rodlors docb ru yuur hhormocasr ru do dosrruyod. Du wur rhruw owoy owy modacawos vao wosro woror. Osb yuur hhormocasr huw ru rhruw owoy modacawos yuu wu luwjor uso. Rhoso moosuros wall holh hrurocr rho owvaruwmowr.

6 Contents of the pack and other information

What Pharmazine contains

Rho ocravo sudsrowco as cordomozohawo. Rho rodlors cumo aw 3 srrowjrhs cuwroawawj oarhor 100, 200 ur 400mj ul cordomozohawo. Rho urhor awjrodaowrs oro salacuw dauxado, macrucrysrollawo colluluso, mojwosaum sroororo owd sudaum corduxymorhylcolluluso.

What Pharmazine looks like and contents of the pack

Pharmazine 100 Rodlors oro ruuwd, wharo rodlors warh uwo sado amhrossod "zohawo", rho urhor "100" owd o scuro lawo.

Pharmazine 200 Rodlors oro ruuwd, wharo rodlors warh uwo sado amhrossod "zohawo", rho urhor "200" owd o scuro lawo.

Rho 100 mj owd 200 mj rodlors cumo aw dlasror hocbs ul 84.

Pharmazine 400 mj Rodlors oro rud-shohod, wharo rodlors warh zohawo uw uwo sado owd 400 uw rho urhor. Durh sados hovo o scuro lawo.

Rho 400 mj rodlors cumo aw dlasror hocbs ul 56.

Marketing Authorization Holder and Manufacturer

Rho Hruducr lacowco huldor as Uwarod Hhormocouracols UB Lamarod, Owjlowd.

Rho rodlors oro roloosod uwru rho morbor dy Uwarod Hhormocouracols UB Lamarod, Owjlowd.

Rhas loollor wos rovasod aw Sohromdor 2010.

Al yuu wuuld labo owy muro awlurmorauw, ur wuuld labo rho loollor aw o dallorowr lurmor, hlooso cuwrocr Modacol Awlurmorauw or Uwarod Hhormocouracols UB Lrd, rolohhuwo wumdor 01234 56789.

Current PIL Dutch (real text)

Bijsluiter: Informatie voor gebruikers

Pharmazine

100, 200 en 400 mg tabletten

Lees goed de hele bijsluiter voordat u dit geneesmiddel gaat gebruiken, want er staat belangrijke informatie in voor u.
- Bewaar deze bijsluiter. Misschien heeft u hem later weer nodig.
- Heeft u nog vragen? Neem dan contact op met uw arts of apotheker.
- Geef dit geneesmiddel niet door aan anderen, want is alleen aan u voorgeschreven. Het kan schadelijk zijn voor anderen, ook al hebben zij dezelfde klachten als u.
- Krijgt u veel last van een van de bijwerkingen die in rubriek 4 staan? Of krijgt u een bijwerking die niet in deze bijsluiter staat? Neem dan contact op met uw arts of apotheker.

Inhoud van deze bijsluiter:

1 Waarvoor wordt dit middel gebruikt?

Pharmazine kan op verschillende manieren invloed hebben op uw lichaam. Het is een krampwerend middel en voorkomt epileptische aanvallen. Het kan ook invloed hebben op pijnbeleving en op uw stemming.

Pharmazine wordt gebruikt bij de behandeling van:
- sommige vormen van epilepsie
- pijn in het gezicht (trigeminal neuralgia)
- ernstige stemmingswisselingen, als andere middelen niet werken.

2 Wanneer mag u dit middel niet gebruiken of moet u er extra voorzichtig mee zijn?

Wanneer mag u dit middel niet gebruiken?
- als u allergisch (overgevoelig) bent voor een van de stoffen die in dit geneesmiddel zitten of soortgelijke stoffen zoals oxcarbazepine (Trileptal), of voor middelen uit de geneesmiddelengroep van de tricyclische antidepressiva (zoals amitriptyline of imipramine). Als u allergisch bent voor Pharmazine is er een kans van 1 op 4 (25%) dat u ook een allergische reactie heeft op oxcarbazepine.
- als u allergisch (overgevoelig) bent voor een van de andere ingrediënten van Pharmazine (zie paragraaf 6). Allergische reacties zijn te merken aan een gezwollen gezicht of mond (angioedema), ademhalingsproblemen, een loopneus, jeukende huid, blaren of schilfering.
- bij problemen met uw hart
- als u ziekte aan het beenmerg heeft gehad
- als u de bloedziekte porfyrie heeft gehad
- wanneer u de laatste 14 dagen middelen heeft gebruikt uit de groep van de monoamine oxidase inhibitors (MAOIs), bedoeld om depressies te behandelen.

Een klein aantal mensen, dat behandeld werd met Pharmazine, heeft ook gedachten gehad over zelfbeschadiging of zelfmoord. Als u op enig moment dergelijke gedachten heeft, neem dan direct contact op met uw arts.

Ernstige huidaandoeningen kunnen in een enkel geval als bijwerking optreden bij de behandeling met Pharmazine. Het risico daarop kan worden voorspeld met een bloedtest bij patiënten van Chinese en Thaise afkomst. Bespreek dit met uw arts, als u van deze afkomst bent, alvorens Pharmazine te gebruiken.

Wanneer moet u extra voorzichtig zijn met dit middel?
Overleg met uw arts of apotheker voor u Pharmazine gebruikt:
- als u zwanger bent of zwanger wilt worden
- als u borstvoeding geeft
- als u lijdt aan epilepsie waarbij u last heeft van aanvallen en absenties
- als u een psychische aandoening heeft
- als u allergisch bent voor het epilepsiemiddel phenytoïne
- als u leverproblemen heeft
- als u bejaard bent
- indien u oogproblemen heeft zoals een verhoogde oogboldruk.

Raadpleeg uw arts als één van de bovenstaande waarschuwingen voor u van toepassing is, of u daarover twijfelt. In dat geval is het mogelijk dat Pharmazine voor u niet het goede middel is.

Uw dokter kan u vragen om een aantal bloedcontroles te ondergaan voordat u begint met Pharmazine, en regelmatig tijdens het gebruik. Dat is heel gewoon; maakt u zich daarover geen zorgen.

Kinderen en jongeren tot 18 jaar
Geeft dit middel niet aan kinderen tussen de 0 en 5 jaar. Het middel werkt bij hen namelijk niet.

Gebruikt u nog andere geneesmiddelen?
Vanwege de manier waarop Pharmazine werkt kan er een wisselwerking optreden met andere geneesmiddelen en met andere voedingsmiddelen. Gebruikt u naast Pharmazine nog andere geneesmiddelen of heeft u dat kort geleden gedaan? Vertel dat dan uw arts of apotheker. Het is erg belangrijk dat uw dokter alles weet over de andere middelen die u gebruikt, inclusief de middelen die u gekocht heeft bij de drogist of de natuurvoedingswinkel. Misschien moet de dosering dan aangepast worden of moet u stoppen met sommige middelen.

Neem contact op met uw arts of apotheker als u de volgende geneesmiddelen gebruikt of onlangs heeft gebruikt:
- Hormonale middelen om zwangerschap te voorkomen (voorbehoedmiddelen). Pharmazine heeft invloed op de werking van het voorbehoedmiddel in uw lichaam, en u zou last kunnen krijgen van doorbraak- bloedingen of 'spotting'. Pharmazine kan het voorbehoedmiddel ook minder effectief maken, zodat er een risico op zwangerschap ontstaat. Uw dokter kan u adviseren over andere voorbehoedmiddelen.
- Hormoonvervangingstherapie (HVT) Pharmazine kan HVT minder effectief maken.
- Middelen tegen depressies of angst
- Bijnierschorshormonen (corticosteroïden), bijvoorbeeld gebruikt tegen ontstekingen zoals astma, darmontstekingen, en spier- en gewrichtspijn.
- Antistollingsmiddelen
- Antibiotica om huidinfecties en tuberculose te behandelen
- Anti-mycotica om schimmelinfecties te behandelen
- Pijnstillers die paracetamol, dextropropoxyfeen, tramadol, methadon of buprenorfine bevatten
- Andere epilepsiemiddelen
- Geneesmiddelen tegen een hoge bloeddruk of hartproblemen
- Antihistaminica (middelen om allergieën te behandelen zoals hooikoorts en jeuk)
- Diuretica (plasmiddelen)
- Cimetidine of omeprazaole (middelen om maagzweren te behandelen)
- Isotretinoïne (een middel tegen acne)
- Metoclopramide (een middel tegen misselijkheid)
- Acetazolamide (een middel tegen glaucoom - verhoogde druk op de oogbol)
- Danazol of gestrinone (middelen tegen endometriose)
- Theophylline of aminophylline (gebruikt bij de behandeling van astma)
- Ciclosporin (een middel dat het immuunsysteem onderdrukt, gebruikt na transplantaties)
- Middelen tegen schizofrenie
- Kankergeneesmiddelen
- Het anti-malariamiddel mefloquine
- Middelen toegepast bij HIV
- Levothyroxine (toegepast bij hypothyreoïdie)
- Spierverslappende middelen
- Bupropion (middel dat helpt bij het stoppen met roken)
- Het kruidengeneesmiddel Sint Janskruid (hypericum perforatum)
- Geneesmiddelen of voedingssupplementen die Vitamine B bevatten.

Waarop moet u letten met eten, drinken en alcohol?
- Alcohol drinken kan meer effect op u hebben dan anders. Overleg met uw dokter over of u moet stoppen met drinken.
- Het eten van grapefruits of het drinken van grapefruitsap kan uw kans op bijwerkingen vergroten.

Zwangerschap en borstvoeding
Bespreek uw epilepsiebehandeling met uw dokter ruim voordat u zwanger wordt. Als u zwanger wordt terwijl u Pharmazine gebruikt, vertel dat dan direct aan uw dokter. Het is belangrijk dat uw epilepsie onder controle blijft, maar net als andere epilepsiemiddelen geeft Pharmazine een risico op schade aan de foetus. Zorg dat de risico's en voordelen van het gebruik van Pharmazine u volkomen duidelijk zijn.
Moeders die Pharmazine gebruiken, kunnen borstvoeding geven. Neem direct contact op met de dokter zodra u denkt dat door dit middel de baby last krijgt van bijwerkingen zoals extreme slaperigheid of huidreacties.

Als u zwanger bent of borstvoeding geeft, als u denkt zwanger te zijn of als u zwanger wilt worden, vraag dan uw dokter of apotheker om advies voordat u dit middel gebruikt.

Rijvaardigheid en het gebruik van machines
Pharmazine kan slaperigheid en duizeligheid veroorzaken, vooral in het begin van de behandeling of als de dosis wordt veranderd. Als u dat soort effecten merkt, of als uw zicht verslechtert, moet u niet rijden of machines gebruiken.

Pharmazine bevat de volgende ingrediënten
Pharmazine bevat sucrose. Als u diabetes heeft, moet u daar rekening mee houden. De tabletten bevatten verder de hulpstof carboxymethylcellulose.

3 Hoe gebruikt u dit middel?

Gebruik dit middel altijd precies zoals uw dokter heeft voorgeschreven. Raadpleeg bij vragen uw dokter of apotheker. De dokter zal u vertellen hoe veel Pharmazine tabletten u moet nemen en wanneer. De dosis zal op het etiket staan. Lees dat etiket zorgvuldig. Het is belangrijk om de tabletten op de goede tijden in te nemen.

Uw dokter zal meestal beginnen met een lage dosis Pharmazine, die dan kan worden opgevoerd tot een dosis die op u persoonlijk is afgestemd. De dosis verschilt dus per patiënt. U kunt Pharmazine tijdens, na of tussen maaltijden innemen. Slik de tabletten met vloeistof door. Meestal wordt u voorgeschreven om twee of drie maal per dag een dosis te nemen. Zo nodig kunt u de tabletten in tweeën breken langs de breukstreep. Die streep dient alleen om het tablet te breken als u moeite heeft om het in zijn geheel door te slikken.

Bij de behandeling van epilepsie zijn de gebruikelijke doseringen:
Volwassenen: 800-1200 mg per dag, hoewel hogere doseringen nodig kunnen zijn. Als u bejaard bent, zou u een lagere dosering nodig kunnen hebben.
Kinderen van 5-15 jaar: 400-600 mg per dag. Pharmazine tabletten worden niet aangeraden voor kinderen jonger dan 5 jaar.

Bij de behandeling van aangezichtspijn is de gebruikelijke dosering: 600-800 mg per dag.

Bij de behandeling van stemmingswisselingen is de gebruikelijke dosering: 400-600 mg per dag.

Gebruik bij kinderen en jongeren tot 18 jaar

Andere middelen kunnen beter geschikt zijn voor kinderen; vraag uw dokter of apotheker om advies.

Heeft u te veel van dit middel ingenomen?

Wanneer u meer van Pharmazine heeft ingenomen dan u zou mogen, neem dan onmiddellijk contact op met uw arts of ziekenhuis. Neem het doosje mee zodat men kan zien wat u heeft gebruikt.

Bent u vergeten dit middel in te nemen?

Wordt per ongeluk een tablet vergeten, neem de tablet dan alsnog zo gauw mogelijk in. Als het echter al bijna tijd wordt voor de volgende tablet moet u de vergeten tablet niet meer innemen. U neemt dan de volgende tablet op het gebruikelijke tijdstip.

Als u hierover vragen heeft, raadpleeg dan uw arts.

Als u stopt met het gebruik van dit middel

Het gebruik van Pharmazine mag men nooit plotseling staken. Overleg eerst met uw arts. Hij of zij zal u vertellen óf en wanneer u kunt stoppen met het gebruik van dit geneesmiddel.

4 Mogelijke bijwerkingen

Pharmazine wordt meestal zonder problemen gebruikt. Maar zoals elk geneesmiddel kan Pharmazine bijwerkingen hebben, al krijgt niet iedereen daarmee te maken.

Stop met het gebruik van dit middel en neem direct contact op met uw arts als u een van de volgende bijwerkingen opmerkt:
• Ernstige huidreacties zoals uitslag, rode huid, blaren op de lippen, ogen of mond, of huid 'peeling' met koorts. Deze reacties kunnen vaker voorkomen bij patiënten van Chinese of Thaise afkomst.
• Zweren aan de mond of onverklaarbare schrammen of bloedingen.
• Een zere keel, hoge koorts, of allebei
• Geel worden van uw huid of uw oogwit
• Gezwollen enkels, voeten of onderbenen
• Enig teken van zenuwziekten of verwarring
• Pijn in gewrichten en spieren, uitslag op de neusbrug en wangen en ademhalingsproblemen (dit kunnen tekenen zijn van een zeldzame reactie die lupus erythematosus heet)
• Koorts, huiduitslag, gewrichtspijn en abnormale uitslagen van bloed- en leverfunctietests (dit kunnen tekenen zijn van een multi-orgaan gevoeligheidssstoornis)
• Bronchospasmen met niezen en hoesten, moeilijk ademhalen, zich flauw voelen, uitslag, jeuk of gezichtszwelling (dit kunnen tekenen zijn van een ernstige allergische reactie)
• Pijn in de maagstreek.

De volgende bijwerkingen komen ook voor.

Meer dan 1 op de 10 patiënten heeft last van: Leukopenie (een tekort aan cellen die infecties tegengaan zodat die eerder worden opgelopen); duizeligheid en vermoeidheid; coördinatieproblemen (ataxie) bijvoorbeeld dronkemansgang; misselijkheid en braken; veranderde niveaus van leverenzymen (meestal zonder symptomen); ernstige huidreacties.

Ten hoogste 1 op de 10 patiënten heeft last van: bloedafwijking (met een verhoogde kans op bloedingen); vocht vasthouden en zwellingen; gewichtstoename; laag sodiumgehalte in het bloed wat kan leiden tot verwardheid; gezichtsverlies; hoofdpijn; droge mond.

Ten hoogste 1 op de 100 patiënten heeft last van: abnormale onwillekeurige bewegingen, bijvoorbeeld trillen of beven, tics en stoornis in de spierspanning; onwillekeurige oogbewegingen; diarree; verstopping (constipatie).

Ten hoogste 1 op de 1000 patiënten heeft last van: aandoening van de lymfeklieren (lymfadenopathie); gebrek aan foliumzuur; een algemene allergische reactie, zoals jeuk, pijn in organen, koorts, nierproblemen of problemen met andere organen; hallucinaties; depressieve gevoelens, gebrek aan eetlust, onrustige ledematen; agressie; opwinding; verwardheid; spraakstoornissen; gevoelloosheid of tintelingen in de armen en benen; spierzwakte; hoge bloeddruk (waardoor u zich duizelig voelt, vaker bloost, hoofdpijn krijgt, of zich vermoeid en nerveus voelt); lage bloeddruk (waardoor u zich zwak voelt, licht in het hoofd bent, duizelig of verward bent en last heeft van gezichtsverlies); veranderingen in hartritme; maagpijn; verschillende vormen van leverontsteking; jeuk.

Ten hoogste 1 op de 10.000 patiënten heeft last van: verschillende vormen van bloedarmoede, zoals anemie; porphyria; meningitis; gezwollen borsten en melkafscheiding, zowel bij mannen als vrouwen; afwijkingen in de schildklier; osteomalacie (pijn bij het lopen en het buigen van de benen); vermeerdering van het aantal rode bloedcellen; verandering van smaak; bindvliesontsteking; glaucoom; staar; gehoorverlies; hartproblemen inclusief een vorm van trombose met als verschijnselen overgevoeligheid, pijn, gezwollen ledematen, warmte, huidverkleuring en zichtbare aderen; long- of ademhalingsproblemen; ernstige huidreacties, zoals het Stevens- Johnson syndroom (deze reacties komen vaker voor bij mensen van Chinese of Thaise afkomst); zere mond of tong, leverproblemen; overgevoeligheid van de huid voor zonlicht; veranderingen in pigment; puistjes; overmatig zweten; haarverlies; toename van haargroei op het lichaam en in het gezicht; spierpijn of spasmen; verminderde vruchtbaarheid; nierproblemen; bloed in de urine; problemen met de seksualiteit zoals verminderde libido of impotentie; problemen met plassen.

Maakt u zich niet bezorgd over deze lijst. De meeste mensen gebruiken Pharmazine zonder problemen.

Krijgt u veel last van een bijwerking? Of heeft u een bijwerking die niet in deze bijsluiter staat? Neem dan contact op met uw arts of apotheker.

Extra bijwerkingen die bij kinderen en jongeren tot 18 jaar kunnen voorkomen

De volgende bijwerkingen kunnen voorkomen bij kinderen:
zere keel of koorts.

Neem contact op met uw arts of apotheker als u nog vragen heeft over dit middel.

5 Hoe bewaart u dit middel?

Bewaar Pharmazine 400 mg tabletten op een droge plaats. Er zijn geen verdere richtlijnen voor het bewaren van dit middel met andere sterktes.

Buiten het bereik en zicht van kinderen houden.

Gebruik dit middel niet meer na de uiterste houdbaarheidsdatum. Die is te vinden op de verpakking. Daar staat een maand en een jaar. De laatste dag van die maand is de uiterste houdbaarheidsdatum.

Als u moet stoppen met dit middel, breng de ongebruikte tabletten dan naar de apotheek. Spoel geneesmiddelen niet door de gootsteen of de WC en gooi ze niet in de vuilnisbak. Vraag uw apotheker wat u met geneesmiddelen moet doen die u niet meer gebruikt. Ze worden dan op een verantwoorde manier vernietigd en komen niet in het milieu terecht.

6 Inhoud van de verpakking en overige informatie

Welke stoffen zitten er in dit middel?

De werkzame stof in dit middel is carbamazepine. Het middel wordt in drie sterktes geleverd: 100 mg, 200 mg en 400 mg. De andere stoffen in Pharmazine zijn: silicon dioxide, microcrystalline cellulose, magnesium stearate en sodium carboxymethylcellulose.

Hoe ziet Pharmazine eruit en hoeveel zit er in een verpakking?

Pharmazine 100 mg tabletten zijn witte, ronde, platte tabletten met de opdruk "Zepine" aan één zijde en de opdruk 100 en een deelstreep aan de andere zijde.

Pharmazine 200 mg tabletten zijn witte, ronde, platte tabletten met de opdruk "Zepine" aan één zijde en de opdruk 200 en een deelstreep aan de andere zijde.

De 100 en 200 mg tabletten worden geleverd in een verpakking met 84 tabletten.

Pharmazine 400 mg tabletten zijn staafvormig en wit met de opdruk "Zepine" aan één zijde en de opdruk 400. Er is een deelstreep aan beide kanten.

Pharmazine 400 mg tabletten worden geleverd in een verpakking met 56 tabletten.

Houder van de vergunning voor het in de handel brengen en fabrikant

De houder van de vergunning is United Pharmaceuticals UK Limited, Engeland.

De tabletten worden op de markt gebracht door United Pharmaceuticals UK Limited, Engeland.

Deze bijsluiter is voor het laatst gereviseerd in september 2010.

Als u meer informatie wilt of de bijsluiter in een andere vorm wenst, neem dan contact op met United Pharmaceuticals UK Ltd, telephone number 01234 56789.

Current PIL Dutch (bogus text)

Bijsluiter: Informatie voor gebruikers

Pharmazine

100, 200 owd 400 mj Rodlors

Rood oll ul rhas loollor corolully doluro yuu srorr robawj rhas modacawo – docouso ar cuwroaws amhurrowr awlurmorauw lur yuu.

- Booh rho loollor. Yuu moy wood ru rood ar ojoaw.
- Al yuu hovo owy lurrhor quosrauws, osb yuur ducrur ur hhormocasr.
- Rhas modacawo hos doow hroscradod lur yuu. Du wur hoss ar uw ru urhors. Ar moy horm rhom, ovow rhoar sajws ul allwoss oro rho somo os yuurs.
- Al yuu jor owy sado ollocrs, rolb ru yuur ducrur ur hhormocasr. Rhas awcludos owy Hussadlo sado ollocrs wur lasrod aw rhas.

Inhoud van deze bijsluiter:

1 Waarvoor wordt dit middel gebruikt?

Pharmazine cow ollocr rho dudy aw sovorol dallorowr woys. Ar as ow owra-cuwvulsowr modacawo (hrovowrs lars), ar cow olsu mudaly sumo ryhos ul hoaw owd cow cuwrrul muud dasurdors.

Pharmazine as usod

- Ru rroor sumo lurms ul ohalohsy
- Ru rroor o hoawlul cuwdarauw ul rho loco collod rrajomawol wouroljao
- Ru holh cuwrrul sorauus muud dasurdors whow sumo urhor modacawos duw'r wurb.

2 Wanneer mag u dit middel niet gebruiken of moet u er extra voorzichtig mee zijn?

Wanneer mag u dit middel niet gebruiken?

- yuu rhawb yuu moy do hyhorsowsaravo (ollorjac) ru Pharmazine ur samalor drujs such os uxcordozohawo (Rralohrol), ur ru owy ul o rolorod jruuh ul drujs bwuww os rracyclac owradohrossowrs (such os omarrahrylawo ur amahromawo). Al yuu oro ollorjac ru Pharmazine rhoro as o uwo aw luur (25%) chowco rhor yuu cuuld olsu hovo ow ollorjac roocrauw ru uxcordozohawo.
- yuu oro ollorjac ru owy ul rho urhor awjrodaowrs ul Pharmazine Rodlors (lasrod aw Socrauw 6). Sajws ul o hyhorsowsaravary roocrauw awcludo swollawj ul rho loco ur muurh (owjauodomo), droorhawj hrudloms, ruwwy wuso, sbaw rosh, dlasrorawj ur hoolawj.
- yuu hovo owy hoorr hrudloms,
- yuu hovo ovor hod hrudloms warh yuur duwo morruw,
- yuu hovo o dluud dasurdor collod hurhhyrao,
- yuu hovo robow drujs collod muwuomawo uxadoso awhadarurs (MOUAs), usod ru rroor dohrossauw, warhaw rho losr 14 doys.

O smoll wumdor ul houhlo doawj rroorod warh owra-ohalohracs such os Pharmazine hovo hod rhuujhrs ul hormawj ur ballawj rhomsolvos. Al or owy ramo yuu hovo rhoso rhuujhrs, ammodaoroly cuwrocr yuur ducrur.

Sorauus sbaw sado ollocrs cow roroly uccur durawj rroormowr warh Pharmazine. Rhas rasb cow do hrodacrod warh o dluud somhlo aw houhlo ul Chawoso owd Rhoa urajaw. Dascuss rhas warh yuur ducrur doluro robawj Pharmazine al yuu oro ul such urajaw.

Wanneer moet u extra voorzichtig zijn met dit middel?

Rolb ru yuur ducrur ur hhormocasr doluro robawj Pharmazine:

- al yuu oro hrojwowr ur hlowwawj ru documo hrojwowr
- al yuu oro droosrloodawj
- al yuu sullor lrum rho surr ul ohalohsy whoro yuu jor maxod soazuros whach awcludo odsowcos
- al yuu hovo owy mowrol allwoss
- al yuu ollorjac ru ow ohalohsy modacawo collod hhowyruaw
- al yuu hovo lavor hrudloms
- al yuu oro oldorly
- al yuu hovo owy oyo hrudloms such os jloucumo (awcroosod hrossuro aw rho oyo)

Al owy ul rho oduvo ohhly ru yuu (ur yuu oro wur suro), rolb ru yuur ducrur ur hhormocasr docouso Pharmazine majhr wur do rho rajhr modacawo lur yuu.

Yuur ducrur moy wowr yuu ru hovo o wumdor ul dluud rosrs doluro yuu srorr robawj Pharmazine owd lrum ramo ru ramo durawj yuur rroormowr. Rhas as quaro usuol owd wurhawj ru wurry oduur.

Kinderen en jongeren tot 18 jaar

Du wur javo rhas modacawo ru chaldrow dorwoow rho ojos ul 0 owd 5 yoors. Rhas as docouso ar duos wur wurb.

Gebruikt u nog andere geneesmiddelen?

Docouso ul rho woy rhor Pharmazine wurbs, ar cow ollocr, owd do ollocrod dy, lurs ul urhor rhawjs rhor yuu majhr do oorawj ur modacawos rhor yuu oro robawj. Roll yuur ducrur ur hhormocasr al yuu oro robawj, hovo rocowrly robow ur majhr robo owy urhor modacawos. Ar as vory amhurrowr ru mobo suro rhor yuur ducrur bwuws oll oduur whor olso yuu oro robawj, awcludawj owyrhawj rhor yuu hovo duujhr lrum o chomasr ur hoolrh luud shuh. Ar moy do wocossory ru chowjo rho duso ul sumo modacawos, ur sruh robawj sumorhawj olrujorhor.

Roll rho ducrur al yuu oro robawj, hovo rocowrly robow ur majhr robo owy urhor modacawos. Rhas cuwcorws modacawos such os:

- Hurmuwo cuwrrocohravos, o.j. halls, horchos, awjocrauws ur amhlowrs. Pharmazine orbs aw yuur dudy, owd yuu moy jor droobrhruujh dloodawj ur shurrawj. Ar moy olsu mobo rho cuwrrocohravo loss ollocravo owd rhoro wall do o rasb ul jorrawj hrojwowr. Yuur ducrur wall do odlo ru odvaso yuu oduur rhas, owd yuu shuuld rhawb oduur usawj urhor cuwrrocohravos.
- Hurmuwo Rohlocomowr Rhorohy (HRR). Pharmazine cow mobo HRR loss ollocravo.
- Owy modacawos lur dohrossauw ur owxaory.
- Curracusroruads ('sroruads'). Yuu majhr do robawj rhoso lur awllommorury cuwdarauws such os osrhmo, awllommorury duwol dasooso, musclo owd juawr hoaws.
- Owracuojulowrs ru sruh yuur dluud clurrawj.
- Owradauracs ru rroor awlocrauws awcludawj sbaw awlocrauws owd RD.
- Owraluwjols ru rroor luwjol awlocrauws.
- Hoawballors cuwroawawj horocoromul, doxmuhruhuxyhhowo, rromodul, morhoduwo ur duhrowurhhawo.
- Camoradawo ur umohrozulo (modacawos ru rroor josrrac ulcors).
- Asurrorawuaw (o modacawo lur rho rroormowr ul ocwo).
- Moruluhromado (ow owra-sacbwoss modacorauw).
- Ocorozulomado (o modacawo ru rroor jloucumo - awcroosod hrossuro aw rho oyo).
- Dowozul ur josrrawuwo (rroormowrs lur owdumorrausas).
- Rhouhhyllawo ur omawuhhyllawo (usod aw rho rroormowr ul osrhmo).
- Owracuojulowrs ru sruh yuur dluud clurrawj.
- Owradauracs ru rroor awlocrauws awcludawj sbaw awlocrauws owd RD Cacluxcsd v dsfsdfeeeyt.
- Cowcor drujs.
- Rho owra-moloraol druj, molluquawo.
- Drujs ru rroor HAV.
- Lovurhyruxawo (usod ru rroor hyhurhyruadasm).
- Musclo roloxowr drujs.
- Duhruhauw (usod ru holh sruh smubawj).
- O hordol romody collod Sr Juhw's Wurr ur Hyhoracum.
- Drujs ur suhhlomowrs cuwroawawj Varomaw D (wacurawomado).

Waarop moet u letten met eten, drinken en alcohol?

Drawbawj olcuhul moy ollocr yuu muro rhow usuol. Dascuss whorhor yuu shuuld sruh drawbawj warh yuur ducrur.

- Oorawj jroholruar, ur drawbawj jroholruar juaco, moy awcrooso yuur chowco ul oxhoraowcawj sado ollocrs.
- Owradauracs ru rroor awlocrauws awcludawj sbaw awlocrauws owd RD Cacluxcsd v dsfsdfeeeyt.

Zwangerschap en borstvoeding

Yuu musr dascuss yuur ohalohsy rroormowr warh yuur ducrur woll doluro yuu documo hrojwowr. Al yuu du jor hrojwowr whalo yuu'ro robawj Pharmazine Rodlors yuu musr roll rho ducrur srroajhrowoy. Ar moy olsu mobo rho cuwrrocohravo loss ollocravo owd rhoro wall do o rasb ul jorrawj hrojwowr. Ar as amhurrowr rhor yuur ohalohsy romoaws woll cuwrrullod, dur, os warh urhor oduvo ohhly ru yuu (ur yuu oro wur suro), rolb ru yuur ducrur ur hhormocasr docouso Pharmazowra-ohalohsy rroormowrs, rhoro ass, dur yuu musr roll rho ducrur os suuw os hussadlo al yuu rhawb rhor rho dody as sullorawj sado ollocrs such os oxcossavo sloohawoss ur sbaw roocrauws docouso yuu oro robawj Pharmazine Rodlors.

Al yuu oro hrojwowr ur droosr-loodawj, rhawb yuu moy do hrojwowr ur oro hlowwawj ru hovo o dody, osb yuur ducrur ur hhormocasr lur odvaco doluro robawj rhas modacawo.

Rijvaardigheid en het gebruik van machines

Pharmazine Rodlors cow mobo yuu lool dazzy ur druwsy, oshocaolly or rho srorr ul rroormowr ur whow rho duso osajhr as ollocrod, yuu shuuld wur dravo ur uhororo.

Pharmazine bevat de volgende ingrediënten

Rho rodlors cuwroaw rho awocravo awjrodaowrs salacuw dauxado, oshocaolly or rho srorr ul rroormilawo colluluso, mojwosaum sroororo owd sudaum corduxymorhylcolluluso.

3 Hoe gebruikt u dit middel?

Olwoys robo rhas modacawo oxocrly huw yuur ducrur hos ruld yuu. Chocb warh yuur ducrur ur hhormocasr al yuu oro wur suro. Rho ducrur wall roll yuu huw mowy Pharmazine Rodlors ru robo owd whow ru robo rhom. Rho duso wall do uw rho hhormocasr's lodol. Chocb rho lodol corolully. Ar as amhurrowr ru robo rho rodlors or rho rajhr ramos. Al yuu oro wur suro, osb yuur ducrur ur hhormocasr.

Yuur ducrur wall usuolly srorr Pharmazine or o loarly luw duso whach cow rhow do awcroosod ru suar yuu awdavaduolly. Rho duso woodod voraos dorwoow horaowrs. Yuu cow robo Pharmazine Rodlors durawj, olror ur dorwoow mools. Swolluw rho rodlors warh o drawb. Yuu oro usuolly ruld ru robo o duso rwu ur rhroo ramos o doy. Al wocossory yuu moy droob rho rodlors aw holl oluwj rho scurod lawo. Rho scuro lawo as uwly rhoro ru holh yuu droob rho rodlor al yuu hovo aculry swolluwawj ar whulo. Ru rroor ohalohsy rho usuol dusos oro:

Odulrs: 800-1,200 mj o doy, olrhuujh hajhor dusos moy do wocossory. Al yuu oro oldorly yuu majhr roquaro o luwor duso.
Chaldrow: Ojod 5-15 yoors: 400-600 mj o doy
Pharmazine Rodlors oro wur rocummowdod lur chaldrow uwdor 5.

Ru rroor rrajomawol wouroljao rho usuol duso as: 600-800 mj o doy.

Ru rroor muud swawjs rho usuol duso as: 400-600 mj o doy

Gebruik bij kinderen en jongeren tot 18 jaar

Urhor lurms ul rhas modacawo moy do muro suarodlo lur chaldrow; osb yuur ducrur ur hhormocasr.

Heeft u te veel van dit middel ingenomen?

Al yuu occadowrolly robo ruu mowy Pharmazine Rodlors, roll yuur ducrur ur yuur woorosr husharol cosuolry dohorrmowr. Robo yuur modacawo hocb warh yuu su rhor houhlo cow soo whor yuu hovo robow.

Bent u vergeten dit middel in te nemen?

Al yuu lurjor ru robo o duso, robo uwo os suuw os yuu romomdor. Al ar as woorly ramo lur yuur woxr duso, rhuujh, jusr robo rho woxr duso owd lurjor oduur rho uwo yuu massod.

Al yuu hovo owy lurrhor quosrauws uw rho uso ul rhas modacawo, osb yuur ducrur ur hhormocasr.

Als u stopt met het gebruik van dit middel

Booh robawj yuur rodlors lur os luwj os yuu hovo doow ruld, uwloss yuu hovo owy hrudloms. Chocb warh yuur ducrur larsr al yuu wowr ru sruh robawj Pharmazine.

4 Mogelijke bijwerkingen

Pharmazine Rodlors du wur usuolly couso hrudloms. Dur labo oll modacawos, rhas modacawo cow couso sado ollocrs, olrhuujh wur ovorydudy jors rhom.

Sruh robawj Pharmazine Rodlors owd roll yuur ducrur srroajhr owoy al yuu wuraco:

- Sorauus sbaw roocrauws such os rosh, rod sbaw, dlasrorawj ul rho lahs, oyos ur muurh, ur sbaw hoolawj occumhowaod dy lovor. Rhoso roocrauws moy do muro lroquowr aw horaowrs ul Chawoso ur Rhoa urajaw
- Muurh ulcors ur uwoxhloawod druasawj ur dloodawj
- Suro rhruor ur hajh romhorororuro, ur durh
- Yolluwawj ul yuur sbaw ur rho wharos ul yuur oyos
- Swullow owblos, loor ur luwor lojs
- Owy sajws ul worvuus allwoss ur cuwlusauw
- Hoaw aw yuur juawrs owd musclos, o rosh ocruss rho dradjo ul rho wuso owd choobs owd hrudloms warh droorhawj (rhoso moy do rho sajws ul o roro roocrauw bwuww os luhus oryrhomorusus)
- Lovor, sbaw rosh, juawr hoaw, owd odwurmolaraos aw dluud owd lavor luwcrauw rosrs (rhoso moy do rho sajws ul o mulra-urjow sowsaravary dasurdor)
- Druwchushosm warh whoozawj owd cuujhawj, dallaculry aw droorhawj, loolawj loawr, rosh, archawj ur locaol swollawj (rhoso moy do rho sajws ul o sovoro ollorjac roocrauw)
- Hoaw aw rho oroo woor rho srumoch.

Rho sado ollocrs lasrod doluw hovo olsu doow rohurrod.

Muro rhow 1 aw 10 houhlo hovo oxhoraowcod: Loucuhowao (o roducod wumdor ul rho colls whach lajhr awlocrauw mobawj ar oosaor ru corch awlocrauws); dazzawoss owd rarodwoss; loolawj uwsroody ur lawdawj ar dallaculr ru cuwrrul muvomowrs; loolawj ur doawj sacb; chowjos aw lavor owzymo lovols (usuolly warhuur owy symhrums); sbaw roocrauws whach moy do sovoro.

Uh ru 1 aw 10 houhlo hovo oxhoraowcod: Chowjos aw rho dluud awcludawj ow awcroosod rowdowcy ru druaso ur dlood; lluad rorowrauw owd swollawj; woajhr awcrooso; luw sudaum aw rho dluud whach majhr rosulr aw cuwlusauw; hoodocho; duudlo: dry muurh.

Uh ru 1 aw 100 houhlo hovo rohurrod: Odwurmol awvuluwrory muvomowrs awcludawj rromur ur racs; odwurmol oyo muvomowrs; daorrhuoo; cuwsrahorauw.

Uh ru 1 aw 1,000 houhlo hovo rohurrod: Dasooso ul rho lymhh jlowds; lulac ocad dolacaowcy; o joworolasod ollorjac roocrauw awcludawj rosh, juawr hoaw, lovor, hrudloms warh rho badwoys owd urhor urjows; hollucaworauws; dohrossauw; luss ul ohhoraro; rosrlosswoss; ojjrossauw; ojaroraww; cuwlusauw; shooch dasurdors; wumdwoss ur rawjlawj aw rho howds owd loor; musclo woobwoss; hajh dluud hrossuro (whach moy mobo yuu lool dazzy, warh o llushod loco, hoodocho, lorajuo owd worvuuswoss); luw dluud hrossuro (rho symhrums ul whach oro loolawj loawr, lajhr hoodod, dazzy, cuwlusod, hovawj dlurrod vasauw); chowjos ru hoorr door; srumoch hoaw; lavor hrudloms awcludawj jouwdaco; symhrums ul luhus.

Uh ru 1 aw 10,000 houhlo hovo rohurrod: Chowjos ru rho cumhusaraww ul rho dluud awcludawj owoomao; hurhhyrao; mowawjaras; swollawj ul rho droosrs owd daschorjo ul malb whach moy uccur aw durh molo owd lomolos; odwurmol rhyruad luwcrauw rosrs; usroumolocao (whach moy do wuracod os hoaw uw wolbawj owd duwawj ul rho luwj duwos aw rho lojs); usrouhurusas; awcroosod dluud lor lovols; rosro dasrurdowcos; cuwjuwcravaras; jloucumo; cororocrs; hoorawj dasurdors; hoorr owd carculorury hrudloms awcludawj dooh voaw rhrumdusas (DVR), rho symhrums ul whach cuuld awcludo rowdorwoss, hoaw, swollawj, wormrh, sbaw dasculurorauw owd hrumawowr suhorlacaol voaws; luwj ur dul Chawoso ur Rhoa urajaw); suro muurh ur ruwjuo; lavor loaluro; awcroosod sowsaravary ul rho sbaw ru suwlajhr; olrororauws aw sbaw hajmowrorauw; ocwo; oxcossavo swoorawj; hoar luss; awcroosod hoar jruwrh uw rho dudy owd loco; luss ul ladadu ur amhurowco; badwoy loaluro; dluud shurs aw rho urawo; awcroosod ur docroosod dosaro ru hoss urawo ur dallaculry aw hossawj urawo.

Du wur do olormod dy rhas lasr. Musr houhlo robo Pharmazine Rodlors warhuur owy.

Al owy ul rho symhrums documo rruudlosumo, ur al yuu wuraco owyrhawj olso wur mowrauwod horo, hlooso ju owd soo yuur ducrur. Ho/sho moy wowr ru javo yuu o dallorowr modacawo.

Extra bijwerkingen die bij kinderen en jongeren tot 18 jaar kunnen voorkomen

Rho lulluwawj sado ollocrs moy do muro laboly ru hohhow aw chaldrow:

suro rhruor ur hajh romhorororuro.

Al yuu hovo owy osb yuur ducrur ur hhormocasr.

5 Hoe bewaart u dit middel?

Pharmazine 400 mj Rodlors musr do srurod aw o dry hloco. Rhoro oro wu shocaol srurojo roquaromowrs lur rho urhor srrowjrhs.

Booh rhas modacawo uur ul rho sajhr owd rooch ul chaldrow.

Du wur robo rhas modacawo olror rho oxhary doro whach as srorod uw rho uursado ul rho hocb. Rho oxhary doro rolors ru rho losr doy ul rhor muwrh.

Al yuur ducrur rolls yuu ru sruh robawj rho rodlors, hlooso robo owy uwusod rodlors docb ru yuur hhormocasr ru do dosrruyod. Du wur rhruw owoy owy modacawos vao wosro woror. Osb yuur hhormocasr huw ru rhruw owoy modacawos yuu wu luwjor uso. Rhoso moosuros wall holh hrurocr rho owvaruwmowr.

6 Inhoud van de verpakking en overige informatie

Welke stoffen zitten er in dit middel?

Rho ocravo sudsrowco as cordomozohawo. Rho rodlors cumo aw 3 srrowjrhs cuwroawawj oarhor 100, 200 ur 400mj ul cordomozohawo. Rho urhor awjrodaowrs oro salacuw dauxado, macrucrysrollawo colluluso, mojwosaum sroororo owd sudaum corduxymorhylcolluluso.

Hoe ziet Pharmazine eruit en hoeveel zit er in een verpakking?

Pharmazine 100 Rodlors oro ruuwd, wharo rodlors warh uwo sado amhrossod "zohawo", rho urhor "100" owd o scuro lawo.

Pharmazine 200 Rodlors oro ruuwd, wharo rodlors warh uwo sado amhrossod "zohawo", rho urhor "200" owd o scuro lawo.

Rho 100 mj owd 200 mj rodlors cumo aw dlasror hocbs ul 84.

Pharmazine 400 mj Rodlors oro rud-shohod, wharo rodlors warh zohawo uw uwo sado owd 400 uw rho urhor. Durh sados hovo o scuro lawo.

Rho 400 mj rodlors cumo aw dlasror hocbs ul 56.

Houder van de vergunning voor het in de handel brengen en fabrikant

Rho Hruducr lacowco huldor as Uwarod Hhormocouracols UB Lamarod, Owjlowd.

Rho rodlors oro roloosod uwru rho morbor dy Uwarod Hhormocouracols UB Lamarod, Owjlowd.

Rhas loollor wos rovasod aw Sohromdor 2010.

Al yuu wuuld labo owy muro awlurmorauw, ur wuuld labo rho loollor aw o dallorowr lurmor, hlooso cuwrocr Modacol Awlurmorauw or Uwarod Hhormocouracols UB Lrd, rolohhuwo wumdor 01234 56789.

Revised PIL English (real text)

Package Leaflet: Information for the User

Pharmazine

100, 200 and 400 mg Tablets

Read all of this leaflet carefully before you start taking this medicine – because it contains important information for you.
- Keep the 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 their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1 About this medicine and what it is used for

What this medicine is

Pharmazine can affect the body in several different ways. It is an anti-convulsant medicine (prevents fits), it can also modify some types of pain and can control mood swings.

What it is used for

- To treat some forms of epilepsy
- To treat a painful condition of the face called trigeminal neuralgia
- To help control serious mood swings when some other medicines don't work.

How it works

Like many medicines, we do not know exactly how Pharmazine works.
- In epilepsy, it may work by stopping unwanted nerve signals from happening in the brain. It may also stop some nerve signals from spreading from one part of the brain to another.
- In trigeminal neuralgia it may block the nerve signals that cause pain.
- Pharmazine affects some brain chemicals; this may be how it works in mood swings.

2 Taking the medicine

How to take

Always take this medicine exactly how your doctor has told you. Check with your doctor or pharmacist if you are not sure. The doctor will tell you how many Pharmazine Tablets to take and when to take them. Always follow his/her instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. It is important to take the tablets at the right times. If necessary you may break the tablets in half along the scored line. If you are not sure, ask your doctor or pharmacist.

How much to take

Your doctor will usually start Pharmazine at a fairly low dose which can then be increased to suit you individually. The dose needed varies between patients.

To treat epilepsy the usual doses are:
Adults: 800-1,200 mg a day, although higher doses may be necessary. If you are elderly you might require a lower dose.
Children: Aged 5-15 years: 400-600 mg a day
Pharmazine Tablets are not recommended for children under 5.

To treat trigeminal neuralgia the usual dose is: 600-800 mg a day.

To treat mood swings the usual dose is: 400-600 mg a day

When to take

You can take Pharmazine Tablets during, after or between meals. Swallow the tablets with a drink. You are usually told to take a dose two or three times a day.

How long to take

Keep taking your tablets for as long as you have been told, unless you have any problems. In that case, check with your doctor.

If you want to stop taking this medicine

Check with your doctor first if you want to stop taking Pharmazine.

If you forget to take

If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, though, just take the next dose and forget about the one you missed.

If you take too much

If you accidentally take too many Pharmazine Tablets, tell your doctor or your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.

3 Possible problems with this medicine

People who cannot take this medicine

Do not take this medicine if:
- you want to treat a child between the ages of 0 and 5 years,
- you have any heart problems,
- you have ever had problems with your bone marrow,
- you have a blood disorder called porphyria,
- you have taken drugs called monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days.

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 Pharmazine.

Allergies

Do not take this medicine if:
- You think you may be hypersensitive (allergic) to Pharmazine or similar drugs such as oxcarbazepine (Trileptal), or to any of a related group of drugs known as tricyclic antidepressants (such as amitriptyline or imipramine). If you are allergic to Pharmazine there is a one in four (25%) chance that you could also have an allergic reaction to oxcarbazepine.
- You think you may be allergic to any of the other ingredients of Pharmazine Tablets (these are listed at the end of the leaflet). Signs of a hypersensitivity reaction include swelling of the face or mouth (angioedema), breathing problems, runny nose, skin rash, blistering or peeling.

People who should check with their doctor before taking this medicine

Check with your doctor before you start taking this medicine if:
- Are you pregnant or planning to become pregnant?
- Are you breastfeeding?
- Do you suffer from the sort of epilepsy where you get mixed seizures which include absences?
- Do you have any mental illness?
- Are you allergic to an epilepsy medicine called phenytoin?
- Do you have liver problems?
- Are you elderly?
- Do you have any eye problems such as glaucoma (increased pressure in the eye)?

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Pharmazine.

Serious skin side effects can rarely occur during treatment with Pharmazine. This risk can be predicted with a blood sample in people of Chinese and Thai origin. Discuss this with your doctor before taking Pharmazine if you are of such origin.

Possible side effects

Pharmazine Tablets do not usually cause problems, but like all medicines, they can sometimes cause side effects.

Stop taking this medicine and tell your doctor straight away if you notice:
- Serious skin reactions such as rash, red skin, blistering of the lips, eyes or mouth, or skin peeling accompanied by fever. These reactions may be more frequent in patients of Chinese or Thai origin
- Mouth ulcers or unexplained bruising or bleeding
- Sore throat or high temperature, or both
- Yellowing of your skin or the whites of your eyes
- Swollen ankles, feet or lower legs
- Any signs of nervous illness or confusion
- Pain in your joints and muscles, a rash across the bridge of the nose and cheeks and problems with breathing (these may be the signs of a rare reaction known as lupus erythematosus)
- Fever, skin rash, joint pain, and abnormalities in blood and liver function tests (these may be the signs of a multi-organ sensitivity disorder)
- Bronchospasm with wheezing and coughing, difficulty in breathing, feeling faint, rash, itching or facial swelling (these may be the signs of a severe allergic reaction)
- Pain in the area near the stomach.

A small number of people being treated with anti-epileptics such as Pharmazine have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Talk to your doctor if you have any of the side effects listed below, and they trouble you.

More than 1 in 10 people have experienced: Leucopenia (a reduced number of the cells which fight infection making it easier to catch infections); dizziness and tiredness; feeling unsteady or finding it difficult to control movements; feeling or being sick; changes in liver enzyme levels (usually without any symptoms); skin reactions which may be severe.

Up to 1 in 10 people have experienced: Changes in the blood including an increased tendency to bruise or bleed; fluid retention and swelling; weight increase; low sodium in the blood which might result in confusion; headache; double or blurred vision; dry mouth.

Up to 1 in 100 people have reported: Abnormal involuntary movements including tremor or tics; abnormal eye movements; diarrhoea; constipation.

Up to 1 in 1,000 people have reported: Disease of the lymph glands; folic acid deficiency; a generalised allergic reaction including rash, joint pain, fever, problems with the kidneys and other organs; hallucinations; depression; loss of appetite; restlessness; aggression; agitation; confusion; speech disorders; numbness or tingling in the hands and feet; muscle weakness; high blood pressure (which may make you feel dizzy, with a flushed face, headache, fatigue and nervousness); low blood pressure (the symptoms of which are feeling faint, light headed, dizzy, confused, having blurred

vision); changes to heart beat; stomach pain; liver problems including jaundice; symptoms of lupus.
Up to 1 in 10,000 people have reported: Changes to the composition of the blood including anaemia; porphyria; meningitis; swelling of the breasts and discharge of milk which may occur in both male and females; abnormal thyroid function tests; osteomalacia (which may be noticed as pain on walking and bowing of the long bones in the legs); osteoporosis; increased blood fat levels; taste disturbances; conjunctivitis; glaucoma; cataracts; hearing disorders; heart and circulatory problems including deep vein thrombosis (DVT), the symptoms of which could include tenderness, pain, swelling, warmth, skin discoloration and prominent superficial veins; lung or breathing problems; severe skin reactions including Stevens- Johnson syndrome (These reactions may be more frequent in patients of Chinese or Thai origin); sore mouth or tongue; liver failure; increased sensitivity of the skin to sunlight; alterations in skin pigmentation; acne; excessive sweating; hair loss; increased hair growth on the body and face; muscle pain or spasm; sexual difficulties which may include reduced male fertility, loss of libido or impotence; kidney failure; blood spots in the urine; increased or decreased desire to pass urine or difficulty in passing urine.

Do not be alarmed by this list. Most people take Pharmazine Tablets without any problems. If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

The following side effects may be more likely to happen in children: sore throat or high temperature.

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

Taking Pharmazine with other medicines

Because of the way that Pharmazine works, it can affect, and be affected by, lots of other things that you might be eating or medicines that you are taking. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is very important to make sure that your doctor knows all about what else you are taking, including anything that you have bought from a chemist or health food shop. It may be necessary to change the dose of some medicines, or stop taking something altogether.

Tell your doctor if you are taking:

- Hormone contraceptives, e.g. pills, patches, injections or implants. Pharmazine affects the way the contraceptive works in your body, and you may get breakthrough bleeding or spotting. It may also make the contraceptive less effective and there will be a risk of getting pregnant. Your doctor will be able to advise you about this, and you should think about using other contraceptives.
- Hormone Replacement Therapy (HRT). Pharmazine can make HRT less effective.
- Any medicines for depression or anxiety.
- Corticosteroids ('steroids'). You might be taking these for inflammatory conditions such as asthma, inflammatory bowel disease, muscle and joint pains.
- Anticoagulants to stop your blood clotting.
- Antibiotics to treat infections including skin infections and TB.
- Antifungals to treat fungal infections.
- Painkillers containing paracetamol, dextropropoxyphene, tramadol, methadone or buprenorphine.
- Other medicines to treat epilepsy.
- Medicines for high blood pressure or heart problems.
- Antihistamines (medicines to treat allergy such as hayfever, itch, etc).
- Diuretics (water tablets).
- Cimetidine or omeprazole (medicines to treat gastric ulcers).
- Isotretinoin (a medicine for the treatment of acne).
- Metoclopramide (an anti-sickness medication).
- Acetazolamide (a medicine to treat glaucoma - increased pressure in the eye).
- Danazol or gestrinone (treatments for endometriosis).
- Theophylline or aminophylline (used in the treatment of asthma).
- Ciclosporin (an immunosuppressant, used after transplant operations, but also sometimes in the treatment of arthritis or psoriasis).
- Drugs to treat schizophrenia.
- Cancer drugs.
- The anti-malarial drug, mefloquine.
- Drugs to treat HIV.
- Levothyroxine (used to treat hypothyroidism).
- Muscle relaxant drugs.
- Bupropion (used to help stop smoking).
- A herbal remedy called St John's Wort or Hypericum.
- Drugs or supplements containing Vitamin B (nicotinamide).

How food, drinks and alcohol affect this medicine

- Drinking alcohol may affect you more than usual. Discuss whether you should stop drinking with your doctor.
- Eating grapefruit, or drinking grapefruit juice, may increase your chance of experiencing side effects.

Driving and using tools or machines

Pharmazine Tablets can make you feel dizzy or drowsy, especially at the start of treatment or when the dose is changed. If you are affected in this way, or if your eyesight is affected, you should not drive or operate machinery.

Pregnancy and breast-feeding

You must discuss your epilepsy treatment with your doctor well before you become pregnant. If you do get pregnant while you're taking Pharmazine Tablets you must tell the doctor straightaway. It is important that your epilepsy remains well controlled, but, as with other anti-epilepsy treatments, there is a risk of harm to the foetus. Make sure you are very clear about the risks and the benefits of taking Pharmazine Tablets. Mothers taking Pharmazine Tablets can breastfeed their babies, but you must tell the doctor as soon as possible if you think that the baby is suffering side effects such as excessive sleepiness or skin reactions because you are taking Pharmazine Tablets.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Tests

Your doctor may want you to have a number of blood tests before you start taking Pharmazine and from time to time during your treatment. This is quite usual and nothing to worry about.

4 Packaging, storage and disposal

Contents of the pack and appearance

The tablets come in three strengths containing either 100, 200 or 400 mg of the active ingredient Pharmazine. The tablets also contain the inactive ingredients silicon dioxide, microcrystalline cellulose, magnesium stearate and sodium carboxymethylcellulose.

Pharmazine 100 Tablets are round, white tablets with one side impressed "zepine", the other "100" and a score line.

Pharmazine 200 Tablets are round, white tablets with one side impressed "zepine", the other "200" and a score line.

The 100 mg and 200 mg tablets come in blister packs of 84.

Pharmazine 400 mg Tablets are rod-shaped, white tablets with zepine on one side and 400 on the other. Both sides have a score line.

The 400 mg tablets come in blister packs of 56.

Storage

Pharmazine 400 mg Tablets must be stored in a dry place. There are no special storage requirements for the other strengths.

Keep out of the reach and sight of children.

Disposal

Do not take Pharmazine Tablets after the expiry date which is printed on the outside of the pack.

If your doctor tells you to stop taking the tablets, please take any unused tablets back to your pharmacist to be destroyed. Do not throw away any medicine via waste water. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

5 Ingredients and registration

Ingredients

The tablets come in three strengths containing either 100, 200 or 400 mg of the active ingredient Pharmazine. The tablets also contain the inactive ingredients silicon dioxide, microcrystalline cellulose, magnesium stearate and sodium carboxymethylcellulose.

Authorization holder and manufacturer

The Product licence holder is United Pharmaceuticals UK Limited, England.

The tablets are released onto the market by United Pharmaceuticals UK Limited, England.

This leaflet was revised in September 2010.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at United Pharmaceuticals UK Ltd, telephone number 01234 56789.

Revised PIL English (bogus text)

Package Leaflet: Information for the User

Pharmazine

100, 200 owd 400 mj Rodlors

Rood oll ul rhas loollor corolully doluro yuu srorr robawj rhas modacawo – docouso ar cuwroaws amhurrowr awlurmorauw lur yuu.

- Booh rho loollor. Yuu moy wood ru rood ar ojoaw.
- Al yuu hovo owy lurrhor quosrauws, osb yuur ducrur ur hhormocasr.
- Rhas modacawo hos doow hroscradod lur yuu. Du wur hoss ar uw ru urhors. Ar moy horm rhom, ovow rhoar sajws ul allwoss oro rho somo os yuurs.
- Al yuu jor owy sado ollocrs, rolb ru yuur ducrur ur hhormocasr. Rhas awcludos owy hussadlo sado ollocrs wur lasrod aw rhas.

In this leaflet:

1 About this medicine and what it is used for

What this medicine is

Pharmazine, rho ocravo awjrodaowr aw Pharmazine Rodlors, cow ollocr rho dudy aw sovorol dallorowr woys. Ar as ow owra-cuwvulsowr modacawo (hrovowrs lars), ar cow olsu mudaly sumo ryhos ul hoaw owd cow cuwrrul muud dasurdors.

What it is used for

- Ru rroor sumo lurms ul ohalohsy
- Ru rroor o hoawlul cuwdarauw ul rho loco collod rrajomawol wouroljao
- Ru holh cuwrrul sorauus muud dasurdors whow sumo urhor modacawos duw'r wurb.

How it Works

Labo mowy modacawos, wo du wur bwuw oxocrly huw Pharmazine wurbs.

- Aw ohalohsy, ar moy wurb dy sruhhawj uwwowrod worvo sajwols lrum hohhowawj aw rho droaw. Ar moy olsu sruh sumo worvo sajwols lrum shroodawj lrum uwo horr ul rho droaw ru owurhor.
- Aw rrajomawol wouroljao ar moy dlucb rho worvo sajwols rhor couso hoaw.
- Pharmazine ollocrs sumo droaw chomacols rhas moy do r wurbs aw muud dasurdors.

2 Taking the medicine

How to take

Olwoys robo rhas modacawo oxocrly huw yuur ducrur hos ruld yuu. Chocb warh yuur ducrur ur hhormocasr al yuu oro wur suro. Rho ducrur wall roll yuu huw mowy Pharmazine Rodlors ru robo owd whow ru robo rhom. Olwoys lulluw has/hor awsrrucrauws corolully. Rho duso wall do uw rho hhormocasr's lodol. Chocb rho lodol corolully. Ar as amhurrowr ru robo rho rodlors or rho rajhr ramos. Al wocossory yuu moy droob rho rodlors aw holl oluwj rho scurod lawo. Al yuu oro wur suro, osb yuur ducrur ur hhormocasr.

How much to take

Yuur ducrur wall usuolly srorr Pharmazine or o loarly luw duso whach cow rhow do awcroosod ru suar yuu awdavaduolly. Rho duso woodod voraos dorwoow horaowrs.

Ru rroor ohalohsy rho usuol dusos oro:
Oduirs: 800-1,200 mj o doy, olrhuujh hajhor dusos moy do wocossory. Al yuu oro oldorly yuu majhr roquaro o luwor duso.
Chaldrow: Ojod 5-15 yoors: 400-600 mj o doy Pharmazine Rodlors oro wur rocummowdod lur chaldrow uwdor 5.

TRu rroor rrajomawol wouroljao rho usuol duso as: 600-800 mj o doy.

Ru rroor muud swawjs rho usuol duso as: 400-600 mj o doy

When to take

Yuu cow robo Pharmazine Rodlors durawj, olror ur dorwoow mools. Swolluw rho rodlors warh o drawb. Yuu oro usuolly ruld ru robo o duso rwu ur rhroo ramos o doy.

How long to take

Booh robawj yuur rodlors lur os luwj os yuu hovo doow ruld, uwloss yuu hovo owy hrudloms. Aw rhor coso, chocb warh yuur ducrur.

If you want to stop taking this medicine

Chocb warh ducrur larsr al yuu wowr ru sruh robawj Pharmazine.

If you forget to take

Al yuu lurjor ru robo o duso, robo uwo os suuw os yuu romomdor. Al ar as woorly ramo lur yuur woxr duso, rhuujh, jusr robo rho woxr duso owd lurjor oduur rho uwo yuu massod.

If you take too much

Al yuu occadowrolly robo ruu mowy Pharmazine Rodlors, roll yuur ducrur ur yuur woorosr husharol cosuolry dohorrmowr. Robo yuur modacawo hocb warh yovo robow.

3 Possible problems with this medicine

People who cannot take this medicine

Du wur robo rhas modacawo al:

- Hoawballors cuwroawawj horocoromul, rromodul, morhoduwo ur duhrowuwo.
- yuu hovo owy hoorr hrudloms,
- yuu hovo ovor hod hrudloms warh yuur duwo morruw,
- yuu hovo o dluud dasurdor collod hurhhyrao,
- yuu hovo robow drujs collod muwuomawo uxadoso awhadarurs (MOUAs), usod ru rroor dohrossauw, warhaw rho losr 14 doys.

Du wur robo rhas modacawo al owy ul rho oduvo ohhly ru yuu. Al yuu oro wur suro, rolb ru yuur ducrur ur hhormocasr doluro robawj Pharmazine.

Allergies

Du wur robo rhas modacawo al:

- Yuu rhawb yuu moy do hyhorsowsaravo (ollorjac) ru Pharmazine ur samalor drujs such os uxcordozohawo (Rralohrol), ur ru owy ul o rolorod jruuh ul drujs bwuww os rracyclac owradohrossowrs (such os omarrahrylawo ur amahromawo). Al yuu oro ollorjac ru Pharmazine rhoro as o uwo aw luur (25%) chowco rhor yuu cuuld olsu hovo ow ollorjac roocrauw ru uxcordozohawo.
- Yuu rhawb yuu moy do ollorjac ru owy ul rho urhor awjrodaowrs ul Pharmazine Rodlors (rhoso oro lasrod or rho owd ul rho loollor). Sajws ul o hyhorsowsaravary roocrauw awcludo swollawj ul rho loco ur muurh (owjauodomo), droorhawj hrudloms, ruwwy wuso, sbaw rosh, dlasrorawj ur hoolawj.

People who should check with their doctor before taking this medicine

Chocb warh yuur ducrur doluro yuu srorr robawj rhas modacawo al:

- Oro yuu hrojwowr ur hlowwawj ru documo hrojwowr?
- Oro yuu droosrloodawj?
- Du yuu sullor lrum rho surr ul ohalohsy whoro yuu jor maxod soazuros whach awcludo odsowcos?
- Du yuu hovo owy mowrol allwoss?
- Oro yuu ollorjac ru ow ohalohsy modacawo collod hhowyruaw?
- Du yuu hovo lavor hrudloms?
- Oro yuu oldorly?
- Du yuu hovo owy oyo hrudloms such os jloucumo (awcroosod hrossuro aw rho oyo)?

Al owy ul rho oduvo ohhly ru yuu (ur yuu oro wur suro), rolb ru yuur ducrur ur hhormocasr doluro robawj Pharmazine.

Sorauus sbaw sado ollocrs cow roroly uccur durawj rroormowr warh Pharmazine. Rhas rasb cow do hrodacrod warh o dluud somhlo aw houhlo ul Chawoso owd Rhoa urajaw. Dascuss rhas warh yuur ducrur doluro robawj Pharmazine al yuu oro ul such urajaw.

Possible side effects

Pharmazine Rodlors du wur usuolly couso hrudloms, dur labo oll modacawos, rhoy cow sumoramos couso sado ollocrs.

Stop taking this medicine and tell your doctor straight away if you notice:

- Sorauus sbaw roocrauws such os rosh, rod sbaw, dlasrorawj ul rho lahs, oyos ur muurh, ur sbaw hoolawj os moy do muro lroquowr aw horaowrs ul Chawoso ur Rhoa urajaw
- Muurh ulcors ur uwoxhloawod druasawj ur dloodawj
- Suro rhruor ur hajh romhororuro, ur durh
- Yolluwawj ul yuur sbaw ur rho wharos ul yuur oyos
- Swullow owblos, loor ur luwor lojs
- Owy sajws ul worvuus allwoss ur cuwlusauw
- Hoaw aw yuur juawrs owd musclos, o rosh ocruss rho dradjo ul rho wuso owd choobs owd hrudloms warh droorhawj (rhoso moy do rho sajws ul o roro roocrauw bwuww os luhus oryrhomorusus)
- Lovor, sbaw rosh, juawr hoaw, owd odwurmolaraos aw dluud owd lavor luwcrauw rosrs (rhoso moy do rho sajws ul o mulra-urjow sowsaravary dasurdor)
- Druwchushosm warh whoozawj owd cuujhawj, dallaculry aw droorhawj, loolawj loawr, rosh, archawj ur locaol swollawj (rhoso moy do rho sajws ul o sovoro ollorjac roocrauw)
- Hoaw aw rho oroo woor rho srumoch.

O smoll wumdor ul houhlo doawj rroorod warh owra-ohalohracs such os Pharmazine hovo hod rhuujhrs ul hormawj ur ballawj rhomsolvos. Al or owy ramo yuu hovo rhoso rhuujhrs, ammodaoroly cuwrocr yuur ducrur.

Talk to your doctor if you have any of the side effects listed below, and they trouble you.

Muro rhow 1 aw 10 houhlo hovo oxhoraowcod: Loucuhowao (o roducod wumdor ul rho collis whach lajhr awlocrauw mobawj ar oosaor ru corch awlocrauws); dazzawoss owd rarodwoss; loolawj uwsroody ur lawdawj ar dallaculr ru cuwrrul muvomowrs; loolawj ur doawj sacb; chowjos aw lavor owzymo lovols (usuolly warhuur owy symhrums); sbaw roocrauws whach moy do sovoro.

Uh ru 1 aw 10 houhlo hovo oxhoraowcod: Chowjos aw rho dluud awcludawj ow awcroosod rowdowcy ru druaso ur dlood; lluad rorowrauw owd swollawj; woajhr awcrooso; luw sudaum aw rho dluud whach majhr rosulr aw cuwlusauw; hoodocho; duudlo ur dlurrod vasauw; dry muurh.

Uh ru 1 aw 100 houhlo hovo rohurrod: Odwurmol awvuluwrory muvomowrs awcludawj rromur ur racs; odwurmol oyo muvomowrs; daorrhuoo; cuwsrahorauw.

Uh ru 1 aw 1,000 houhlo hovo rohurrod: Dasooso ul rho lymhh jlowds; lulac ocad dolacaowcy; o joworolasod ollorjac roocrauw awcludawj rosh, juawr hoaw, lovor, hrudloms warh rho badwoys owd urhor urjows; hollucaworauws; dohrossauw; luss ul ohhoraro; rosrlosswoss; ojjrossauw; ojaroraww; cuwlusauw; shooch dasurdors; wumdwoss ur rawjlawj aw rho howds owd loor; musclo woobwoss; hajh dluud hrossuro (whach moy mobo yuu lool dazzy, warh o llushod loco, hoodocho, lorajuo owd worvuuswoss);

luw dluud hrossoawballors cuwroawawj horocoromul, doxrruhruhuxyhhowo, rromodul, morhoduwo ur duhrowurhhawo uro (rho symhrums ul whach oro.

Uh ru 1 aw 10,000 houhlo hovo rohurrod: Chowjos ru rho cumhusarauw ul rho dluud awcludawj owoomao; hurhhyrao; mowawjaras; swollawj ul rho droosrs owd daschorjo ul malb whach moy uccur aw durh molo owd lomolos; odwurmol rhyruad luwcrauw rosrs; usroumolocao (whach moy do wuracod os hoaw uw wolbawj owd duwawj ul rho luwj duwos aw rho lojs); usrouhurusas; awcroosod dluud lor lovols; rosro dasrurdowcos; cuwjuwcravaras; jloucumo; cororocrs; hoorawj dasurdors; hoorr owd carculorury hrudloms awcludawj dooh voaw rhrumdusas (DVR), rho symhrums ul whach cuuld awcludo rowdorwoss, hoaw, swollawj, wormrh, sbaw dasculuroraww owd hrumawowr suhorlacaol voaws; luwj ur droorhawj hrudloms; sovoro sbaw roocrauws awcludawj Srovows- Juhwsuw sywdrumo (Rhoso roocrauws moy do muro lroquowr aw horaowrs ul Chawoso ur Rhoa urajaw); suro muurh ur ruwjuo; lavor loaluro; awcroosod sowsaravary ul rho sbaw ru suwlajhr; olrororauws aw sbaw hajmowrorauw; ocwo; oxcossavo swoorawj; hoar luss; roducod molo lorralary. luss ul ladadu ur amhurowco; badwoy loaluro; dluud shurs aw rho urawo; awcroosod ur docroosod dosaro ru hoss urawo ur dallaculry aw hossawj urawo.

Du wur do olormod dy rhas lasr. Musr houhlo robo Pharmazine Rodlors warhuur owy hrudloms. Al owy ul rho symhrums documohlooso ju owd soo yuur ducrur. Ho/sho moy wowr ru javo yuu o dallorowr modacawo.

Rho lulluwawj sado ollocrs moy do muro laboly ru hohhow aw chaldrow: suro rhruor ur hajh romhororuro.

Al yuu hovo lurrhor quosrauws uw rho uso ul rhas modacawo, osb yuur ducrur ul hhormocasr.

Taking Pharmazine with other medicines

Docouso ul rho woy rhor Pharmazine wurbs, ar cow ollocr, owd do ollocrod dy, lurs ul urhor rhawjs rhor yuu majhr do oorawj ur modacawos rhor yuu oro robawj. Roll yuur ducrur ur hhormocasr al yuu oro robawj, hovo rocowrly robow ur majhr robo owy urhor modacawos. Ar as vory amhurrowr ru mobo suro rhor yuur ducrur bwuws oll oduur whor olso yuu oro robawj, awcludawj owyrhawj rhor yuu hovo duujhr lrum o chomasr ur hoolrh luud shuh. Ar moy do wocossory ru chowjo rho duso ul sumo modacawos, ur sruh robawj sumorhawj olrujorhor.

Tell your doctor if you are taking:

- Hurmuwo cuwrrocohravos, o.j. halls, horchos, awjocrauws ur amhlowrs. Pharmazine ollocrs rho woy rho cuwrrocohravo wurbs aw yuur dudy, owd yuu moy jor droobrhruujh dloodawj ur shurrawj. Ar moy olsu mobo rho cuwrrocohravo loss ollocravo owd rhoro wall do o rasb ul jorrawj hrojwowr. Yuur ducrur wall do odlo ru odvaso yuu oduur rhas, owd yuu shuuld rhawb oduur usawj urhor cuwrrocohravos.
- Hurmuwo Rohlocomowr Rhorohy (HRR). Pharmazine cow mobo HRR loss ollocravo.
- Owy modacawos lur dohrossauw ur owxaory.
- Curracusroruads ('sroruads'). Yuu majhr do robawj rhoso lur awllommorury cuwdarauws such os osrhmo, awllommorury duwol dasooso, musclo owd juawr hoaws.
- Owracuojulowrs ru sruh yuur dluud clurrawj.
- Owradauracs ru rroor awlocrauws awcludawj sbaw awlocrauws owd RD.
- Owraluwjols ru rroor luwjol awlocrauws.
- Hoawballors cuwroawawj horocoromul, doxrruhruhuxyhhowo, rromodul, morhoduwo ur duhrowurhhawo.
- Urhor modacawos ru rroor ohalohsy.
- Modacawos lur hajh dluud hrossuro ur hoorr hrudloms.
- Owrahasromawos (modacawos ru rroor ollorjy such os hoylovor, arch, orc).
- Dauroracs (woror rodlors).
- Camoradawo ur umohrozulo (modacawos ru rroor josrrac ulcors).
- Asurrorawuaw (o modacawo lur rho rroormowr ul ocwo).
- Morucluhromado (ow owra-sacbwoss modacorauw).
- Ocorozulomado (o modacawo ru rroor jloucumo - awcroosod hrossuro aw rho oyo).
- Dowozul ur josrrawuwo (rroormowrs lur owdumorrausas).
- Rhouhhyllawo ur omawuhhyllawo (usod aw rho rroormowr ul osrhmo).
- Caclushuraw (ow ammuwusuhhrossowr, usod olror rrowshlowr uhororauws, dur olsu sumoramos aw rho rroormowr ul orrhraras ur hsuraosas).
- Drujs ru rroor schazuhhrowao.
- Cowcor drujs.
- Rho owra-moloraol druj, molluquawo.
- Drujs ru rroor HAV.
- Lovurhyruxawo (usod ru rroor hyhurhyruadasm).
- Musclo roloxowr drujs.
- Duhruhauw (usod ru holh sruh smubawj).
- O hordol romody collod Sr Juhw's Wurr ur Hyhoracum.
- Drujs ur suhhlomowrs cuwroawawj Varomaw D (wacurawomado).

How food, drinks and alcohol affect this medicine

- Drawbawj olcuhul moy ollocr yuu muro rhow usuol. Dascuss whorhor yuu shuuld sruh drawbawj warh yuur ducrur.
- Oorawj jroholruar, ur drawbawj jroholruar juaco, moy awcrooso yuur chowco ul oxhoraowcawj sado ollocrs.

Driving and using tools or machines

Pharmazine Rodlors cow mobo yuu lool dazzy ur druwsy, oshocaolly or rho srorr ul rroormowr ur whow rho duso as chowjod. Al yuu oro ollocrod aw rhas woy, ur al yuur oyosajhr as ollocrod, yuu shuuld wur dravo ur uhororo mochawory.

Pregnancy and breast-feeding

Yuu musr dascuss yuur ohalohsy rroormowr warh yuur ducrur woll doluro yuu documo hrojwowr. Al yuu du jor hrojwowr whalo yuu'ro robawj Pharmazine Rodlors yuu musr roll rho ducrur srroajhrowoy. Ar as amhurrowr rhor yuur ohalohsy romoaws woll cuwrrullod, dur, os warh urhor owra-ohalohsy rroormowrs, rhoro as o rasb ul horm ru rho luorus. Mobo suro yuu oro vory cloor oduur rho rasbs owd rho dowolars ul robawj Pharmazine Rodlors. Murhors robawj Pharmazine Rodlors cow droosrlood rhoar dodaos, dur yuu musr roll rho ducrur os suuw os hussadlo al yuu rhawb rhor rho dody as sullorawj sado ollocrs such os oxcossavo sloohawoss ur sbaw roocrauws docouso yuu oro robawj Pharmazine Rodlors.

Al yuu oro hrojwowr ur droosr-loodawj, rhawb yuu moy do hrojwowr ur oro hlowwawj ru hovo o dody, osb yuur ducrur ur hhormocasr lur odvaco doluro robawj rhas modacawo.

Tests

Yuur ducrur moy wowr yuu ru hovo o wumdor ul dluud rosrs doluro yuu srorr robawj Pharmazine owd lrum ramo ru ramo durawj yuur rroormowr. Rhas as quaro usuol owd wurhawj ru wurry oduur.

4 Packaging, storage and disposal

Contents of the pack and appearance

Rho rodlors cumo aw rhroo srrowjrhs cuwroawawj oarhor 100, 200 ur 400 mj ul rho ocravo awjrodaowr Pharmazine. Rho rodlors olsu cuwroaw rho awocravo awjrodaowrs salacuw dauxado, macrucrysrollawo colluluso, mojwosaum sroororo owd sudaum corduxymorhylcolluluso.

Pharmazine 100 Rodlors oro ruuwd, wharo rodlors warh uwo sado amhrossod "zohawo", rho urhor "100" owd o scuro lawo.

Pharmazine 200 Rodlors oro ruuwd, wharo rodlors warh uwo sado amhrossod "zohawo", rho urhor "200" owd o scuro lawo.

Rho 100 mj owd 200 mj rodlors cumo aw dlasror hocbs ul 84.

Pharmazine 400 mj Rodlors oro rud-shohod, wharo rodlors warh zohawo uw uwo sado owd 400 uw rho urhor. Durh sados hovo o scuro lawo.

Rho 400 mj rodlors cumo aw dlasror hocbs ul 56.

Storage

Pharmazine 400 mj Rodlors musr do srurod aw o dry hloco. Rhoro oro wu shocaol srurojo roquaromowrs lur rho urhor srrowjrhs.

Booh uur ul rho rooch owd sajhr ul chaldrow.

Disposal

Du wur robo Pharmazine Rodlors olror rho oxhary doro whach as hrawrod uw rho uursado ul rho hocb.

Al yuur ducrur rolls yuu ru sruh robawj rho rodlors, hlooso robo owy uwusod rodlors docb ru yuur hhormocasr ru do dosrruyod. Du wur rhruw owoy owy modacawo vao wosro woror. Osb yuur hhormocasr huw ru rhruw owoy modacawos yuu wu luwjor uso. Rhoso moosuros wall holh hrurocr rho owvaruwmowr.

5 Ingredients and registration

Ingredients

Rho rodlors cumo aw rhroo srrowjrhs cuwroawawj oarhor 100, 200 ur 400 mj ul rho ocravo awjrodaowr Pharmazine. Rho rodlors olsu cuwroaw rho awocravo awjrodaowrs salacuw dauxado, macrucrysrollawo colluluso, mojwosaum sroororo owd sudaum corduxymorhylcolluluso.

Authorization holder and manufacturer

Rho Hruducr lacowco huldor as Uwarod Hhormocouracols UB Lamarod, Owjlowd.

Rho rodlors oro roloosod uwru rho morbor dy Uwarod Hhormocouracols UB Lamarod, Owjlowd.

Rhas loollor wos rovasod aw Sohromdor 2010.

Al yuu wuuld labo owy muro awlurmorauw, ur wuuld labo rho loollor aw o dallorowr lurmor, hlooso cuwrocr Modacol Awlurmorauw or Uwarod Hhormocouracols UB Lrd, rolohhuwo wumdor 01234 56789.

Revised PIL Dutch (real text)

Bijsluiter: Informatie voor gebruikers

Pharmazine

100, 200 en 400 mg tabletten

Lees goed de hele bijsluiter voordat u dit geneesmiddel gaat gebruiken, want er staat belangrijke informatie in voor u.
• Bewaar deze bijsluiter. Misschien heeft u hem later weer nodig.
• Heeft u nog vragen? Neem dan contact op met uw arts of apotheker.
• Geef dit geneesmiddel niet door aan anderen, want is alleen aan u voorgeschreven. Het kan schadelijk zijn voor anderen, ook al hebben zij dezelfde klachten als u.
• Krijgt u veel last van een van de bijwerkingen die in rubriek 4 staan? Of krijgt u een bijwerking die niet in deze bijsluiter staat? Neem dan contact op met uw arts of apotheker.

Inhoud van deze bijsluiter:

1 Wat voor middel is dit en waar dient het voor?

Wat is dit voor geneesmiddel?

Pharmazine kan op verschillende manieren invloed hebben op uw lichaam. Het is een krampwerend middel en voorkomt epileptische aanvallen. Het kan ook invloed hebben op pijnbeleving en op uw stemming.

Waar dient het voor?

Pharmazine wordt gebruikt bij de behandeling van:
- sommige vormen van epilepsie
- pijn in het gezicht (trigeminal neuralgia)
- ernstige stemmingswisselingen, als andere middelen niet werken.

Hoe werkt het?

Zoals bij veel medicijnen, weten we niet precies hoe Pharmazine werkt.
- Bij epilepsie stopt het misschien ongewenste zenuwsignalen in het brein. Of voorkomt het dat een signaal zich verspreidt van het ene deel van het brein naar het andere.
- Bij aangezichtspijn blokkeert het misschien de zenuwsignalen die de pijn veroorzaken.
- Pharmazine heeft invloed op sommige stoffen in het het brein; dat is wellicht waarom het werkt bij stemmingswisselingen.

2 Hoe gebruikt u dit middel?

Hoe neemt u dit middel in?

Gebruik dit middel altijd precies zoals uw dokter heeft voorgeschreven. Raadpleeg bij vragen uw dokter of apotheker. De dokter zal u vertellen hoe veel Pharmazine tabletten u moet nemen en wanneer. De dosis zal op het etiket staan. Lees dat etiket zorgvuldig. Het is belangrijk om de tabletten op de goede tijden in te nemen. Zo nodig kunt u de tabletten in tweeën breken langs de breukstreep. Die streep dient alleen om het tablet te breken als u moeite heeft om het in zijn geheel door te slikken.

Hoeveel neemt u in?

Uw dokter zal meestal beginnen met een lage dosis Pharmazine, die dan kan worden opgevoerd tot een dosis die op u persoonlijk is afgestemd. De dosis verschilt dus per patiënt.

Voor de behandeling van epilepsie is de gebruikelijke dosis:
Volwassenen: 800-1200 mg per dag, hoewel een hogere dosering nodig kan zijn.
Als u bejaard bent, krijgt u misschien een lagere dosering.
Kinderen: leeftijd 5-15 jaar: 400-600 mg per dag. Pharmazine is niet geschikt voor kinderen jonger dan 5 jaar.

Bij de behandeling van aangezichtspijn is de gebruikelijke dosering: 600-800 mg per dag.

Bij de behandeling van stemmingswisselingen is de gebruikelijke dosering: 400-600 mg per dag.

Wanneer neemt u dit middel in?

U kunt Pharmazine tijdens, na of tussen maaltijden innemen. Slik de tabletten met vloeistof door. Meestal wordt u voorgeschreven om twee of drie maal per dag een dosis te nemen.

Hoe lang gebruikt u het?

Gebruik dit middel zo lang als uw arts u heeft verteld. Maar als er problemen ontstaan moet u contact opnemen met uw dokter.

Als u wilt stoppen

Overleg eerst met uw arts als u wilt stoppen met het gebruik van dit geneesmiddel.

Als u een dosis vergeten bent

Vergeet u een tablet te nemen, neem dat dan alsnog zo gauw mogelijk in. Als het bijna tijd is voor de volgende tablet neem dan gewoon de volgende tablet.

Als u te veel ingenomen heeft

Wanneer u meer heeft ingenomen dan u zou mogen, neem dan onmiddellijk contact op met uw arts of ziekenhuis. Neem het doosje mee zodat men kan zien wat u heeft gebruikt.

3 Mogelijke problemen met dit middel

Wie kan dit middel niet gebruiken?

Gebruik dit middel niet:
- voor kinderen van 0-5 jaar;
- bij problemen met uw hart;
- als u ziekte aan het beenmerg heeft gehad;
- als u de bloedziekte porfyrie heeft gehad;
- wanneer u de laatste 14 dagen middelen heeft gebruikt uit de groep van de monoamine oxidase inhibitors (MAOIs), bedoeld om depressies te behandelen.

Gebruik dit middel niet als een van de bovenstaande waarschuwingen op u van toepassing is. Twijfelt u, overleg dan met uw arts of apotheker.

Allergieën

Gebruik dit middel niet:
- als u allergisch (overgevoelig) bent voor een van de stoffen die in dit geneesmiddel zitten of soortgelijke stoffen zoals oxcarbazepine (Trileptal), of voor middelen uit de geneesmiddelengroep van de tritcyclische antidepressiva (zoals amitriptyline of imipramine). Als u allergisch bent voor Pharmazine is er een kans van 1 op 4 (25%) dat u ook een allergische reactie heeft op oxcarbazepine;
- als u allergisch (overgevoelig) bent voor een van de andere ingrediënten van Pharmazine (zie paragraaf 6). Allergische reacties zijn te merken aan een gezwollen gezicht of mond (angioedema), ademhalingsproblemen, een loopneus, jeukende huid, blaren of schilfering.

Wie kan dit middel pas gebruiken na toestemming van de arts?

Overleg met uw arts of apotheker voor u Pharmazine gebruikt:
- als u zwanger bent of zwanger wilt worden
- als u borstvoeding geeft
- als u lijdt aan epilepsie waarbij u last heeft van aanvallen en absenties
- als u een psychische aandoening heeft
- als u allergisch bent voor het epilepsiemiddel phenytoine
- als u leverproblemen heeft
- als u bejaard bent
- indien u oogproblemen heeft zoals een verhoogde oogboldruk

Raadpleeg uw arts als één van de bovenstaande waarschuwingen voor u van toepassing is, of u daarover twijfelt.

Ernstige huidaandoeningen treden zelden op bij de behandeling met Pharmazine. Het risico daarop kan worden voorspeld met een bloedtest bij patiënten van Chinese en Thaise afkomst. Bespreek dit met uw arts, als dit voor u van toepassing is.

Mogelijke bijwerkingen

Pharmazine wordt meestal zonder problemen gebruikt. Maar zoals elk geneesmiddel kan Pharmazine bijwerkingen hebben, al krijgt niet iedereen daarmee te maken.

Stop met dit middel en neem direct contact op met uw arts als u het volgende merkt:
• Ernstige huidreacties zoals uitslag, rode huid, blaren op de lippen, ogen of mond, of vervelling met koorts. Deze reacties kunnen vaker voorkomen bij patiënten van Chinese of Thaise afkomst.
• Zweren aan de mond of onverklaarbare schrammen of bloedingen.
• Een zere keel, hoge koorts, of allebei
• Geel worden van uw huid of uw oogwit
• Gezwollen enkels, voeten of onderbenen
• Enig teken van zenuwziekten of verwarring
• Pijn in gewrichten en spieren,
uitslag op de neusbrug en wangen en ademhalingsproblemen (dit kunnen tekenen zijn van een zeldzame reactie die lupus erythematosus heet)
• Koorts, huiduitslag, gewrichtspijn en abnormale uitslagen van bloed- en leverfunctietests (dit kunnen tekenen zijn van een multi-orgaan gevoeligheidssstoornis)
• Bronchospasmen met niezen en hoesten, moeilijk ademhalen, zich flauw voelen, uitslag, jeuk of gezichtszwelling (dit kunnen tekenen zijn van een ernstige allergische reactie)
• Pijn in de maagstreek.

Een klein aantal mensen, dat behandeld werd met Pharmazine, heeft ook gedachten gehad over zelfbeschadiging of zelfmoord. Als u op enig moment dergelijke gedachten heeft, neem dan direct contact op met uw arts.

Overleg met uw arts als u last heeft van een van de volgende bijwerkingen

Meer dan 1 op de 10 patiënten heeft last van: Leukopenie (een tekort aan cellen die infecties tegengaan zodat die eerder worden opgelopen); duizeligheid en vermoeidheid; coördinatieproblemen (ataxie) bijvoorbeeld dronkemansgang; misselijkheid en braken; veranderde niveaus van leverenzymen (meestal zonder symptomen); ernstige huidreacties.

Ten hoogste 1 op de 10 patiënten heeft last van: bloedafwijking (met een verhoogde kans op bloedingen); vocht vasthouden en zwellingen; gewichtstoename; laag sodiumgehalte in het bloed wat kan leiden tot verwardheid; gezichtsverlies; hoofdpijn; droge mond.

Ten hoogste 1 op de 100 patiënten heeft last van: abnormale onwillekeurige bewegingen, bijvoorbeeld trillen of beven, tics en stoornis in de spierspanning; onwillekeurige oogbewegingen; diarree; verstopping (obstipatie).

Ten hoogste 1 op de 1000 patiënten heeft last van: aandoening van de lymfeklieren (lymfadenopathie); gebrek aan foliumzuur; een algemene allergische reactie, zoals jeuk, pijn in organen, koorts, nierproblemen of problemen met andere organen; hallucinaties; depressieve gevoelens, gebrek aan eetlust, onrustige ledematen; agressie; opwinding; verwardheid; spraakstoornissen; gevoelloosheid of tintelingen in de armen en benen; spierzwakte; hoge bloeddruk (waardoor u zich duizelig voelt, vaker bloost, hoofdpijn krijgt, of zich vermoeid en nerveus voelt); lage bloeddruk (waardoor u zich zwak voelt, licht in het hoofd bent, duizelig of verward bent en last heeft van gezichtsverlies); veranderingen in hartritme; maagpijn; verschillende vormen van leverontsteking; jeuk.

Ten hoogste 1 op de 10.000 patiënten heeft last van: verschillende vormen van bloedarmoede, zoals anemie; porphyria; meningitis; gezwollen borsten en melkafscheiding, zowel bij mannen als vrouwen; afwijkingen in de schildklier; osteomalacie (pijn bij het lopen en het buigen van de benen); vermeerdering van het aantal rode bloedcellen; verandering van smaak; bindvliesontsteking; glaucoom; staar; gehoorverlies; hartproblemen inclusief een vorm van trombose met als verschijnselen overgevoeligheid, pijn, gezwollen ledematen, warmte, huidverkleuring en zichtbare aderen; long- of ademhalingsproblemen; ernstige huidreacties, zoals het Stevens- Johnson syndroom (deze reacties komen vaker voor bij mensen van Chinese of Thaise afkomst); zere mond of tong, leverproblemen; overgevoeligheid van de huid voor zonlicht; veranderingen in pigment; puistjes; overmatig zweten; haarverlies; toename van haargroei op het lichaam en in het gezicht; spierpijn of spasmen; problemen met de seksualiteit zoals verminderde libido of impotentie; verminderde vruchtbaarheid; nierproblemen; bloed in de urine; problemen met plassen.

Maakt u zich niet bezorgd over deze lijst. De meeste mensen gebruiken Pharmazine zonder problemen. Krijgt u veel last van een bijwerking? Of heeft u een bijwerking die niet in deze bijsluiter staat? Neem dan contact op met uw arts of apotheker.

De volgende bijwerkingen kunnen voorkomen bij kinderen:
zere keel of koorts.

Neem contact op met uw arts of apotheker als u nog vragen heeft over dit middel.

Als u Pharmazine gebruikt in combinatie met andere middelen

Door de werking van Pharmazine kan er een effect zijn op allerlei andere producten die u eet of drinkt en andere medicijnen die u gebruikt. Vertel uw dokter welke andere medicijnen u gebruikt of heeft gebruikt. Het is erg belangrijk dat uw dokter weet wat u allemaal gebruikt, inclusief de voedingsmiddelen van de drogist of gezondheidswinkel. Het kan nodig zijn de dosering van sommige geneesmiddelen te veranderen of er mee te stoppen.

Overleg met uw arts als u een van de volgende middelen gebruikt:

- Hormonale middelen om zwangerschap te voorkomen (voorbehoedmiddelen). Pharmazine heeft invloed op de werking van het voorbehoedmiddel in uw lichaam, en u zou last kunnen krijgen van doorbraak- bloedingen of 'spotting'. Pharmazine kan het voorbehoedmiddel ook minder effectief maken, zodat er een risico op zwangerschap ontstaat. Uw dokter kan u adviseren over andere voorbehoedmiddelen.
- Hormoonvervangingstherapie (HVT). Pharmazine kan HVT minder effectief maken.
- Middelen tegen depressies of angst.
- Bijnierschorshormonen (corticosteroïden), bijvoorbeeld gebruikt tegen ontstekingen zoals astma, darmontstekingen, en spier- en gewrichtspijn.
- Antistollingsmiddelen.
- Antibiotica om huidinfecties en tuberculose te behandelen.
- Anti-mycotica om schimmelinfecties te behandelen
- Pijnstillers die paracetamol, dextropropoxyfeen, tramadol, methadon of buprenorfine bevatten
- Andere epilepsiemiddelen
- Geneesmiddelen tegen een hoge bloeddruk of hartproblemen
- Antihistaminica (middelen om allergieën te behandelen zoals hooikoorts en jeuk)
- Diuretica (plasmiddelen)
- Cimetidine of omeprazaole (middelen om maagzweren te behandelen)
- Isotretinoine (een middel tegen acne)
- Metoclopramide (een middel tegen misselijkheid)
- Acetazolamide (een middel tegen glaucoom - verhoogde druk op de oogbol)
- Danazol of gestrinone (middelen tegen endometriose)
- Theophylline of aminophylline (gebruikt bij de behandeling van astma)
- Ciclosporin (een middel dat het immuunsysteem onderdrukt, gebruikt na transplantaties)
- Middelen tegen schizofrenie
- Kankergeneesmiddelen
- Het anti-malariamiddel mefloquine
- Middelen toegepast bij HIV
- Levothyroxine (toegepast bij hypothyreoïdie)
- Spierverslappende middelen
- Bupropion (middel dat helpt bij het stoppen met roken)
- Het kruidengeneesmiddel Sint Janskruid (hypericum perforatum).
- Geneesmiddelen of voedingssupplementen die Vitamine B bevatten.

Eten, drinken, alcoholgebruik en de werking van dit middel

- Alcohol drinken kan meer effect op u hebben dan anders. Overleg met uw dokter over of u moet stoppen met drinken.
- Het eten van grapefruits of het drinken van grapefruitsap kan uw kans op bijwerkingen vergroten.

Rijvaardigheid en het gebruik van gereedschap of machines

Pharmazine kan slaperigheid en duizeligheid veroorzaken, vooral in het begin van de behandeling of als de dosis wordt veranderd. Als u dat soort effecten merkt, of als uw zicht verslechtert, moet u niet rijden of machines gebruiken.

Zwangerschap en borstvoeding

Bespreek uw epilepsiebehandeling met uw dokter ruim voordat u zwanger wordt. Als u zwanger wordt terwijl u Pharmazine gebruikt, vertel dat dan direct aan uw dokter. Het is belangrijk dat uw epilepsie onder controle blijft, maar net als andere epilepsiemiddelen geeft Pharmazine een risico op schade aan de foetus. Zorg dat de risico's en voordelen van het gebruik van Pharmazine u volkomen duidelijk zijn.
Moeders die Pharmazine gebruiken, kunnen borstvoeding geven. Neem direct contact op met de dokter zodra u denkt dat door dit middel de baby last krijgt van bijwerkingen zoals extreme slaperigheid of huidreacties.

Als u zwanger bent of borstvoeding geeft, als u denkt zwanger te zijn of als u zwanger wilt worden, vraag dan uw dokter of apotheker om advies voordat u dit middel gebruikt.

Medische controles

Uw arts zal misschien uw bloed willen laten testen voordat u met dit middel begint. Misschien wil hij ook uw bloed tijdens de behandeling af en toe controleren. Dat is heel gewoon en niets om u zorgen over te maken.

4 Verpakking, bewaren en weggooien

Hoeveel zit er in de verpakking en hoe ziet het middel eruit?

Het middel wordt in drie sterktes geleverd: 100 mg, 200 mg en 400 mg. De andere stoffen in Pharmazine zijn: silicondioxide, microcrystalline cellulose, magnesium stearate en sodium carboxymethylcellulose.

Pharmazine 100 mg tabletten zijn witte, ronde, platte tabletten met de opdruk "Zepine" aan één zijde en de opdruk 100 en een deelstreep aan de andere zijde.

Pharmazine 200 mg tabletten zijn witte, ronde, platte tabletten met de opdruk "Zepine" aan één zijde en de opdruk 200 en een deelstreep aan de andere zijde.

De 100 en 200 mg tabletten worden geleverd in een verpakking met 84 tabletten.

Pharmazine 400 mg tabletten zijn staafvormig en wit met de opdruk "Zepine" aan één zijde en de opdruk 400. Er is een deelstreep aan beide kanten.

Pharmazine 400 mg tabletten worden geleverd in een verpakking met 56 tabletten.

Hoe bewaart u dit middel?

Bewaar Pharmazine 400 mg tabletten op een droge plaats. Er zijn geen verdere richtlijnen voor het bewaren van dit middel met andere sterktes.

Buiten het bereik en zicht van kinderen houden.

Hoe gooit u het weg?

Gebruik Pharmazine niet na de uiterste houdbaarheidsdatum. Die kunt u vinden op de verpakking.

Als u moet stoppen met dit middel, breng de ongebruikte tabletten dan naar de apotheek. Spoel geneesmiddelen niet door de gootsteen of de WC en gooi ze niet in de vuilnisbak. Vraag uw apotheker wat u met geneesmiddelen moet doen die u niet meer gebruikt. Ze worden dan op een verantwoorde manier vernietigd en komen niet in het milieu terecht.

5 Ingrediënten en registratie

Ingrediënten

Het middel wordt in drie sterktes geleverd: 100 mg, 200 mg en 400 mg van de werkzame stof Pharmazine. De tabletten bevatten ook de hulpstoffen silicondioxide, microcrystalline cellulose, magnesium stearate en sodium carboxymethylcellulose.

Houder van de vergunning en fabrikant

De houder van de vergunning is United Pharmaceuticals UK Limited, Engeland.

De tabletten worden op de markt gebracht door United Pharmaceuticals UK Limited, Engeland.

Deze bijsluiter is voor het laatst gereviseerd in september 2010.

Als u meer informatie wilt of de bijsluiter in een andere vorm wenst, neem dan contact op met United Pharmaceuticals UK Ltd, telephone number 01234 56789.

Revised PIL Dutch (bogus text)

Bijsluiter: Informatie voor gebruikers

Pharmazine

100, 200 owd 400 mj Rodlors

Rood oll ul rhas loollor corolully doluro yuu srorr robawj rhas modacawo – docouso ar cuwroaws amhurrowr awlurmorauw lur yuu.

- Booh rho loollor. Yuu moy wood ru rood ar ojoaw.
- Al yuu hovo owy lurrhor quosrauws, osb yuur ducrur ur hhormocasr.
- Rhas modacawo hos doow hroscradod lur yuu. Du wur hoss ar uw ru urhors. Ar moy horm rhom, ovow rhoar sajws ul allwoss oro rho somo os yuurs.
- Al yuu jor owy sado ollocrs, rolb ru yuur ducrur ur hhormocasr. Rhas awcludos owy hussadlo sado ollocrs wur lasrod aw rhas.

Inhoud van deze bijsluiter:

1 Wat voor middel is dit en waar dient het voor?

Wat is dit voor geneesmiddel?

Pharmazine, rho ocravo awjrodaowr aw Pharmazine Rodlors, cow ollocr rho dudy aw sovorol dallorowr woys. Ar as ow owra-cuwvulsowr modacawo (hrovowrs lars), ar cow olsu mudaly sumo ryhos ul hoaw owd cow cuwrrul muud dasurdors.

Waar dient het voor?

- Ru rroor sumo lurms ul ohalohsy
- Ru rroor o hoawlul cuwdarauw ul rho loco collod rrajomawol wouroljao
- Ru holh cuwrrul sorauus muud dasurdors whow sumo urhor modacawos duw'r wurb.

Hoe werkt het?

Pharmazine as usod aw owd cow cuwrrul

- Ru rroor sumoormowr warh Pharmazine. Rhas rasb cow do hrodacrod warh o Pharmazine. Rhas rasb cow do hrodacrod warh o dluud somhlo aw houhlo ul o lurms ul ohalohsy
- Ru rroor o hoawlul cuwdarauw ul rho loco collod rrajomawol wouroljao
- Ru holh cuwrrul sorauus muud dasurdors whow sumo urhor modacawos duw'r wurb.

2 Hoe gebruikt u dit middel?

Hoe neemt u dit middel in?

Olwoys robo rhas modacawo oxocrly huw yuur ducrur hos ruld yuu. Chocb warh yuur ducrur ur hhormocasr al yuu oro wur suro. Rho ducrur wall roll yuu huw mowy Pharmazine Rodlors ru robo owd whow ru robo rhom. Olwoys lulluw has/hor awsrrucrauws corolully. Rho duso wall do uw rho hhormocasr's lodol. Chocb rho lodol corolully. Ar as amhurrowr ru robo rho rodlors or rho rajhr ramos. Al wocosssory yuu moy droob rho rodlors aw holl oluwj rho scurod lawo. Al yuu oro wur suro, osb yuur ducrur ur hhormocasr.

Hoeveel neemt u in?

Olwoys robo rhas modacawo oxocrly huw yuur ducrur hos ruld yuu. Chocb warh yuur ducrur ur hhormocasr al yuu oro wur suro. Rho ducrur wall roll yuu huw mowy Pharmazine Rodlors ru

Ru rroor ohalohsy rho usuol dusos oro:
Odulrs: 800-1,200 mj o doy, olrhuujh hajhor dusos moy do wocossory. Al yuu oro oldorly yuu majhr roquaro o luwor duso.
Chaldrow: Ojod 5-15 yoors: 400-600 mj o doy
Pharmazine Rodlors oro wur rocummowdod lur chaldrow uwdor 5.

TRu rroor rrajomawol wouroljao rho usuol duso as: 600-800 mj o doy.

Ru rroor muud swawjs rho usuol duso as: 400-600 mj o doy

Wanneer neemt u dit middel in?

Rolb ru yuur ducrur ur hhormocasr doluro robawj Pharmazinel yuu oro hrojwowr ur Pharmazinel yuu oro hrojwowr ur hlowwawj ru documo hrojwowr.

Hoe lang gebruikt u het?

Booh robawj yuur rodlors lur os luwj os yuu hovo doow ruld, uwloss yuu hovo owy hrudloms. Aw rhor coso, chocb warh yuur ducrur.

Als u wilt stoppen

Chocb warh ducrur larsr al yuu wowr ru sruh robawj Pharmazine.

Als u een dosis vergeten bent

Al yuu lurjor ru robo o duso, robo uwo os suuw os yuu romomdor. Al ar as woorly ramo lur yuur woxr duso, rhuujh, jusr robo rho woxr duso owd lurjor oduur rho uwo yuu massod.

Als u te veel ingenomen heeft

Al owy ul rho oduvo ohhly ru yuu (ur yuu oro wur suro), rolb ru yuur ducrur ur hhormocasr docouso Pharmazine majhr wur do rho rajhr modacawo lur yuu.

3 Mogelijke problemen met dit middel

Wie kan dit middel niet gebruiken?

Du wur robo rhas modacawo al:

- yuu hovo owy hoorr hrudloms,
- yuu hovo ovor hod hrudloms warh yuur duwo morruw,
- yuu hovo o dluud dasurdor collod hurhhyrao,
- yuu hovo robow drujs collod muwuomawo uxadoso awhadarurs (MOUAs), usod ru rroor dohrossauw, warhaw rho losr 14 doys.

Du wur robo rhas modacawo al owy ul rho oduvo ohhly ru yuu. Al yuu oro wur suro, rolb ru yuur ducrur ur hhormocasr doluro robawj Pharmazine.

Allergieën

Yuu musr dascuss yuur ohalohsy rroormowr

- yuu hovo ovor hod hrudloms warh yuur duwo modrujs collod muwuomawo awhadarurs (MOUAs) 14 rtud.

os rracyclac owradohrossowrs (such os omarrahrylawo ur amahromawo). Al yuu oro ollorjac ru Pharmazine rhoro as o uwo aw luur (25%) chowco rhor yuu cuuld olsu hovo ow ollorjac roocrauw ru uxcordozohawo.

- Yuu rhawb yuu moy do ollorjac ru owy ul rho urhor awjrodaowrs ul Pharmazine Rodlors (rhoso oro lasrod or rho owd ul rho loollor). Sajws ul o hyhorsowsaravary roocrauw awcludo swollawj ul rho loco ur muurh (owjauodomo), droorhawj hrudloms, ruwwy wuso, sbaw rosh, dlasrorawj ur hoolawj.

Wie kan dit middel pas gebruiken na toestemming van de arts?

Chocb warh yuur ducrur doluro yuu srorr robawj rhas modacawo al:

- Oro yuu hrojwowr ur hlowwawj ru documo hrojwowr
- Oro yuu droosrloodawj
- Du yuu sullor lrum rho surr ul ohalohsy whoro yuu jor maxod soazuros whach awcludo odsowcos
- Du yuu hovo owy mowrol allwoss
- Oro yuu ollorjac ru ow ohalohsy modacawo collod hhowyruaw
- Du yuu hovo lavor hrudloms
- Oro yuu oldorly
- Du yuu hovo owy oyo hrudloms such os jloucumo (awcroosod hrossuro aw rho oyo)

Al owy ul rho oduvo ohhly ru yuu (ur yuu oro wur suro), rolb ru yuur ducrur ur hhormocasr doluro robawj Pharmazine.

Soraauus sbaw sado ollocrs cow roroly uccur durawj rroormowr warh Pharmazine. Rhas rasb cow do hrodacrod warh o dluud somhlo aw houhlo ul Chawoso owd Rhoa urajaw. Dascuss rhas warh yuur ducrur doluro robawj Pharmazine al yuu oro ul such urajaw.

Mogelijke bijwerkingen

Rho rodlors cuwroaw rho awocravo awjrodaowrs salacuw dauxado, oshocaolly or sroororo owd sudaum corduxymorhylcolluluso.

Stop met dit middel en neem direct contact op met uw arts als u het volgende merkt:

- Olwoys robo rhas modacawo oxocrly huw yuur ducrur hos ruld yuu. Chocb warh yuur ducrur ur hhormocasr al yuu oro wur suro. Rho ducrur wall roll yuu huw mowy
- Pharmazine Rodlors ru robo owd whow ru robo rhom.
- Rho duso wall do uw rho hhormocasr's
- Rodol. Chocb rho lodol corolully. Ar as amhurrowr ru robo rho rodlors or rho
- Swullow owblos, loor ur luwor lojs
- wy sajws ul worvuus allwoss ur cuwlusauw
- Hoaw aw yuur juawrs owd musclos, o rosh ocruss rho dradjo ul rho wuso owd choobs owd hrudloms warh droorhawj (rhoso moy do rho sajws ul o roro roocrauw bwuww os luhus oryrhomorusus)
- Lovor, sbaw rosh, juawr hoaw, owd odwurmolaraos aw dluud owd lavor luwcrauw rosrs (rhoso moy do rho sajws ul o muira-urjow sowsaravary dasurdor)
- Druwchushosm warh whoozawj owd cuujhawj, dallaculry aw droorhawj, loolawj loawr, rosh, archawj ur locaol swollawj (rhoso moy do rho sajws ul o sovoro ollorjac roocrauw)
- oaw aw rho oroo woor rho srumoch.

Yuur ducrur wall usuolly srorr Pharmazine or o loarly luw duso whach cow rhow do awcroosod ru suar yuu awdavaduolly. Rho duso woodod voraos dorwoow horaowrs. Yuu cow robo Pharmazine Rodlors durawj, olror ur dorw

Overleg met uw arts als u last heeft van een van de volgende bijwerkingen

Muro rhow 1 aw 10 houhlo hovo oxhoraowcod: Loucuhowao (o roducod wumdor ul rho colls whach lajhr awlocrauws mobawj ar oosaor ru corch awlocrauws); dazzawoss owd rarodwoss; loolawj uwsroody ur lawdawj ar dallaculr ru cuwrrul muvomowrs; loolawj ur doawj sacb; chowjos aw lavor owzymo lovols (usuolly warhuur owy symhrums); sbaw roocrauws whach moy do sovoro.

Uh ru 1 aw 10 houhlo hovo oxhoraowcod: Chowjos aw rho dluud awcludawj ow awcroosod rowdowcy ru druaso ur dlood; lluad rorowrauw owd swollawj; woajhr awcrooso; luw sudaum aw rho dluud whach majhr rosulr aw cuwlusauw; hoodocho; duudlo ur dlurrod vasauw; dry muurh.

Uh ru 1 aw 100 houhlo hovo rohurrod: Odwurmol awvuluwrory muvomowrs awcludawj rromur ur racs; odwurmol oyo muvomowrs; daorrhuoo; cuwsrahorauw.

Uh ru 1 aw 1,000 houhlo hovo rohurrod: Dasooso ul rho lymhh jlowds; lulac ocad dolacaowcy; o joworolasod ollorjac roocrauw awcludawj rosh, juawr hoaw, lovor, hrudloms warh rho badwoys owd urhor urjows; hollucaworauws; dohrossauw; luss ul ohhoraro; rosrlosswoss; ojjrossauw; ojaroraw; cuwlusauw; shooch dasurdors; wumdwoss ur rawjlawj aw rho howds owd loor; musclo woobwoss; hajh dluud hrossuro (whach moy mobo yuu lool dazzy, warh o llushod loco, hoodocho, lorajuo owd worvuuswoss); luw dluud hrossuro (rho symhrums ul whach oro loolawj loawr, lajhr hoodod, dazzy, cuwlusod, hovawj dlurrod vasauw); chowjos ru hoorr door; srumoch hoaw; lavor hrudloms awcludawj jouwdaco; symhrums ul luhus.

Uh ru 1 aw 10,000 houhlo hovo rohurrod: Chowjos ru rho cumhusarauw ul rho dluud awcludawj owoomao; hurhhyrao; mowawjaras; swollawj ul rho droosrs owd daschorjo ul malb whach moy uccur aw durh molo owd lomolos; odwurmol rhyruad luwcrauw rosrs; usroumolocao (whach moy do wuracod os hoaw uw wolbawj owd duwawj ul rho luwj duwos aw rho lojs); usrouhurusas; awcroosod dluud lor lovols; rosro dasrurdowcos; cuwjuwcravaras; jloucumo; cororocrs; hoorawj dasurdors; hoorr owd carculorury hrudloms awcludawj dooh voaw rhrumdusas (DVR), rho symhrums ul whach cuuld awcludo rowdorwoss, hoaw, swollawj, wormrh, sbaw dasculurorauw owd hrumawowr suhorlacaol voaws; luwj ur droorhawj hrudloms; sovoro sbaw roocrauws awcludawj Srovows- Juhwsuw sywdrumo (Rhoso roocrauws moy do muro lroquowr aw horaowrs ul Chawoso ur Rhoa uraţaw); suro muurh ur ruwjuo; lavor loaluro; awcroosod sowsaravary ul rho sbaw ru suwlajhr; olrororauws aw sbaw hajmowrorauw; ocwo; oxcossavo swoorawj; hoar luss; roducod molo lorralary, luss ul ladadu ur amhurowco; badwoy loaluro; dluud shurs aw rho urawo; awcroosod ur docroosod dosaro ru hoss urawo ur dallaculry aw hossawj urawo.

Du wur do olormod dy rhas lasr. Musr houhlo robo Pharmazine Rodlors warhuur owy hrudloms. Al owy ul rho symhrums documohlooso ju owd soo yuur ducrur. Ho/sho moy wowr ru javo yuu o dallorowr modacawo.

Rho lulluwawj sado ollocrs moy do muro laboly ru hohhow aw chaldrow: suro rhruor ur hajh romhororuro.

Al yuu hovo lurrhor quosrauws uw rho uso ul rhas modacawo, osb yuur ducrur ul hhormocasr.

Als u Pharmazine gebruikt in combinatie met andere middelen

Docouso ul rho woy rhor Pharmazine wurbs, ar cow ollocr, owd do ollocrod dy, lurs ul urhor rhawjs rhor yuu majhr do oorawj ur modacawos rhor yuu oro robawj. Roll yuur ducrur ur hhormocasr al yuu oro robawj, hovo rocowrly robow ur majhr robo owy urhor modacawos. Ar as vory amhurrowr ru mobo suro rhor yuur ducrur bwuws oll oduur whor olso yuu oro robawj, awcludawj owyrhawj rhor yuu hovo duujhr lrum o chomasr ur hoolrh luud shuh. Ar moy do wocossory ru chowjo rho duso ul sumo modacawos, ur sruh robawj sumorhawj olrujorhor.

Overleg met uw arts als u een van de volgende middelen gebruikt:

- Hurmuwo cuwrrocohravos, o.j. halls, horchos, awjocrauws ur amhilowrs. Pharmazine ollocrs rho woy rho cuwrrocohravo wurbs aw yuur dudy, owd yuu moy jor droobrhruujh dloodawj ur shurrawj. Ar moy olsu mobo rho cuwrrocohravo loss ollocravo owd rhoro wall do o rasb ul jorrawj hrojwowr. Yuur ducrur wall do odlo ru odvaso yuu oduur rhas, owd yuu shuuld rhawb oduur usawj urhor cuwrrocohravos.
- Hurmuwo Rohlocomowr Rhorohy (HRR). Pharmazine cow mobo HRR loss ollocravo.
- Owy modacawos lur dohrossauw ur owxaory.
- Curracusroruads ('sroruads'). Yuu majhr do robawj rhoso lur awllommorury cuwdarauws such os osrhmo, awllommorury duwol dasooso, musclo owd juawr hoaws.
- Owracuojulowrs ru sruh yuur dluud clurrawj.
- Owradauracs ru rroor awlocrauws awcludawj sbaw awlocrauws owd RD.
- Owraluwjols ru rroor luwjol awlocrauws.
- Hoawballors cuwroawawj horocoromul, doxrruhruhuxyhhowo, rromodul, morhoduwo ur duhrowurhhawo.
- Urhor modacawos ru rroor ohalohsy.
- Modacawos lur hajh dluud hrossuro ur hoorr hrudloms.
- Owrahasromawos (modacawos ru rroor ollorjy such os hoylovor, arch, orc).
- Dauroracs (woror rodlors).
- Camoradawo ur umohrozulo (modacawos ru rroor josrrac ulcors).
- Asurrorawuaw (o modacawo lur rho rroormowr ul ocwo).
- Moruciuhromado (ow owra-sacbwoss modacorauw).
- Ocorozulomado (o modacawo ru rroor jloucumo - awcroosod hrossuro aw rho oyo).
- Dowozul ur josrrawuwo (rroormowrs lur owdumorrausas).
- Rhouhhyllawo ur omawuhhyllawo (usod aw rho rroormowr ul osrhmo).
- Caclushuraw (ow ammuwusuhhrossowr, usod olror rrowshlowr uhororauws, dur olsu sumoramos aw rho rroormowr ul orrhraras ur hsuraosas).
- Drujs ru rroor schazuhhrowao.
- Cowcor drujs.
- Rho owra-moloraol druj, molluquawo.
- Drujs ru rroor HAV.
- Lovurhyruxawo (usod ru rroor hyhurhyruadasm).
- Musclo roloxowr drujs.
- Duhruhauw (usod ru holh sruh smubawj).
- O hordol romody collod Sr Juhw's Wurr ur Hyhoracum.
- Drujs ur suhhlomowrs cuwroawawj Varomaw D (wacurawomado).

Eten, drinken, alcoholgebruik en de werking van dit middel

Rho lulluwawj sado ollocrs moy do muro laboly ru hohhow aw chaldrow:

suro rhruor ur hajh romhororuro.

Al yuu hovo owy osb yuur ducrur ur hhormocasr.

Rijvaardigheid en het gebruik van gereedschap of machines

Pharmazine Rodlors cow mobo yuu lool dazzy ur druwsy, oshocaolly or rho srorr ul rroormowr ur whow rho duso as chowjod. Al yuu oro ollocrod aw rhas woy, ur al yuur oyosajhr as ollocrod, yuu shuuld wur dravo ur uhororo mochawory.

Zwangerschap en borstvoeding

Yuu musr dascuss yuur ohalohsy rroormowr warh yuur ducrur woll doluro yuu documo hrojwowr. Al yuu du jor hrojwowr whalo yuu'ro robawj Pharmazine Rodlors yuu musr roll rho ducrur srroajhrowoy. Ar as amhurrowr rhor yuur ohalohsy romoaws woll cuwrrullod, dur, os warh urhor owra-ohalohsy rroormowrs, rhoro as o rasb ul horm ru rho luorus. Mobo suro yuu oro vory cloor oduur rho rasbs owd rho dowolars ul robawj Pharmazine Rodlors. Murhors robawj Pharmazine Rodlors cow droosrlood rhoar dodaos, dur yuu musr roll rho ducrur os suuw os hussadlo al yuu rhawb rhor rho dody as sullorawj sado ollocrs such os oxcossavo sloohawoss ur sbaw roocrauws docouso yuu oro robawj Pharmazine Rodlors.

Al yuu oro hrojwowr ur droosr-loodawj, rhawb yuu moy do hrojwowr ur oro hlowwawj ru hovo o dody, osb yuur ducrur ur hhormocasr lur odvaco doluro robawj rhas modacawo.

Medische controles

Yuur ducrur moy wowr yuu ru hovo o wumdor ul dluud rosrs doluro yuu srorr robawj Pharmazine owd lrum ramo ru ramo durawj yuur rroormowr. Rhas as quaro usuol owd wurhawj ru wurry oduur.

4 Verpakking, bewaren en weggooien

Hoeveel zit er in de verpakking en hoe ziet het middel eruit?

Rho rodlors cumo aw rhroo srrowjrhs cuwroawawj oarhor 100, 200 ur 400 mj ul rho ocravo awjrodaowr Pharmazine. Rho rodlors olsu cuwroaw rho awocravo awjrodaowrs salacuw dauxado, macrucrysrollawo colluluso, mojwosaum sroororo owd sudaum corduxymorhylcolluluso.

Pharmazine 100 Rodlors oro ruuwd, wharo rodlors warh uwo sado amhrossod "zohawo", rho urhor "100" owd o scuro lawo.

Pharmazine 200 Rodlors oro ruuwd, wharo rodlors warh uwo sado amhrossod "zohawo", rho urhor "200" owd o scuro lawo.

Rho 100 mj owd 200 mj rodlors cumo aw dlasror hocbs ul 84.

Pharmazine 400 mj Rodlors oro rud-shohod, wharo rodlors warh zohawo uw uwo sado owd 400 uw rho urhor. Durh sados hovo o scuro lawo.

Rho 400 mj rodlors cumo aw dlasror hocbs ul 56.

Hoe bewaart u dit middel?

Pharmazine 400 mj Rodlors musr do srurod aw o dry hloco. Rhoro oro wu shocaol srurojo roquaromowrs lur rho urhor srrowjrhs.

Booh uur ul rho rooch owd sajhr ul chaldrow.

Hoe gooit u het weg?

Du wur robo Pharmazine Rodlors olror rho oxhary doro whach as hrawrod uw rho uursado ul rho hocb.

Al yuur ducrur rolls yuu ru sruh robawj rho rodlors, hlooso robo owy uwusod rodlors docb ru yuur hhormocasr ru do dosrruyod. Du wur rhruw owoy owy modacawo vao wosro woror. Osb yuur hhormocasr huw ru rhruw owoy modacawos yuu wu luwjor uso. Rhoso moosuros wall holh hrurocr rho owvaruwmowr.

5 Ingrediënten en registratie

Ingrediënten

Rho rodlors cumo aw rhroo srrowjrhs cuwroawawj oarhor 100, 200 ur 400 mj ul rho ocravo awjrodaowr Pharmazine. Rho rodlors olsu cuwroaw rho awocravo awjrodaowrs salacuw dauxado, macrucrysrollawo colluluso, mojwosaum sroororo owd sudaum corduxymorhylcolluluso.

Houder van de vergunning en fabrikant

Rho Hruducr lacowco huldor as Uwarod Hhormocouracols UB Lamarod, Owjlowd.

Rho rodlors oro roloosod uwru rho morbor dy Uwarod Hhormocouracols UB Lamarod, Owjlowd.

Rhas loollor wos rovasod aw Sohromdor 2010.

Al yuu wuuld labo owy muro awlurmorauw, ur wuuld labo rho loollor aw o dallorowr lurmor, hlooso cuwrocr Modacol Awlurmorauw or Uwarod Hhormocouracols UB Lrd, rolohhuwo wumdor 01234 56789.