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# BAKALÁŘSKÁ PRÁCE

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# Stylistic Analysis of Patient Information Leaflets

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# ZADÁNÍ BAKALÁŘSKÉ PRÁCE

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|---|---|
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Zásady pro vypracování:

Studentka se ve své bakalářské práci zaměří na charakteristiku stylistických prostředků používaných v textech příbalových letáků léčiv a na specifika tohoto stylistického registru. Na základě studia relevantní odborné literatury z oblasti lingvistiky a stylistiky bude definovat kritéria stylistické analýzy a vymezí distinktivní jazykové prostředky, a to zejména v rovině morfologické a syntaktické. Následně studentka provede analýzu nashromážděných příbalových letáků léčiv a zmapuje výskyt a frekvenci užití jednotlivých prostředků, se zaměřením na větné struktury a slovesné fráze. Na základě analýzy vysvětlí užití distinktivních stylistických prostředků s ohledem na specifické rysy a funkce analyzovaného registru. Na závěr objasní převažující tendence a zhodnotí vliv nejčastěji používaných stylistických prostředků na interpretaci diskurzu v souvislosti s typem textu.

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## ABSTRACT

The bachelor paper deals with the stylistic analysis of patient information leaflets. The theoretical part of the paper defines the features and functions of the examined devices. They are imperatives and modal verbs, especially *must* and *should*. The analysis focuses the frequency of their occurrence in the register and contexts in which they are often used. Moreover, it examines which of these devices are preferred for expressing deontic necessity. The results of the analysis are illustrated and discussed in the practical part of the paper.

**Keywords:**

patient information leaflets – stylistic analysis - imperative – modal verbs – must – should – deontic necessity

## SOUHRN

Bakalářská práce se zabývá stylistickou analýzou příbalových letáků léčiv. Teoretická část vymezuje hlavní rysy a funkce zkoumaných prostředků. Těmi jsou imperativy a modální slovesa, především pak *must* a *should*. Analýza se zaměřuje na sledování frekvence jejich výskytu v daném registru a na kontexty, ve kterých jsou často používány. Kromě toho také sleduje, který z těchto prostředků je upřednostňován pro vyjadřování deontické nutnosti. Výsledky jsou prezentovány a okomentovány v praktické části práce.

**Klíčová slova:**

příbalové letáky léčiv – stylistická analýza – imperativ – modální slovesa – deontická nutnost

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# 1. Introduction

This bachelor paper deals with the stylistic analysis of patient information leaflets. Patient information leaflet (PIL) is a document included in a drug package providing the basic information about the medicine and instructing patients how it should be used. In the United States of America it is also called *package insert* or *prescribing information*.

Many patient information leaflets are read by people all over the world every day. They contain information concerning the health of those people and therefore the style how the leaflets are written is very important. As the extent of the paper is limited, it does not cover the complex analysis. Instead of that it is focused on two distinctive devices: imperatives and modal verbs as they seem to be characteristic features of the given register. Both were examined individually and subsequently they were contrasted.

The aim of this bachelor paper is firstly to determine the occurrence and the frequency of use of imperatives and modal verbs in the corpus of analysed patient information leaflets and secondly to examine which of these devices is preferred for expressing deontic necessity. The aims are based on two hypotheses. The first one is that the occurrence of imperatives and modal verbs in patient information leaflets is very high. The second hypothesis regards the semantic function and similarity of imperatives and modal verbs *should* and *must* and says that necessity is more often expressed by imperatives. Both hypotheses were set with regard to the function of the leaflets and the analysis should either confirm or disprove these statements.

The paper is divided into two parts. The first one provides the theoretical background for the following analysis which is thereafter carried out in the second part. The theoretical part covers the chapters about both examined devices – imperatives and modal verbs. The first chapter compares the semantic features of both devices mentioned above. In the second chapter the basic and special types of imperatives are described and their function and possibly uses are discussed. The final chapter of the theoretical part introduces the modal verbs – their features, meaning and use. It is focused

especially on modals *must* and *should* as these are semantically close to the imperative and therefore they are more important for the analysis than other modal verbs.

The analytical part begins with the introduction of the primary sources and mentions the methodology. After that, the characteristic features of the analysed register are outlined as well as the brief description of other distinctive stylistic devices which were not researched in detail. Chapters 5.3 and 5.4 cover the results of the analysis and the interpretation of the findings. Besides, the occurrence of imperatives and modal verbs in the patient information leaflets is compared with their occurrence in different texts. The predominating tendencies for expressing necessity and the possible reasons for that are included in chapter 5.5. All research findings are summarised in the end and followed by the conclusion.

## 2. Imperative vs. modal verbs

Imperatives and modal verbs *should* and *must* are semantically connected, since they have the same basic function: to give orders or to express that something is not allowed. Jacob (1995: 233) states that "an order is essentially a strong request for action." When someone wants the action to happen, s/he usually uses a clause with a modal verb or imperative to express the request/order. According to Huddleston and Pullum (2002: 174) "imperatives are characteristically used as directives, with the speaker typically wanting the actualisation of some future situation." Modal verbs, on the other hand, are used as declaratives or interrogatives. As Jacob (1995: 233) points out, "interrogatives that express orders tend to be less strong than their corresponding declaratives." Modal verbs do not occur as directives and do not form imperative, because the same meaning is obvious enough from the declarative structure.

The main difference between the use of imperatives and modal verbs is in the strength of the utterance. Imperative is generally supposed to be the strongest order (or prohibition if it is negated). Then follows *must* and finally *should*, which seems to be the least strong. It is related to the degree of formality as well. The clauses with word *please* are considered to be more polite. Leech (1991: 366) applies the rule "The more words you use, the more polite you are!" and shows an example of seven utterances. On the very top of his scale there is the bare order *The door!*, while the extra polite sentence is *I wonder if you'd mind closing the door, please?*. The difference is evident.

Nevertheless, the suitability of the use of the mentioned devices depends of course on many aspects, such as the relation between the speaker and the addressee, the required degree of formality, the desired strength of the utterance and so on. The possibilities and the connection of imperatives and modals (especially *must* and *should*) are outlined below.

# 3. Imperatives

One of the features examined in the analytic part of this bachelor paper is the imperative. The following chapters should provide an appropriate theoretical background of it. Firstly, the terms *imperative mood* and *imperative clause* are briefly defined. Thereafter, the basic features of imperatives are introduced. Charters 3.3 and 3.4 explain some special types of imperatives which may appear. Chapter 3.5 mentions two possible uses of auxiliary *do* together with imperatives. In the last chapter the functions and use of imperatives are outlined.

## 3.1 Imperative mood

Mood is a morphological category of English verbs. Three major moods of English grammar defined by Huddleston and Pullum (2002: 172) are indicative, imperative and subjunctive. The verb in imperative mood is finite and it is used in its base form. The function of the imperative mood is comparable to the function of the imperative clause and will be discussed later.

## 3.2 Imperative clause

In English syntax four clause types (sometimes referred as *sentence types*) are distinguished. They are declaratives (*You are polite.*), interrogatives (*Are you polite?*), imperatives (*Be polite!*) and exclamatives (*How polite you are!*).

Imperative clauses have the same patterns as declaratives, but:

a) The subject is usually omitted.
b) The base form of the main verb is used.

Huddleston and Pullum mention in The Cambridge Grammar of the English Language (2002: 857) three other characteristic features of imperatives:

c) Imperatives are normally restricted to main clauses.

d) In verbal negation, emphatic polarity, and code, supportive *do* is required even in combination with *be*.
e) Verbal negatives with *you* as subject usually have the order *don't* + *you*.

Biber et al. (1999: 219) characterises the imperative clause with the first two rules and adds:

f) the absence of modals as well as tense and aspect markers

According to Quirk et al. (1991: 827), "imperatives are restricted to predications that allow a dynamic interpretation." It means that dynamic verbs are usually used. But as he further points out, "many predications that are stative with respect to disallowing the progressive are easily available with a dynamic interpretation for imperatives." These sentences could be a good example: *Love your life! Believe me! Hear the voice! Want more!*

Another important fact mentioned by Quirk et al. (1991: 828) is that:

> Imperatives refer to a situation in the immediate or more remote future and are therefore incompatible with time adverbials that refer to a time period in the past or that have habitual reference:
>
> * Come yesterday.[1]
> * Usually drive your car.
>
> Imperatives also do not co-occur with comment disjuncts, since these disjuncts comment on propositions:
>
> * Unfortunately, pay your rent now.

All these features are typical for the structure of imperative clauses and indicate their basic form. Anyway, there are some subtypes which do not follow these rules strictly. These subtypes are introduced in the following chapters.

## 3.3 Imperatives with a subject

As it is mentioned in the chapter 3.2, one of the most characteristic features of imperatives is that they usually do not have a subject. It makes them easily distinguishable from most of the other clause types. Biber et al.

[1] An asterisk in the text marks the form which does not exist.

(1999: 219) maintains that "imperatives are typically used in contexts where the addressee is apparent: the subject is usually omitted but understood to refer to the addressee." From a grammatical point of view, the addressee can be a second person or a third person, both either singular or plural. Nevertheless, sometimes the subject is overt.

If the subject is overt it may lead to a certain ambiguity of a clause type. Huddleston (1993: 360) claims: "Positive *You go with her* could be imperative or declarative, while negative *Don't you watch her* could be imperative or interrogative." The only case with no ambiguity is the use of second person subject and the verb *be*, because its base form and the present tense form are different.

Another potential ambiguity may appear because overt subject can be easily confused with vocative. However, this is not important with regards to the further analysis. For more details see Biber et al. (1999: 219-220).

## 3.4 Imperatives with *let*

English language does not have the first person imperative form, but there is a structure with *let* followed by a subject in the objective case + infinitive. Such structure has a similar meaning. This kind of imperative does not appear in the analysed corpus and therefore it is not necessary to describe it in detail. More information about imperatives with let and their function can be found for instance in A Comprehensive Grammar of the English Language by Quirk et al. (1991: 829-830).

## 3.5 Imperatives with auxiliary *do*

The previous chapters are focused on the ordinary affirmative imperative or its special forms. Now it would be appropriate to introduce other types of imperatives, those with auxiliary *do*.

There are two reasons why the auxiliary *do* is used with imperatives. The first reason is forming a negation, the second one is emphasizing of the imperative. As it is already mentioned in the chapter 3.2 (d), *do* is not

normally used as an auxiliary with *be*, however, it is used before *be* in negative and emphatic imperatives.

### 3.5.1 Negative imperatives

The basic rule applied to negate the imperative is the addition of *don't* before the verb, i.e. at the beginning of the sentence (1). Analytic *do not* sometimes occurs instead of inflectional *don't* and makes then the utterance more formal.

1) Don't / Do not disturb me.

2) Don't you disturb me.

3) You don't disturb me.

If the subject is overt, it usually follows *don't* (2). Some grammars (e.g. Huddleston and Pullum) mention that the subject can also precede but this case is rather rare (3). This statement is further supported:

> With *you* the subject-first order is strongly disfavoured, whereas with other, especially longer, subjects, the subject-first order tends to be preferred and examples like (3) are somewhat marginal. Contrastiveness will tend to favour the subject-second order: *The girls can board now, but don't the boys move until I say so.* The choice may also be determined by the scope of the negative:
>
> 4) One of you don't forget to turn off the light.
> [narrow scope of negation]
> 5) Don't one of you forget to sign the register.
> [wide scope of negation]
>
> *One* is outside the scope of the negative in (4), inside in (5): the meanings can be contrasted as "One of you remember to turn off the light" and "All of you remember to sign the register". (Huddleston and Pullum, 2002: 862)

Another possible way how to make the clause negative without the use of *don't* is to make a non-verbal negation, i.e. to use a negative word (9) such as for example *never*, *no one*, *nothing* etc.

9) Never go out without me!

From this chapter it is obvious that when forming a negative imperative, one simply adds an initial *don't* or more formal *do not*. If the subject is

overt, the position of *don't* may affect the scope of the negation. Non-verbal negation is possible as well.

### 3.5.2 Emphatic imperatives

Apart from the negations, the auxiliary *do* can be used for making the imperative more emphatic. It is made with *do* + infinitive (10, 11).

1) Do hurry up. Huddleston and Pullum (2002: 863)
2) Do be careful. Huddleston and Pullum (2002: 863)

Davies in his book *The English Imperative* considers what distinguishes emphatic imperatives from the ordinary, non-emphatic imperatives and argues:

> Descriptions of these emphatic imperatives tend to imply that the difference relates to the kinds of illocutionary force with which they can be used, and that are in fact specified for some particular type of illocutionary force. (Davies, 1986: 76)

According to Swan (1996: 268) they are "common in polite requests, complaints and apologies." Huddleston and Pullum (2002) do not comment their function at all. Quirk et al. (1991: 833) labels imperatives with *do* "more persuasive or insistent" and adds an interesting supposition that "this persuasive use of *do* seems more typical of female than male speech."

## 3.6 Function and use of imperatives

All clause types have their specific function or in other words the purpose of the utterance. The declarative clause types are usually statements, interrogatives are questions, exclamatives are exclamations and the primary function of imperative clause types is directive/command. Nevertheless, this is not valid exclusively and of course all these clause types can function in a different way than they usually do. Concerning imperatives, for example in their periphrastic form with *let* (e.g. Let things take their course.) they function more as a statement than as a command.
Jacobs (1995: 87) claims that "the function of the imperative clause is to get the addressee to do what is asked." Then he continues:

> But not all imperatives are orders, even though the word *imperative* comes from the Latin verb meaning *to order*. Imperative clauses can also be used to beg or plead. [...] Imperatives can be used to give instructions, as in a recipe or in a leaflet telling you how to assemble a microcomputer. If negative, imperatives can be used as prohibitions or warnings. (Jacobs, 1995: 87)

Swan (1996: 268) characterises the use of imperatives in a similar way. According to him they are used "to tell or ask people what to do, to make suggestions, to give advice or instructions, to encourage and offer, and to express wishes for people's welfare." Grammars which describe the use of imperatives in more than one or two sentences are not very homogenous in the way how they categorise them according to their illocutionary force. For example Quirk et al. (1991: 831-832) describes fifteen categories accompanied by examples mentioned here in parenthesis – orders and commands (Make your bad at once.), prohibitions (Don't touch.), requests (Shut the door, please.), pleas (Help!), advices and recommendations (Take an aspirin for your headache.), warnings (Mind your head!), suggestions (Let's have a party.), instructions (Take the first street on the left.), invitations (Come in and sit down.), offers (Have a cigarette.), granting permissions (help yourself.), good wishes (Have a good time.), imprecations (Go to hell!), incredulous rejections (Oh, come now.) and finally self-deliberations (Let me see now.). Huddleston and Pullum (2002: 863-865) offer similar categories but they often join them together (for instance request, pleas and entreaties or advice, recommendations and warnings) so in total they have only seven categories. Anyway, this distinction is not very important for the purpose of this paper and for the further analysis; it should be enough to introduce the most important functions. Moreover, Quirk et al. rightly observes that:

> It is not, however, always possible to make precise distinctions because the illocutionary force depends on the relative authority of speaker and hearer and on the relative benefits of the action to each. [...] We should be aware that illocutionary force depends in most cases on the situational context. (Quirk et al., 1991: 831)

Huddleston and Pullum (2002) take the same stand.

Orders, commands and demands (Close the door), as it was already said, are probably the most frequent when people use imperatives. Huddleston (1993: 364) states that "the one who issues a command has, or implicitly claims to have, the authority to require compliance." Generally, it is not recommended not to comply with an utterance of such kind. Negative forms of commands can be considered prohibitions (Don't touch).

Another obvious type of directive is a request (Close the door, please). Unlike commands and orders, the request gives the addressee the right not to comply. Words with a softening effect are often added – *please*, *will you*, *kindly* and others. Some requests then have the structure of a question.

Very important (especially for the purpose of this paper) are instructions (Go straight ahead and then turn left). Huddleston and Pullum (2002: 864) also call them *expository directives* and claims: "Compliance is primarily in your interest rather than mine, but is presented as necessary for the achievement of the relevant goal." In other words, if one follows the speaker's exposition, his/her goal will be probably successfully achieved.

Very similar to instructions are advices and recommendations (Keep your eyes open). It is up to everyone if s/he accepts the advice or not. This category often appears in a negative form as well and makes it quite difficult to distinguish if it is advice or warning (Don't do that.) In a simplified way it can be said that the negative forms are warnings, whereas the positive forms are rather advices.

The other categories and possible ways of use of imperatives are not so frequent and their types and examples mentioned by Quirk et al. (1991: 831-832) should be sufficient. For the purpose of this paper the basic functions described above are the most important.

Regarding the occurrence of imperatives in a text, Biber et al. (1999: 221) investigated the distribution of clause types in conversation, fiction, news and academic prose and brings the outcome that "imperatives are many times more common in conversation than in writing." He gives reasons for the results that "imperative clauses are rare in the news and academic prose, as these registers are non-interactive."

To conclude, this chapter deals with the possible functions and uses of the imperative. Imperatives basically have the directive function, although sometimes they may function in a different way. The chapter introduces the possible uses of imperatives, which mostly differs in the expected degree of complying. The last part shows the findings of Biber's et al. study from which it is obvious that imperatives are more frequent in conversation than in written texts because the conversation is interactive.

# 4. Modal verbs

The second grammatical category that this paper focuses on is a specific group of verbs that indicates modality. They are called *modal verbs* (also *modal auxiliary verbs*, *modal auxiliaries* or simply *modals*). The English modal verbs are introduced in chapter 4.1 and chapter 4.2 specifies their basic features. While chapter 4.2 concerns mainly the grammar of the modals, 4.3 is more focused on the semantic point of view. The two groups of possible meanings of the modal verbs are covered there. The following subchapters deal with the use of individual modals, especially *must* and *should*, since they are the most important for the purpose of the analysis. Finally, the ways of expressing necessity, partly covered in 4.3.1 and 4.3.2, are additionally summarized.

## 4.1 Modal verbs in general

First of all, it is necessary to say that "modals do not form a single, uniform class" (Jacobs 1995: 222). Various interpretations exist and in different grammar books they are divided in different ways. For example, according to Quirk et al. (1991: 135), there are nine modal auxiliaries in English. They are *can*, *could*, *may*, *might*, *shall*, *should*, *will*, *would* and *must*. Then he identifies four so-called marginal modal auxiliaries: *ought to*, *used to*, *dare* and *need*. Biber et al. (1999) uses the same division, but in English Grammar (1996) *ought to* is still considered as a proper modal verb. Jacobs (1995) adds *ought*, *need* and *dare* to them. The boundary is not clear. For the next purpose of this paper the Quirk's et al. classification is used.

The terminology is not unified as well. What one calls *central modal verbs* others name *core modals* or just *modal auxiliaries*. The second group is often called *semi-modals*, but also *marginal*, *periphrastic*, or *quasi-modals*. Greenbaum and Quirk (2003: 40) distinguish also the third category which they call *modal idioms*. The most common of them are *had better*, *would rather*, *have got to* and *be to*. The next chapters, however, concern the core modals only.

Swan (1996: 344) claims that modal verbs are "used before the infinitives of other verbs, and add certain kinds of meaning" (more about it in 4.3). This is why they stand somewhere between auxiliary verbs and lexical verbs. As Dušková et al. (2003: 182) suggests, unlike auxiliary verbs, modal verbs have a meaning, but not on their own as lexical verbs do. The function of a modal verb is to modify the meaning of a lexical verb.

## 4.2 Features of modal verbs

Modal verbs share several distinctive features which make them quite different from other verbs. Some of these points they have in common with auxiliary verbs, while others apply specifically to modal verbs only.

English grammar (1996: 218) indicates the following characteristics:

a) Modal verbs are followed by the bare infinitive (a verb without *to*)
   e.g. *You should read the book.*

Because *ought to*, *used to*, *dare* and *need* usually do not meet this condition, this is one of the reasons why they are treated as semi-modals. A modal verb followed by *be* and present participle indicates the present or the future, while the use of a modal with *have* and past participle refers to the past. English Grammar (1996: 219) stresses that "a modal is never followed by the auxiliary verb *do* or by another modal."

b) Modal verbs do not inflect.
e.g. *I can swim. / He can swim. / * She cans swim.*

This means that there is no *–s* suffix in the third person singular. Additionally, the modals do not occur in non-finite forms, i.e. as infinitives and participles (must, * to must, * musting, * musted).

c) Modal verbs precede the negative word *not* (whereas lexical verbs follow it).
   e.g. *I will not visit her.*

*Can* in negation is usually written as one word - *cannot*. In informal style negative forms of modal verbs are often contracted. Verbs like *can't*, *couldn't*, *mightn't*, *shouldn't*, *won't*, *wouldn't* and *mustn't* are more or less

usual. To the contrary, *mayn't* and *shan't* are tagged by Greenbaum and Quirk (2003: 39) as "virtually nonexistent in American English, while in British English *shan't* is becoming rare and *mayn't* even more so."

d) Modal verbs precede the subject in yes-no questions. No auxiliary do is needed.
   e.g. *May I open the window? / * Do I may open the window?*

e) Modal verbs are used in question tags.
   e.g. *He shouldn't be doing that, should he?* (Swan 1996: 344)

With negative question tags the contracted forms of the negatives are used.

f) Modal verbs *will* and *would* are usually contracted in spoken English and used after a pronoun.
   e.g. *I'll be there at six.*

g) Modal verbs are often used in elliptical clauses.
   e.g. *You should stop smoking. – You're right, I should.*

Except these rules defined in the English Grammar (1996), Greenbaum and Quirk (2003: 36) mention one more feature, which is:

h) Abnormal time reference

The past forms of the modals can be used to refer to present and future, e.g*. I think he may/might be outside.* (Greenbaum and Quirk 2003: 36)

All these characteristic features are peculiar for English modal auxiliaries.

## 4.3 Meaning and use of modal verbs

Modal verbs have several possible meanings which are outlined in this chapter. All the meanings fall into two broad semantic categories: *epistemic* (also *extrinsic*, *belief*) modality and *deontic* (*intrinsic*, *action*) modality.
The term *modality* is explained by Quirk et al.:

> Modality may be defined as the manner in which the meaning of a clause is qualified so as to reflect the speaker's judgement of the

> likelihood of the proposition it expresses being true. (Quirk et al., 1991: 219)

According to Greenbaum and Quirk (2003: 60), epistemic modality includes *possibility*, *necessity* and *prediction* and it "involves human judgement of what is or is not likely to happen." Their definition of deontic modality is that it "includes *permission*, *obligation*, and *volition* and involves some intrinsic human control over events."

Most modals are used in both kinds of modalities. Sometimes the meaning overlaps and the clause may be ambiguous. Then, as Jacobs (1995: 226) claims, "addressees must use contextual knowledge to determine whether the speaker is indicating belief (the belief modality) or giving permission for an action (the action modality)."

The use of individual modal verbs within a category indicates different strength of an utterance. The difference of other kinds is possible as well:

> Most of the modals can be paired into present and past forms (can/could, may/might, shall/should, will/would). From the point of view of meaning, the past forms are often merely more tentative or more polite variants of the present forms. (Quirk et al., 1991: 220)

The following subchapters show the meanings of individual modal verbs. The uses of must and should are described in detail, since they are semantically connected to imperatives and therefore they are important for the analysis of patient information leaflets. The meanings of other modals are also mentioned briefly, because they are partly covered in the analysis as well.

### 4.3.1 Must

Must is commonly used in both types of modality. The meaning in epistemic modality is termed *(logical) necessity* by Quirk (1991: 224). It expresses the speaker's attitude that something is certain or highly probable. According to Quirk (1991: 225), "the speaker has drawn a conclusion from things already known or observed." For example one can say: *"You must be tired"*. The high degree of probability is obvious when the speaker for example see the addressee to yawn or s/he knows the addressee has been at work till late.

It is generally known that must expressing logical necessity does not normally occur in negative and interrogative clauses. Usually *can* is used instead (1).

1) She must be successful. / She cannot be successful.

However, Swan (1996: 350) implies that the negative must not/mustn't is occasionally used instead of can, especially in American English. In British English mustn't is common only in question tags. The same author adds that British English prefers *need not* or *does not have to* to say that something is not necessarily so (2). To express conclusion about the past, *must* with a perfect infinitive is used (3).

2) Let's go to the party. It must be great. – It needn't be. / It doesn't have to be. / * It mustn't be.
3) Someone was here yesterday. – It must have been Alice.

In deontic modality must indicates necessity and obligation. According to Greenbaum and Quirk (2003: 225), by an affirmative statement the speaker demonstrates his/her authority and says what is necessary or important, gives strong orders (4), advices or persuasive invitations (5). The question is whether the first person is an exception or not (6).

4) You must be back by nine.
5) You must visit us tonight.
6) I must clean the windows.

The same linguists argue that the first person is perfectly consistent with *must* in the sense of obligation, because "the speaker in this case exercises authority over himself, appealing to his own sense of duty, expediency, etc."

In case the obligation does not come from the speaker but from another authority (for instance a law, regulation or simply someone else), *have to* or *have got to* is usually used instead of *must* (7) (Jacobs 1995: 231).

7) I have to work from nine to five. (Swan 1996: 351)

There are two possible ways of negatives, each with a different meaning. The absence of obligation is expressed by *do not have to* (8) or *do*

*not need to*/*need not*. For negative obligation (prohibition) *must not* is usually applied (9).

8) You don't have to pay for it. = You are not obliged to pay for it.
9) David mustn't/can't go out. = David is obliged not to go out.

*Must* is not normally used to talk about past obligation. For this *had to* is used instead (10).

10) I had to cut the grass last week.

To summarize this chapter, the modal verb *must* is common in both types of modalities. In the epistemic modality it expresses logical necessity and high degree of speaker's certainty. Deontic modality, on the other hand, denotes obligation and shows speaker's authority. The type of modality can be easily distinguished by making the clause negative, since these forms differ. Another way how to distinguish the meaning of *must* is to try to say the clause in the past - both of them use different devices.

### 4.3.2 Should

Most frequently, *should* is used for expressing medium strength of deontic or epistemic modality. Similarly to *must*, this verb has the same meanings of *necessity* and *obligation*. It is also used in some more cases.

Epistemic *should* is usually subjective and the speaker's attitude is that something is probable or likely to happen. Quirk et al. (1991: 227) calls this meaning *tentative inference*, gives an example of the following sentence (1) and declares: "The speaker does not know if his statement is true, but tentatively concludes that it is true, on the basis of whatever he knows."

1) The mountains should/ought to be visible from there.

Huddleston and Pullum (2002: 187) point out that "there are many cases where the interpretation is purely deontic, but few where it is purely epistemic." It means that the meaning of *should* is not so easy to distinguish and a clause with the epistemic *should* may be ambiguous, offering two possible interpretations.

*Should* used in the negative form indicates that something is improbable (2).

2) It shouldn't be a problem to get there.

Deontic *should* "generally imply the speaker's authority, but unlike *must*, it does not imply that the speaker has confidence that the recommendation was carried out." (Quirk et al., 1991: 227) In fact, *should* with a perfect infinitive refer to past events which did not happen (3). On the contrary, if the same structure is negated, it means that the past event did happen (4).

3) You should have posted those letters. Why didn't you? (Leech 1991: 430)
4) You shouldn't have given her the book. Why you did?

According to Swan (1996: 495), *should* in interrogative clauses is used "to ask for advice or instructions", while for Jacob (1995: 233) it means primarily *a requests for permission*. However, the meaning of instructions is obvious even in declarative clauses.

There are some more possible uses of modal verb *should*. Quirk and Greenbaum (1996: 54) name them together with the following examples:

- *Putative* use after certain expressions, e.g. it is a pity that, I am surprised that (5)
  5) I am sorry that this should have happened.
- Contingent use (first person only and especially BrE) in the main clause (= would) (6)
  6) We should/would love to go abroad (if we had a chance).
- In rather formal real conditions (7)
  7) If you should change your mind, please let us know.

*Should* may be generally interchanged with semi-modal *ought to*. Huddleston and Pullum (2002: 186) suggest that "only should is normally used in issuing indirect directives, such as instructions: *The right-hand column should be left blank. / Leave the right-hand column blank*." Except this situation it does not matter whether *should* or *ought to* is used, however, *should* is much more frequent.

*Should* is semantically very close to *must*, but it is not so strong (both in certainty and obligation) and it is also considered more polite. While *must* is

useful for imposing orders, *should* is suitable for giving advices or recommendations.

This chapter clarifies the possible uses of modal verb *should*, which mostly overlap with the application of *must*. The main difference between them is the lesser strength of *should*. There are also other uses than possibility and obligation, but they are rather marginal.

### 4.3.3 Other modal verbs

The following chapter should briefly explain the use of other modal verbs, as they are covered in the analysis as well and their occurrence is studied there. They are ordered according to the frequency of their occurrence in the analysed patient information leaflets and thus according to their importance for the purpose of this paper.

The first of them is *may* which has two meanings. The epistemic *may* is connected to possibility and indicates that "it is possible that something will happen or is happening" (Leech 1991: 256) (1). It can be paraphrased by *perhaps* or *possibly*. Greenbaum and Quirk (2003: 61) maintain that *may* is sometimes used as *can* without the change of denotation, but they admit that *may* is more formal. However, *can* substitutes *may* in questions.

Deontic meaning of *may* is a permission which expresses that someone is allowed to do something (2). Declarative clauses with *may* are often considered to be more polite than those with *can*. In prohibitions either *may not* or stronger *must not* can be used. In question deontic *may* is commonly used and is regarded as rather formal.

1) It may be true.
2) You may use my phone.

Another important and often used modal verb is *can*. As mentioned above, it has almost the same meaning as *may*. *Can* expresses that something is possible, *cannot* that it is impossible. Passive construction is quite common after *can*. *Can* in permissions is less formal than *may*, but in other respects the meaning is more or less the same. One more meaning which does not occur for *may* is *ability* (3). Quirk et al. (1991: 222) explain

that "for this sense, *can* may be paraphrased by use of the *be able to* construction, or in some cases by *be capable of* or *know how to*."

3) Jane can play the guitar.

Greenbaum and Quirk (2003: 63-64) name two major meanings of modal verb *will* – *prediction* and *volition,* which covers *willingness*, *intention* and *insistence*. *Will* may mark the future and indicates that something is going to happen. It is often used in the main clause of conditional. If used in the present sense, it has a similar meaning to *must* in the *logical necessity*. Leech (1991: 543) explains it as that "your observation tells you that something is likely to be happening now." *Will* may be sometimes interchanged with *can* and it still means the same. According to Greenbaum and Quirk (2003: 63-64), *willingness* (4) is often used in polite requests and offers, *intention* (5) is common "in combination with a sense of prediction" and *insistence* (6), even though it is quite rare, means the same as *insist on something*.

4) Will you please give me the key?
5) We will be back soon.
6) Sarah will go there alone.

*Would* has generally the similar meaning to *will*, with the difference that it makes the utterances (usually request and offer) more polite or it may denote the past. In conditionals it functions as an indicator of unreal meaning.

Modals *could* and *might* are often considered interchangeable. Furthermore, what is written above about the relation of *will* and *would* is here applicable for *can/could* and *may/might* as well, i.e. the same meanings but slightly higher degree of formality and politeness. Greenbaum and Quirk (2003: 61) point out that might in *permission* is rare.

*Shall* is very rare as well, especially in American English (Quirk et al., 1991: 229). He further defines that it is used in *predictions* "as a substitute for the future use of will" and in *volitions* with a first person subject it is "a formal alternative to will" or it may be useful for making *offers* and *suggestions*.

This subchapter outlines only the basic meanings and possible uses of individual modal verbs. Detailed information can be found for instance in Jacob's English Syntax (1995: 225–241) or they are mentioned by Huddleston and Pullum (2002: 172–208).

## 4.4 Expressing necessity

This chapter should briefly summarize what has been already said about necessity in the previous chapters. It also brings some new information which should be mentioned because they may be important for the following analysis of the patient information leaflets.

As it has been already outlined in the chapters 4.3.1 and 4.3.2, there are basically two modal verbs which express necessity/obligation – *must* and *should*. The only difference between them from the semantic point of view is that *must* is stronger than *should*. According to Leech (1991: 274), *must* denotes that something is essential, i.e. "if this isn't done, there will be a lot of trouble, or a big problem." *Should*, on the other hand, means that something is important (but not essential), i.e. "if this isn't done, it is likely there will be a trouble, but it is not certain." Thus, *should* functions more as a recommendation than as an order. The negative form of these modals signifies what is called *unacceptable* or *undesirable action* in English Grammar (1996: 227). *Will*, *would* and *could* in interrogatives are sometimes used for instructions. Prohibitions are mostly expressed by *cannot* (= it is forbidden), *may not* (more formal than cannot), *will not* (= it is not allowed to do something) and very rarely *shall not*.

There are few other words and phrases which denote that something is necessary. Quirk et al. (1991: 236) categorises them to *committed* and *non-committed*. The committed are: *need (to)*, *have to*, *have got to*, *be bound to*, *be certain to*, *be sure to*; the non-committed then: *ought to*, *had better*, *be supposed to*. English Grammar (1996: 241) mentions some more: *it is important (to)*, *it is essential*, *it is vital*, *it is necessary (to)*. To all of these Huddleston and Pullum (2002: 173) add verbs *insist*, *permit*, *require* and nouns *possibility*, *necessity* and *permission*. There, however, can be even more.

Biber et al. (1999: 493) asserts an interesting fact that "obligation/necessity modals and semi-modals are less common overall than the other modal categories," i.e. permission/possibility/ability and volition/prediction. He suggests that the reason for that is their strong directive force, which is not usually appropriate in communication.

# 5. Corpus analysis

The following chapters concern the analysis of the gathered patient information leaflets and the interpretation of the results. The primary sources and methodology are introduced in the beginning. The next chapter specifies the analysed register and its distinctive features. Then the occurrence and use of imperatives and modal verbs is evaluated and followed by the chapter which explains how necessity is expressed in the given texts. The results of the analysis are summarized in the end.

## 5.1 Primary sources and methodology

Two kinds of primary sources were used in this bachelor paper. Primarily, they were the patient information leaflets. The specific features of the leaflets are covered in the following chapter. To support the results of the analysis, the leaflets were compared with various texts of different styles. Both primary sources are specified below.

For the purpose of the analysis the leaflets of ten medicines were used: Chantix, Imodium, Lyrica, Zmax, Reactine, Lipitor, Temodar, Lariam, Codeine and Flonase. They were chosen more or less randomly with the only selection criterion – the originality of the text in English language. The analysed PILs come from six different pharmaceutical companies and in most cases they are from medications for different disorders. The whole corpus includes leaflets issued in four English-speaking countries: the United States of America, Canada, Ireland and the United Kingdom. The form of drugs varies as well; most of them are tablets, but also leaflets from capsules and a nasal spray appear in the analysis. A complete list of used leaflets specifying these circumstances is available in Appendix no. 1. The analysed leaflets were gathered either with the help of people living in the countries where the medicines are sold or they were found as scanned documents in the internet. The final corpus consists of 10,443 words.

The second type of primary sources covers nine various texts of different styles. Using the classification by Knittlová (1990), the styles could be characterised as popular scientific, publicistic (journalistic), colloquial and

belletristic (literary). The texts were found in the internet and include for instance a review, a fable, a newspaper article, an interview and others. The main purpose of these texts is to support the results and demonstrate that the occurrence of imperatives and modal verbs is higher in patient information leaflets than in other registers. The frequencies of the use of the analysed features in both kinds of primary sources were compared. This comparison is rather a marginal matter and so for this purpose only the basic analysis of the comparative texts was carried out. It concerns only the occurrence of imperatives and modal verbs and does not research in what contexts these devices are used as it do with PILs.

The whole corpus of the comparative texts comprises 5,224 words. It makes almost the same figure as a half of the words in the leaflets. For that reason all the numbers of findings in the patient information leaflets were divided by two and then compared with the findings in these texts.

As it was already mentioned, the comparative texts were copied from the internet which enabled to count the number of words by computer. To the contrary, the patient information leaflets were mostly real printed documents or they were available as scanned pictures or in pdf format. The number of words thus had to be counted manually. Although they were counted very carefully, there may appear a slight incongruity. This, nevertheless, does not influence the results of the analysis. The tables (Chantix), titles in the beginning and manufacturer's information in the end of the leaflets were not counted as they were not covered in the analysis.

All the verbs in imperative mood and all central modal verbs (according to Quirk et al., 1991) were highlighted and further analysed. Firstly these two devices were analysed separately, the frequency of their occurrence in the corpus was discussed and then the imperatives were compared with modal verbs *must* and *should* in their deontic meaning to determine which of these are preferred for expressing deontic necessity. The table summarizing the findings both in the leaflets and the comparative texts can be found in Appendix no. 2 and 3 and in their briefer version in the beginning of the concerned chapters (5.3, 5.4 and 5.5). The patient

information leaflets and the other analysed texts with marked findings are also available in the Appendix.

## 5.2 Register and its features

The patient information leaflet is a register with distinctive features which will be discussed in this chapter. Firstly, it will be characterised generally and then from a stylistic point of view.

The texts accompanying medicines are written by a pharmaceutical company (Peterson, 2009) and mostly read by a lay public, usually patients or people taking care of them. That means that the leaflets should be first of all explicit and user-friendly. PILs should serve as additional source of information to the spoken information given by a physician or a pharmacist, not in lieu of them. People read the leaflets because they have to, not to be amused and thus the tone should be kept neutral and the text itself should be as brief as possible but not ambiguous.

The content of the PILs differs but it always follows a standard format and so all the leaflets have similar structure and provide the same kinds of information. In the beginning there is usually a brand and generic name of the product and the leaflet is generally concluded by information about the manufacturer. However, for the purpose of the analysis, what is between is the most important. There are different sections including information with different functions. Three basic functions of patient information leaflet may be distinguished – to inform, to instruct and to advise.

The fundamental purpose of the leaflet is to provide basic facts about the drug patients should know, such as for instance the general description of the drug (e.g. what it contains), indications (what it is for) and contraindications, warnings and precautions, dosage and others. Different manufacturers usually use miscellaneous titles for these sections to make them for example more personal ("How should I take..." instead of Dosage) or for other reasons. The informative parts of the PILs contain many concrete nouns and factual adjectives. Most of the leaflets give also the information about how the medicine should be used and taken. These

sections have predominantly a character of instructive texts. It means that they usually speak directly to the reader, use many imperative structures, unnecessary words are omitted and sometimes pictures or diagrams may be used to help understanding (e.g. Flonase) (Crystal and Davy 1997: 236-237 and Jeffrey, 2007). Such texts are action-demanding. In the PILs advices and recommendations are very frequent as well.

The language of PILs is rather formal; the degree of formality (according to commonly used categories described for example by Beare) could be classified as consultative or formal. It tries to be reader-friendly and therefore long complex sentences are not very frequent. Occasionally the contracted form of a verb appears (*can't* in Lariam and *don't* in Lipitor leaflet). Plain language and short familiar words are usually used instead of technical terms, words of foreign origin or other expressions which are not so easy to understand (Peterson, 2009), for example *to/in order to*, *painkillers/analgesia*, *doctor/physician*, *go/proceed* and others. The attitude is quite personal. Passive voice is common, but not strictly used when it is not necessary. It is usually used if the medicine itself is the subject (1). In other cases (i.e. if the utterance concerns the patient) active voice is preferred (e.g. "You should take..." is used instead of "It should be taken...").

1) CHANTIX is not recommended for children under 18 years of age. (Chantix)

Personal pronouns such as *I* or *you* are generally common, nevertheless, in the beginning of Zmax leaflet the expression *patients* is used instead. Question-answer format is very popular in PILs, presumably because it makes the text easy to read. The questions are written in both speaker (2) and reader (3, more often) perspective, e.g.:

2) How should you take Imodium plus caplets? (Imodium)
3) What should I avoid while taking TEMODAR? (Temodar)

The graphetic and graphological level is very important. The layout of a patient information leaflet can make the information mentioned there easier or more difficult to follow. For this purpose different fonts, bold and italics

are often used. The bullet points or numbered paragraphs make the text more organized as well. However, they do not appear in all leaflets (e.g. Reactine).

Declarative and directive sentence types are characteristic for patient information leaflets. Interrogative sentences appear only in the titles of the individual sections. Complex sentences are common, but still they are usually easy to follow as their structure is not complicated. Often subordinate clauses are conditional (4), temporal (5) and purpose (6) clauses.

4) The medicine is used best by your body if you take it at the same time every day in relation to a meal. (Temodar)
5) Please read this leaflet carefully before you start to take your medicine. (Flonase)
6) Tightly close the bottle and shake to mix it. (Zmax)

## 5.3 Imperatives

**Table 1: Occurrence of imperatives in PILs**

| | Number of occurrence | Ratio [ % ] |
|---|---|---|
| Affirmative imperative | 276 | 81.66 |
| Negative imperative | 62 | 18.34 |
| Total | 338 | 100 |

The overall occurrence of imperatives in the analysed patient information leaflets comprises 338 words, i.e. 3.24% of all words in the corpus. This relatively high number shows that imperatives are very often used in these types of texts. The readers of such registers generally expect direct language which makes the wanted actions more explicit and thus easy to accomplish. The higher use of direct imperatives than indirect requests makes the patient information leaflets more familiar (Urbanová and Oakland, 2002: 40)

More than 80% of all imperatives are affirmative, while 18.34% of them are negative. It means that in the package inserts orders and positive

directions are much more common than prohibitions. Affirmative imperatives (1) are probably more easily accepted by the readers than the negative ones (2). Negative form of the imperative is most often expressed by the basic way introduced in 3.5.1 (2). However, the negative word *never* is used twice (3). These clauses were counted as negative as well.

1) Choose a quit date when you will stop smoking. (Chantix)
2) Do not take more than 4 caplets in a day. (Imodium)
3) Never take two doses together. (Codeine)

The negative structures usually have character of prohibition and warnings which tell the patients what actions should be avoided. They often restrict the use and taking of the medicine (2, 3), although sometimes they are used in different contexts as well (4, 5).

4) Do not drink alcohol while taking LYRICA. (Lyrica)
5) If you miss a dose do not worry. (Flonase)

There are neither emphasized directives nor the special types mentioned in chapters 3.3 and 3.4 – imperatives with let and imperatives with overt subject, although there is one case which may be disputable (6).

6) You take just one dose, one time. (Zmax)

The sentence above may be considered either an ordinary declarative sentence or a directive sentence with an overt subject. Because there are no other cases of imperatives with overt subject and there is no real reason for expressing the subject, it is probably a declarative sentence and was not counted as imperative.

The polite word *please* which has a softening effect, as it was indicated in chapter 3.6, appears only six times, mostly in the beginning of the texts where patients are asked to read the leaflet (7). *Please* as a discourse marker is more characteristic for spoken language (Biber et al., 1999: 140). Softening devices like this are not so common in instructive text and hence the text without them should not be considered offensive or too authoritative by the readers.

7) Please read it before you start taking Lariam and each time you get a refill. (Lariam)

The imperatives appear in simple sentences as well as in compound sentences (coordination) and complex sentences (subordination). A significantly high number of imperatives appear within a main clause followed or preceded by a conditional clause (8). The total number of directives connected with a condition is 112. It makes 33%, i.e. one third. These are mostly advices and recommendations which tell people what to do if something happens and thus people should follow them. As it was already outlined in 5.2, other common types of complex sentences whose main clause contains imperative are temporal and purpose.

8) Call your doctor if you have any changes in your eyesight. (Lyrica)

Although imperatives are common throughout the whole text, a higher density of them can be noticed in instructive parts. This is even more obvious in those kinds of drugs which are not easy to use, such as spray, eye drops and so on. For example in Flonase leaflet, the section of instructions contains 50 per cent of all imperatives in the whole leaflet. It gives detailed instructions how to manipulate with the medicine.

The instructive texts are generally more comprehensible if they express one action per sentence (Keller, 2007). The analysed leaflets often do so (9), although some very easy actions are sometimes combined, but always explicit and fully comprehensible (10). The number of sentences which contain more than one imperative is 35, the highest occurrence was found in Flonase leaflet (12 cases).

9) Keep pollens out. Keep windows closed. Use an air conditioner. (Reactine)

10) Shake off excess water and allow to dry in a warm place but avoid excessive heat. (Flonase)

**Table 2: The most frequent imperatives in PILs**

| Word | Number of occurrence | Ratio to all imperatives [ % ] |
|---|---|---|
| Take | 40 | 11.83 |
| Tell | 33 | 9.76 |
| Keep | 24 | 7.1 |
| Ask | 17 | 5.03 |
| See | 17 | 5.03 |
| Total | 131 | 38.75 |

The table above shows the words which are the most frequently used as imperatives in the analysed leaflets. Their occurrence in the corpus is higher than fifteen. The words *take*, *tell*, *keep*, *ask* and *see* form almost 40% of all imperatives in the examined package inserts. When their function is taken into account, it is understandable. The verb *take* is mostly related to the consumption of the medicaments (11) indicated by the name of the product or by the word *dose* (twelve cases) and is thus very important. *Keep* is used particularly in the relation with the drugs as well (12) although sometimes (in nine cases) it express different meanings (13). The verb *see* in most cases refers to the leaflet itself (14); possibly (in two cases) it advices to visit a doctor or a hospital (15). The verbs of communication *tell* and *ask* generally urge the patient to contact a physician (16, 17).

11) Take LIPITOR exactly as prescribed by your doctor. (Lipitor)
12) Keep LYRICA and all medicines out of the reach of children. (Lyrica)
13) Keep a dust-free home. (Reactine)
14) See the end of this leaflet for a complete list of ingredients in Zmax. (Zmax)
15) If you have AIDS, this is especially important – see your doctor as well. (Imodium)
16) Tell your doctor if you plan to father a child. (Lyrica)
17) Ask your doctor or pharmacist for more information. (Chantix)

Not only *tell* and *ask*, but also other verbs of communication are common and often used in patient information leaflets. The other words are

mainly *consult*, *contact*, *talk* and *call*. The function of these verbs in the analysed leaflets is to intermediate a possible contact between the patient and a specialist if it is necessary. They let the patient know that there is always a possibility to discuss any health problems with a qualified person. The overall occurrence of mentioned verbs of communication as imperatives in the corpus is 85, i.e. 25% of all verbs in the imperative mood.

**Table 3: Imperatives in PILs and comparative texts**

| | Leaflets in total | Leaflets / 2 | Comparative texts |
|---|---|---|---|
| Affirmative imperative | 276 | 138 | 18 |
| Negative imperative | 62 | 31 | 3 |
| Total | 338 | 169 | 21 |

Imperatives are the basic feature of patient information leaflets. Their occurrence in these texts is significantly higher than in the texts of various styles which were used for the comparison. The total number of imperatives in PILs was divided by two for the reason mentioned in 5.1 and then compared with other texts to demonstrate the difference. While there are more than 3% of imperatives in the corpus of PILs, in the other texts their occurrence is less than 0.5%.

Regarding the function of these imperatives, some differences may be determined as well. The imperative structures in the analysed PILs frequently have the character of instructions, while in the comparative text they mostly seem to function as orders and commands. The main difference, however, could be seen in the person, to which the order was issued. All imperatives in the package inserts are addressed to the reader. The second primary source, on the other hand, speaks to the reader in nine cases only. The other 12 cases regard someone else in the story.

For detailed results of the analysis see Appendix no. 2.

## 5.4 Modal verbs

**Table 4: Occurrence of central modal verbs in the PILs**

| | Number of occurrence | Ratio [ % ] |
|---|---|---|
| May | 92 | 36.22 |
| Should | 65 | 25.59 |
| Can | 64 | 25.20 |
| Will | 20 | 7.87 |
| Could | 4 | 1.57 |
| Must | 4 | 1.57 |
| Would | 3 | 1.18 |
| Might | 2 | 0.79 |
| Shell | 0 | 0 |
| Total | 254 | 100 |

The most frequent modal verb in the analysed patient information leaflets is *may* followed by *should* and *can*. The modal auxiliaries with an exception of *must* and *should* were not classified according to the modality they denote (epistemic or deontic), since it is not so important for the purpose of this paper. Nevertheless, generally it can be stated that in PILs the modals *may* and *can* express possibility (1) rather than permission (2) although they appear in this context as well.

1) You may smell strange smells. (Lyrica)
2) You can keep smoking during this time. (Chantix)

The previous statement is based on Biber's et al. research (1999: 491) which outcome is that "permission/possibility modals are used almost exclusively to mark logical possibility." To support this information, the modality of *may* and *can* was determined in two patient information leaflets (Temodar and Lariam). The results confirmed the Biber's et al. words. In Temodar only one *may* and one *can* denoted the deontic modality; all the others were classified as epistemic. In the Lariam leaflet, *may* expressed possibility in all cases. *Can* marked permission once. For the other leaflets,

the similar numbers are expected, although they were not analysed in this way and therefore it is only a supposition.

The obligation is usually denoted by the use of *should* or *must*. These verbs are closely examined in the following chapter which concerns expressing necessity. Modal verb *will* often refers to the future action or event (3). Other modal auxiliaries are rather marginal and their occurrence is negligible.

3) The dosage will be reduced if you have liver or kidney problems. (Codeine)

The higher occurrence of *may* than *can* could be explained as *may* according to many linguists (see for instance Greenbaum and Quirk, 2003: 61) denotes a higher degree of formality. However, in some of the analysed leaflets (Lipitor, Reactine) *can* predominates. This may be supposed an intention to make the leaflets a bit more personal and thus closer to the reader, but the reasons for it may be different.

Similarly to the imperatives, modal verbs often appear with conditions. Contrary to the imperatives, they may appear within a conditional clause (not only in the main clause) and in fact there are ten cases when they do so. Twenty-two more modals are part of the main clause preceding or following conditional clause. As well as imperatives, some of them function as recommendations or advices (4). In some other cases they can also express possibility bounded to a condition (5).

4) If the nozzle becomes blocked it can be removed as above and left to soak in warm water. (Flonase)

5) If you are allergic to drugs similar to TEMODAR, you may also have an allergic reaction to TEMODAR. (Temodar)

**Table 5: Central modal verbs in PILs and comparative texts**

| | Leaflets in total | Leaflets / 2 | Comparative texts |
|---|---|---|---|
| Can | 64 | 32 | 14 |
| Could | 4 | 2 | 17 |
| May | 92 | 46 | 1 |
| Might | 2 | 1 | 2 |
| Must | 4 | 2 | 1 |
| Shell | 0 | 0 | 0 |
| Should | 65 | 32,5 | 3 |
| Will | 20 | 10 | 21 |
| Would | 3 | 1,5 | 12 |
| Total | 254 | 127 | 71 |

When comparing the presence of the modal verbs in the examined patient information leaflets with the other text, it is indisputable that they are more characteristic feature of the first corpus than the second one. Although the difference is not as significant as for imperatives, there are still 44% more modals in PILs than in the comparative texts.

From the table above it is obvious that the greatest difference is with the use of the verb *may*, which presumably has to do with the degree of formality as suggested above. On the other hand, verbs like *could*, *might* and *would* are more frequent in the texts of different styles. There they occasionally refer to the past which is not expressed in the package inserts.

Considering the ratio of modal verbs to the whole text, it also brings interesting results. The overall occurrence of modals in PILs is 2.43% and 1.36% of the comparative texts. Nevertheless, their occurrence in the individual leaflets differs from 0.73% to 3.46%. It means that the statement that modal verbs are more common in patient information leaflets than in other texts is not always true.

Comparing the two primary sources, it should be considered that while the corpus of patient information leaflets is homogenous, the corpus of other texts is not. The texts are written in different styles and have different functions. Some of them contain many and some only few modal verbs.

Moreover, not all styles are included there. For that reason the comparison only suggests the possible results and more detailed analysis would be necessary to prove the higher occurrence of modal verbs in PILs.

For detailed results of the analysis see Appendix no. 3.

## 5.5 Expressing necessity

**Table 6: Occurrence of imperative and deontic must and should**

| | Number of occurrence | Ratio [ % ] |
|---|---|---|
| Imperative | 338 | 83.25 |
| Deontic should | 64 | 15.76 |
| Deontic must | 4 | 0.99 |
| Total | 406 | 100 |

As it is already outlined in chapter 2, there are basically two major possibilities how to express deontic necessity - by the imperative structure or by using either *must* or *should* in their deontic meaning. The first one is considered stronger and more direct, while the second possibility is softer, especially when using *should* (see chapter 2 for this outcome).

In the analysed corpus deontic necessity is usually expressed by imperatives (1). There are 338 of them in total, i.e. 83.25%. To the contrary, *should* is used 64 times (2) and *must* only four times (3). Only one *should* in the whole corpus was classified as epistemic and thus it is not included.

1) Know all the medicines you take. (Lipitor)
2) You and your doctor should decide whether you should take LYRICA or breastfeed, but not both. (Lyrica)
3) If you travel to parts of the world where the mosquitoes carry the malaria parasite, you must take a malaria prevention medicine. (Lariam)

Imperative predominates in most of the leaflets. The only exception is Temodar with 16 imperatives and 17 occurrences of *should* and one *must*. The difference is not so significant and the reasons for that would be only

speculations. Other extraordinary results were noticed in Reactine leaflet which does not include any modal verb expressing deontic necessity and Flonase leaflet where there is only one *should*. A noteworthy fact is that both mentioned PILs are issued by a Canadian manufacturer. Nevertheless, the examined sample is too little to make any conclusions from such results.

As imperative is regarded stronger (see chapter 2), it is usually used for direct orders for actions which are required to be done and for instructions. They make the utterance shorter and therefore easier to understand and follow. Necessity expressed by *should* tends to be milder and not so authoritative; it extends the clause. For these reasons it is mostly used for recommendations as it was mentioned in 4.3.2.

The subject in the analysed imperative structures is always *you*, while in the clauses with *should* it appears only in 15 cases (for the overall occurrence of *should* of 64). Even more frequent subject is a different personal pronoun *I* which was counted 19 times and which is used in interrogative structures. Other subjects are for instance *patients* (12 cases) or the drugs referred either by their name (two cases) or by a pronoun (two cases) or in a different way, i.e. *medicines*, *medication*, *tablets* (five cases).

The previous paragraph mentions the occurrence of modal verb *should* in interrogative sentences. They are used as the titles of individual sections of the leaflet (4) and enable the texts to be more interactive. The use of *should* in these structures accounts for 25 cases in total, i.e. almost 40% of the overall occurrence of this modal verb.

4) How should I take TEMODAR? (Temodar)

There are 17 clauses in the corpus, where *should* is followed by a verb in passive voice. Such utterances mark a higher degree of formality and make the text a bit impersonal. Biber et al. (1999: 500) claims that modals *must* and *should* "are used to express a kind of collective (personal) obligation, but the passive voice is used to avoid explicit identification of the person who is obliged to act." However, from the context it can be supposed that most often they are patients or their physicians.

*Must* is used very rarely in the examined corpus, probably for its strength. It is followed by active voice in all cases. The subject is three times *you* and once *patients*. *Must* denotes the action which is really necessary to be done. The sentence (5) could be paraphrased by imperative, similarly the sentence (6), but they are not.

5) Another schedule should be taken for 5 consultative days only then you must STOP taking TEMODAR for the next 23 days. / ...then STOP taking... (Temodar)
6) If you travel to parts of the world where the mosquitoes carry the malaria parasite, you must take a malaria prevention medicine. / ...the malaria parasite, take a malaria prevention medicine. (Lariam)

Chapter 4.3.1 mentions the use of periphrastic *have to* instead of *must* but this semi-modal does not occur in the analysed leaflets. The first supposed reason for it can be the absence of the higher authority such as for example law or regulation. The orders always come from the author of the leaflet. The second possible use of *have to* is when referring to past, which is not expressed in the PILs and so the semi-modal verb is not used in this sense. Another feature chapter 4.3.1 concerns is the negative form of *must*. It may be expressed either by phrase *do not have to/do not need to* or *must not* (for details see 4.3.1). No negative form of *must* appears in the examined package inserts. The orders are therefore affirmative in all cases and prohibitions are expressed in a different way (usually by imperative).

The Chapter 4.4 mentions also other expressions which denote necessity. Only two of those listed there appear in the analysed corpus. They are *need to* (10 occurrences) and *be important* (4 occurrences). The examples are below (7, 8). These expressions make the language of PILs more varied.

7) It briefly outlines the most important things you need to know. (Codeine)
8) It is important that you doctor knows that you are taking Ritonavir. (Flonase)

## 5.6 Summary of the corpus findings

The analysis reveals that imperatives occur very often in the patient information leaflets. Most of them are affirmative, telling people what they should do, while prohibitions in form of negative imperative are not so common. The imperatives in all analysed texts have their basic structure and they are rarely softened by the word *please*. Most often they appear as instructions or they are dependent on a condition. The most frequent verbs used in imperative structures are those connected to the drug or the leaflet or the verbs of communicative meaning. The comparison with the corpus consisting of various texts of different styles distinctly proved that the imperative structures are far more typical for the analysed register than for the others.

Regarding modal verbs, the most frequent are *may*, *should*, *can* and *will*, while *might*, *could* and *would* are rather rare; *shell* is not used at all. As it is illustrated in the examples in 5.4., they express both epistemic and deontic modality. Modal verbs are more common in the package inserts than in the comparative texts, although the numbers do not differ as much as in the analysis of imperatives. For the results it is necessary to take into consideration a high variety of the texts as it is outlined in the end of the chapter 5.4.

Comparing the use of imperatives and deontic *must* and *should* for expressing necessity, it is evident that the first mentioned is preferred. Imperatives seem to be more suitable for the main purpose of the given register – to order and to instruct the patients. *Should* is preferred primarily in the context of giving advices and for recommendations. It is often used in the interrogatives in the titles and sometimes in the passive structures. *Must* is probably regarded to be too strong and not so polite as *should* and for that reason it appears only in rare and really necessary cases.

# 6. Conclusion

To conclude this bachelor paper, the contents and the results should be recapitulated and summarized with respect to the aims.

The first part of the paper is focused on the theoretical background of the examined devices, which are imperatives and modal verbs. Their basic features, functions and uses are described there. The way how they express necessity is mentioned as well. The theory is followed by the analysis of the corpus consisting of ten patient information leaflets.

The first aim of the research was to chart the occurrence and the frequency of use of the chosen devices. The hypothesis supposes that the occurrence of imperatives and modal verbs in patient information leaflets is very high. Regarding imperatives the hypothesis is definitely confirmed. In the corpus consisting of 10,443 words there are 338 of them, i.e. more than 3%. Without a comparison it could be difficult to determine if the number is high or not. For that reason a corpus including nine various texts of different styles was analysed as well. There were counted less then 0.5% of imperatives. On the other hand, the results were not so clear when talking about modal verbs. Their overall occurrence in the package inserts is almost 2.5%, while in the other texts it is 1.36%. The difference is quite obvious. Nevertheless, when examining the PILs individually the number is less than 1.36% in three cases. For that reason the occurrence of modal verbs in patient information leaflets should be considered only *high*, rather than *very high*. The first aim was successfully achieved and the hypothesis appears to be confirmed, though not completely.

The second goal of this paper was to find out if necessity is primarily expressed by imperative or rather by semantically similar modals *should* and *must*. For that purpose both devices were contrasted. The hypothesis preferred the imperatives and it appeared to be right. In the whole corpus there are 338 imperatives while *should* denotes the necessity in 64 cases and *must* only four times. Imperative is mostly applied in instructive parts which are action-demanding and direct language is required. Although it could be considered offensive, it is a characteristic feature of such register.

Necessity expressed by *should* is not so strong and thus it is often used for recommending. It mostly denotes the required action rather than necessary. *Must* seems to be too strong for this register; it is often avoided and paraphrased by different devices.

Another research and corpus analysis could be carried out in this field in the future. They could examine different features, for example conditional clauses which are very frequent or the use of active and passive voice could be contrasted. Additionally, the comparison of some features in English and Czech patient information leaflets would probably show interesting results.

# 7. Resumé

Tato bakalářská práce se zabývá stylistickou analýzou příbalových letáků léčiv. Je zaměřena především na analýzu dvou distinktivních jazykových prostředků, kterými jsou modální slovesa (zejména *must* a *should*) a imperativ. Tyto prostředky byly zvoleny s ohledem na jejich sémantickou blízkost a také proto, že se zdají být charakteristickým rysem zkoumaného registru. Cílem práce je především zmapovat výskyt a frekvenci užití imperativu a modálních sloves v příbalových letácích a zároveň zjistit, který z těchto prostředků je upřednostňován pro vyjadřování deontické nutnosti. Práce je rozdělena na část teoretickou a část analytickou.

Teoretická část poskytuje informace o hlavních znacích, funkcích a významech imperativu a modálních sloves, především *must* a *should*. Její první kapitola vymezuje tyto prostředky, porovnává je a upozorňuje na jejich společné rysy a hlavní rozdíly mezi nimi. Oba jevy jsou si významově podobné, protože plní stejnou funkci – komunikují příkazy a zákazy. Rozdíl tkví především v jejich výpovědní síle. Za nejsilnější rozkaz jsou považovány imperativy, následované modálním slovesem *must*. Věty obsahující sloveso *should* jsou nejen slabším rozkazem, či spíše doporučením, ale zároveň jsou i formálnější.

Druhá kapitola teoretické části podrobně popisuje distinktivní znaky imperativu a v závěru přibližuje jeho různé funkce a možné způsoby užití. Nejcharakterističtější z nich je pravděpodobně funkce prostého rozkazu. Imperativ se dále hojně využívá pro různé žádosti, instrukce, rady a doporučení.

Následující kapitola seznamuje s modálními slovesy. Představuje jejich typické rysy, specifika a kategorizaci. Dále se zabývá jednotlivými modály především pak *must* a *should*, které jsou z hlediska následné analýzy nejdůležitější, neboť jimi lze vyjádřit deontickou nutnost.

Teoretickou část následuje část analytická, která prezentuje a komentuje zjištěné výsledky. K analýze bylo použito deset příbalových letáků od těchto léčiv: Chantix, Imodium, Lyrica, Zmax, Reactine, Lipitor, Temodar, Lariam, Codeine a Flonase. Léky vyrobilo šest různých

farmaceutických společností ze čtyř anglicky mluvících zemí (USA, Spojené království, Irsko a Kanada). To mělo zajistit jejich dostatečnou variabilitu. Druhý primární zdroj tvoří soubor devíti textů různých stylů. Tyto texty posloužily k porovnání výsledků s analyzovanými letáky a pomohly určit rozdílnou míru výskytu zkoumaných jevů i jejich rozdílné užití.

Začátek analytické části zmiňuje specifika zkoumaného registru a stručně popisuje ostatní stylisticky významné jevy, které nebyly zahrnuty do následné analýzy. V této kapitole jsou definovány hlavní funkce příbalového letáku, které lze charakterizovat jako informativní a instruktivní; často také radí a doporučuje. Jako nejvýznamnější se jeví funkce informativní, díky níž se pacient může dovědět nezbytné informace o léku, které potřebuje vědět. K zajištění správného užívání léku většinou slouží instruktivní části letáků, které pacientům říkají, co mají s medikamentem dělat. Příbalové letáky jsou psané formálním jazykem, který je však obvykle zcela srozumitelný a nekomplikovaný. Vyskytují se jak jednoduché věty tak i souvětí, která ovšem nebývají zbytečně složitá. Cizí a přejatá slova jsou zpravidla nahrazována slovy anglosaského původu. Trpný rod se zde sice vyskytuje, ale ne příliš často a převážně na místech, kde je žádoucí, například nelze-li přesně určit konatele děje.

Praktická analýza se nejprve zaměřuje na imperativy, sleduje jejich výskyt a užití. V korpusu deseti příbalových letáků se vyskytlo celkem 338 imperativů, z toho 276 kladných a 62 záporných. To znamená, že v letácích se objevuje více přímých rozkazů než zákazů. Negativní konstrukce omezují především konzumaci léku, ale mohou se vztahovat i k jiným informacím. Slovo *please* zjemňující danou výpověď se vyskytuje jen zřídkakdy. Imperativy lze nalézt ve větách jednoduchých i v souvětích, a to souřadných i podřadných. Častým typem vedlejší věty je věta podmínková, časová a účelová. Imperativ v hlavní větě následované nebo předcházené podmínkovou větou se objevil celkem ve 112 případech, což činí jednu třetinu všech imperativů v textu. Takovéto konstrukce upozorňují pacienty na možné situace, které mohou nastat a radí jim, jak se v takových případech zachovat.

Nejfrekventovanějšími slovesy v imperativu jsou *take*, *tell*, *keep*, *ask* a *see*. Ve zkoumaných letácích bylo každé z nich napočítáno více než patnáctkrát. Jejich vysoký výskyt je vzhledem k povaze textů pochopitelný. Sloveso *take* je spojené především s konzumací léku, stejně tak i *keep*, i když to se objevuje i v iných významech. Sloveso *see* referuje o letáku samotném, případně doporučuje návštěvu lékaře. Ke kontaktu s odborníkem nabádají i slovesa *tell* a *ask*. Tato i další slovesa vztahující se ke komunikaci (*consult*, *contact*, *talk* a *call*) jsou významným jevem příbalových letáků. Dohromady se jich zde vyskytuje celkem 85, což představuje 25 % všech nalezených imperativů.

Srovnání výsledků s frekvencí užití imperativů v dalších textech potvrzuje jejich velmi vysoký výskyt ve zkoumaném registru. Slovesa v imperativu tvoří 3 % všech slov v příbalových letácích léčiv; u srovnávacích textů tento poměr nedosahuje ani 0,5 %. Rozdíl lze spatřit i v jejich funkci. Zatímco imperativy v příbalových letácích mají často charakter instrukcí, v porovnávacích textech vyjadřují spíše příkazy. Druhým významným rozdílem je adresát. Příbalové letáky oslovují výhradně jejich čtenáře; rozkazy ve srovnávacích textech pak mohou být určeny i jiným osobám, například druhé postavě v příběhu.

Analytická část se dále zabývá rozborem modálních sloves. Zkoumané příbalové letáky jich obsahují celkem 254. Nejfrekventovanější z nich je sloveso *may*, dále následuje *can* a *will*. Modály *could*, *must*, *would* a *might* se objevují spíše sporadicky a *shell* nebylo zaznamenáno vůbec. Slovesa *may* a *can* v letácích vyjadřují spíše epistemickou než deontickou modalitu. *Will* se často vztahuje k budoucnosti. Porovnání celkových výsledků frekvencí výskytu v letácích a v jiných textech dokazuje, že i v tomto případě jsou modály typičtější pro příbalové letáky. Toto však neplatí výhradně, neboť některé letáky obsahují modálních sloves méně a jiné zase více. Zároveň je třeba zohlednit fakt, že srovnávací texty nejsou narozdíl od příbalových letáků léčiv homogenním korpusem a také nezahrnují všechny styly.

V další části je imperativ kontrastován s modály *must* a *should*. Cílem tohoto srovnání bylo zjistit, který z těchto prostředků je preferován pro vyjadřování deontické nutnosti. Analýza jasně dokázala, že je jím imperativ. Těch bylo v příbalových letácích napočítáno celkem 338, přičemž sloveso *should* vyjadřující deontickou modalitu se objevilo celkem v 64 případech a *must* pouze čtyřikrát. Jedinou výjimkou mezi letáky byl Temodar, ve kterém zmíněná modální slovesa nepatrně převažují. Práce nastiňuje několik možných důvodů pro upřednostňování imperativu, většinou však jde o pouhé domněnky. Jedním z důvodů by mohl být fakt, že imperativ se zdá být vhodnější pro vyjádření přímých rozkazů a instrukcí, jelikož je direktnější a činní výpověď kratší. Nutnost vyjádřená pomocí slovesa *should* není tolik autoritativní a prodlužuje větu, užívá se ho tedy především tam, kde je potřeba komunikovat doporučení. Podmětem v rozkazovací větě je vždy oslovovaný čtenář (tj. osobní zájmeno *you*). Ve větě s *should* je tomu tak pouze v patnácti případech. Jiným podmětem pak může být například jiné osobní zájmeno *I* (19 případů), pacienti (12 případů) nebo léky referované různými slovy (9 případů). Sloveso *should* se neobjevuje pouze v oznamovacích větách, obvyklý je i jeho výskyt ve větách tázacích. Ty jsou časté zejména jako názvy jednotlivých sekcí letáku. *Should* se v těchto konstrukcích objevuje celkem 25krát, což pokrývá téměř 40 % veškerého výskytu tohoto modálu. Sloveso *must* je použito jen sporadicky, pravděpodobně kvůli jeho síle a menší míře zdvořilosti. Většinou značí činnost, která je opravdu nezbytná. V několika případech je nutnost v letácích vyjádřena opisnými výrazy *need to* a *be important*. Tato slova dělají jazyk příbalových letáků léčiv pestřejší.

Závěrem lze říci, že oba cíle bakalářské práce byly naplněny a hypotézy stanovené na začátku práce byly s větší či menší průkazností potvrzeny. Dokládají tak vysoký výskyt imperativů a modálních sloves v příbalových letácích lečiv i upřednostňování imperativů pro vyjádření deontické nutnosti.

# 8. Bibliography

## Primary sources


Chantix, patient information leaflet. Pfizer Labs, 2006.

Codeine phosphate, patient information leaflet. TEVA UK, 2005.

Flonase, patient information leaflet. GlaxoSmithKline.

Imodium Plus, patient information leaflet. McNeil, 2005.

Lariam, patient information leaflet. Roche Laboratories, 2003.

Lipitor, patient information leaflet. Pfizer Ireland Pharmaceuticals, 2006.

Lyrica, patient information leaflet. Pfizer Pharmaceuticals LLC, 2007.

Reactine, patient information leaflet. Pfizer Canada.

Temodar, patient information leaflet. Schering Corporation, 2004.

Zmax, patient information leaflet. Pfizer Labs, 2008.


**Electronic sources:**


CAMPBELL, Jean. *Make Jewelry More Colorful with Resin Beads* [online]. Beading Daily, November 2009 [cited 2009-12-02]. Available from WWW: <http://www.beadingdaily.com/blogs/daily/archive/2009/11/04/ideas-for-using-resin-beads.aspx>

CHOWDHURY, Rohini. *The Monkey and the Crocodile* [online]. Last revision October 2007 [cited 2009-12-02]. Available from WWW: <http://www.longlongtimeago.com/llta_fables_monkeycroc.html>

*Cops shoot dead police killer* [online]. The Sun. December 2009 [cited 2009-12-02]. Available from WWW: <http://www.thesun.co.uk/sol/homepage/news/2751231/Cops-shoot-dead-police-killer.html#ixzz0YRoS1Z5Z>

GAGE, Nicholas. *Of Love and War* [online]. The Washington Post, 17th October 2004 [cited 2009-12-02]. Available from WWW: <http://www.washingtonpost.com/wp-dyn/articles/A34136-2004Oct14.html>

GANZ, Caryn. *Rufus Wainwright* [online]. Interview Magazine [cited 2009-12-02]. Available from WWW: <http://www.interviewmagazine.com/music/rufus-wainwright/>

*Hit The Floor – A True Story* [online]. April 2001 [cited 2009-12-02]. Available from WWW: <http://www.allcleanhumor.com/jokesarchive/arc92.shtml>

*Introducing Madagascar* [online]. Lonely Planet. Last revision 27th October 2009 [cited 2009-12-02]. Available from WWW: <http://www.lonelyplanet.com/madagascar>

*Nokia N93 Cell Phone* [online]. November 2005 [cited 2009-12-02]. Available from WWW: <http://www.mobilewhack.com/reviews/nokia_n93_cell_phone.html>

SARGEANT, Frank. *Dolphin at a Glance* [online]. Florida Sportsman [cited 2009-12-02]. Available from WWW: <http://www.floridasportsman.com/sportfish/dolphin/S_0005_Dolphin_Description/>

## Secondary sources

Anonymous. *Collins Cobuild English Grammar*. London: HarperCollins Publishers, 1996. 486 p. ISBN 0-00-370257-X

BIBER, Douglas et al. *Longman Grammar of Spoken and Written English*. Harlow: Longman, 1999. 1204 p. ISBN 0-582-237254

CRYSTAL, David - DAVY, Derek. *Investigating English Style*. Harlow: Addison Wesley Longman, 1969. 264 p. ISBN 0-582-55011-4

DUŠKOVÁ, Libuše et al. *Mluvnice současné angličtiny na pozadí češtiny*. Praha: Academia, 2003. 674 p. ISBN 80-200-1073-4

GREENBAUM, Sidney - QUIRK, Randolph. *A Student's Grammar of the English Language*. Harlow: Pearson Education, Longman, 2003. 490 p. ISBN 0-582-0597-1.2

HUDDLESTON, Rodney - PULLUM, Geoffrey K. *The Cambridge Grammar of the English Language*. Cambridge: Cambridge University Press, 2002. 1842 p. ISBN 0-521-43146-8

HUDDLESTON, Rodney. *Introduction to the Grammar of English*. Cambridge: Cambridge University Press, 1993. 483 p. ISBN 0-521-29704-4

JACOBS, Roedrick A. *English Syntax: A Grammar for English Language Professionals*. Oxford: Oxford University Press, 1995. 378 p. ISBN 0-19-434277-8

KNITTLOVÁ, Dagmar. Funkční styly v angličtině a češtině. Olomouc: Univerzita Palackého, 1990.

LEECH, Geoffrey. *An A-Z of English Grammar and Usage*. London: Nelson English Language Teaching, 1991. 575 p. ISBN 0-17-556021-8

QUIRK, Randolph – GREENBAUM, Sidney. *A University Grammar of English*. Harlow: Addison Wesley Longman, 1996. 484 p. ISBN 0-582 55207-9

QUIRK, Randolph et al. *A Comprehensive Grammar of the English Language*. London: Longman, 1991. 1779 p. ISBN 0-582-51734-6

SWAN, Michael. *Practical English Usage*. Oxford: Oxford University Press, 1996. 654 p. ISBN 0-19-442146-5

URBANOVÁ, Ludmila - OAKLAND, Andrew. *Úvod do anglické stylistiky*. Brno: Barrister & Principal, 2002. 148 p. ISBN 80-86598-33-0

**Electronic sources:**


DAVIES, Eirlys. *The English Imperative* [online]. Kent: Mackays and Chatham, 1986, [cited 2010-02-26]. 279 p. ISBN 0-7099-4513-2. Available from WWW: <http://books.google.cz/books?id=uaYOAAAAQAAJ&printsec=frontcover#v=onepage&q=&f=false>

PETERSON, Jan. *What Makes A Good Patient Information Leaflet?* [online]. Article Friendly. October 2009, [cited 2010-03-23]. Available from WWW: <http://www.articlefriendly.net/Art/30909/335/What-Makes-A-Good-Patient-Information-Leaflet.html>

BEARE, Kenneth. *Introduction to Vertical Register Usage* [online]. [cited 2010-03-21]. Available from WWW: <http://esl.about.com/od/advancedspeakingskills/a/v_register.htm>

JEFFREY, Laura. *Different types of texts* [online]. April 2007, [cited 2010-03-21]. Available from WWW: <http://www.skillsworkshop.org/text/e3l1l2texttypeshandout.pdf>

KELLER, Arnold. *The Language of Instructions* [online]. Last revision 31st January 2007, [cited 2010-03-17]. Available from WWW: <http://web.uvic.ca/akeller/pw408/r_lang_of_instructions.html>

# 9. Appendices

## List of appendices:



## Legend:

Imperatives and modal verbs in the analysed patient information leaflets are marked in the following way:

- imperative
- modal verbs

In the comparative text they are highlighted like this:

- imperative
- modal verbs

# Appendix 1

**Patient information leaflets, general information**

| Drug | Producer | Country | Form of drug |
|---|---|---|---|
| CHANTIX | Pfizer | USA | tablets |
| IMODIUM | McNeil | UK | caplets |
| LYRICA | Pfizer | USA | capsules |
| ZMAX | Pfizer | USA | tablets |
| REACTINE | Pfizer | Canada | tablets |
| LIPITOR | Pfizer | Ideland | tablets |
| TEMODAR | Schering | USA | capsules |
| LARIAM | Roche | USA | tablets |
| CODEINE | Teva UK | UK | tablets |
| FLONASE | GlaxoSmithKline | Canada | nasal spray |

# Appendix 2

**Imperative in the analysed texts**

| Name of drug | Words | Affirmative imperative | Negative imperative | Total | Ratio [%] |
|---|---|---|---|---|---|
| CHANTIX | 745 | 27 | 3 | 30 | 4.03 |
| IMODIUM | 546 | 14 | 7 | 21 | 3.85 |
| LYRICA | 1560 | 35 | 14 | 49 | 3.14 |
| ZMAX | 1400 | 47 | 3 | 50 | 3.57 |
| REACTINE | 685 | 29 | 5 | 34 | 4.96 |
| LIPITOR | 1083 | 28 | 10 | 38 | 3.51 |
| TEMODAR | 1156 | 13 | 3 | 16 | 1.38 |
| LARIAM | 1089 | 19 | 1 | 20 | 1.84 |
| CODEINE | 1012 | 15 | 8 | 23 | 2.27 |
| FLONASE | 1167 | 49 | 8 | 57 | 4.88 |
| Total | 10443 | 276 | 62 | 338 | 3.24 |
| Leaflets / 2 | 5221.5 | 138 | 31 | 169 | 3.24 |
| Comparative texts | 5224 | 18 | 3 | 21 | 0.40 |

# Appendix 3

**Modal verbs in the analysed texts**

| Name of drug | Words | Must | Should | May | Might | Can | Could | Will | Would | Shell | Total | Ratio [%] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CHANTIX | 745 | 0 | 4 | 8 | 0 | 2 | 0 | 3 | 1 | 0 | 18 | 2.42 |
| IMODIUM | 546 | 0 | 2 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 4 | 0.73 |
| LYRICA | 1560 | 0 | 15 | 26 | 0 | 13 | 0 | 2 | 1 | 0 | 57 | 3.65 |
| ZMAX | 1400 | 2 | 13 | 7 | 1 | 5 | 2 | 5 | 0 | 0 | 35 | 2.5 |
| REACTINE | 685 | 0 | 0 | 2 | 0 | 6 | 0 | 1 | 0 | 0 | 9 | 1.31 |
| LIPITOR | 1083 | 0 | 5 | 9 | 0 | 14 | 0 | 1 | 1 | 0 | 30 | 2.77 |
| TEMODAR | 1156 | 1 | 17 | 10 | 1 | 8 | 1 | 2 | 0 | 0 | 40 | 3.46 |
| LARIAM | 1089 | 1 | 4 | 14 | 0 | 8 | 0 | 3 | 0 | 0 | 30 | 2.75 |
| CODEINE | 1012 | 0 | 4 | 8 | 0 | 2 | 1 | 1 | 0 | 0 | 16 | 1.58 |
| FLONASE | 1167 | 0 | 1 | 7 | 0 | 6 | 0 | 1 | 0 | 0 | 15 | 1.29 |
| Total | 10443 | 4 | 65 | 92 | 2 | 64 | 4 | 20 | 3 | 0 | 254 | 2.43 |
| Leaflets / 2 | 5221,5 | 2 | 32.5 | 46 | 1 | 32 | 2 | 10 | 1.5 | 0 | 127 | 2.43 |
| Comparative texts | 5224 | 1 | 3 | 1 | 2 | 14 | 17 | 21 | 12 | 0 | 71 | 1.36 |

# Appendix 4

## Chantix, patient information leaflet

**PATIENT INFORMATION**

**CHANTIX™**
**(varenicline) Tablets**

Read the patient information that comes with CHANTIX before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your condition or treatment.

**WHAT IS CHANTIX?**

CHANTIX is a prescription medicine to help adults stop smoking.

**WHO SHOULD NOT TAKE CHANTIX?**

CHANTIX has not been studied in children under 18 years of age. CHANTIX is not recommended for children under 18 years of age.

Do not take CHANTIX if you are allergic to anything in it. See a complete list of ingredients at the end of this leaflet.

**WHAT SHOULD I TELL MY DOCTOR BEFORE STARTING CHANTIX?**

Tell your doctor about all of your medical conditions including if you:

- have kidney problems or get kidney dialysis. Your doctor may prescribe a lower dose of CHANTIX for you.
- are pregnant or plan to become pregnant. CHANTIX has not been studied in pregnant women. It is not known if CHANTIX will harm your unborn baby. It is best to stop smoking before you get pregnant.
- are breast-feeding. Although it was not studied, CHANTIX may pass into breast milk. You and your doctor should discuss alternative ways to feed your baby if you take CHANTIX.

Tell your doctor about all your other medicines including prescription and nonprescription medicines, vitamins and herbal supplements. Especially, tell your doctor if you take:

- insulin
- asthma medicines
- blood thinners.

When you stop smoking, there may be a change in how these and other medicines work for you.

Know the medicines you take. Keep a list of them with you to show your doctor and pharmacist.

**HOW DO I TAKE CHANTIX?**

1. Choose a **quit date** when you will stop smoking.
2. Start taking CHANTIX 1 week (7 days) before your **quit date**. This lets CHANTIX build up in your body. You can keep smoking during this time. Make sure that you try and stop smoking on your **quit date**. If you slip, try again. Some people need a few weeks for CHANTIX to work best.
3. Take CHANTIX after eating and with a full glass (8 ounces) of water.
4. Most people will keep taking CHANTIX for up to 12 weeks. If you have completely quit smoking by 12 weeks, ask your doctor if another 12 weeks of CHANTIX may help you stay cigarette-free.

- CHANTIX comes as a white tablet (0.5 mg) and a blue tablet (1 mg). You start with the white tablet and then usually go to the blue tablet. See the chart below for dosing instructions.

| | |
|---|---|
| Day 1 to Day 3 | • White tablet (0.5 mg), 1 tablet each day |
| Day 4 to Day 7 | • White tablet (0.5 mg), twice a day<br>• 1 in the morning and 1 in the evening |
| Day 8 to end of treatment | • Blue tablet (1 mg) twice a day<br>• 1 in the morning and 1 in the evening |

- This dosing schedule may not be right for everyone. Talk to your doctor if you are having side effects such as nausea or sleep problems. Your doctor may want to reduce your dose.
- If you miss a dose, take it as soon as you remember. If it is close to the time for your next dose, wait. Just take your next regular dose.

**WHAT ARE THE POSSIBLE SIDE EFFECTS OF CHANTIX?**

The most common side effects of CHANTIX include:

- nausea
- changes in dreaming
- constipation
- gas
- vomiting

Tell your doctor about side effects that bother you or that do not go away.

These are not all the side effects of CHANTIX. Ask your doctor or pharmacist for more information.

**HOW SHOULD I STORE CHANTIX?**

- Store CHANTIX at room temperature, 59 to 86°F (15 to 30°C).
- Safely dispose of CHANTIX that is out of date or no longer needed.
- **Keep CHANTIX and all medicines out of the reach of children.**

**GENERAL INFORMATION ABOUT CHANTIX**

Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not use **CHANTIX** for a condition for which it was not prescribed. Do not give your **CHANTIX** to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about CHANTIX. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about CHANTIX that is written for healthcare professionals.

To find out more about CHANTIX and tips on how to quit smoking:

- Go to the CHANTIX website at **www.CHANTIX.com**.
- Call **1-877-CHANTIX (877-242-6849)**.

**WHAT IS IN CHANTIX?**

**Active ingredient:** varenicline tartrate

**Inactive ingredients:** microcrystalline cellulose (NF), anhydrous dibasic calcium phosphate (USP), croscarmellose sodium (NF), colloidal silicon dioxide (NF), magnesium stearate (NF), Opadry® White (for 0.5 mg), Opadry® Blue (for 1 mg), and Opadry® Clear (for both 0.5 mg and 1 mg)

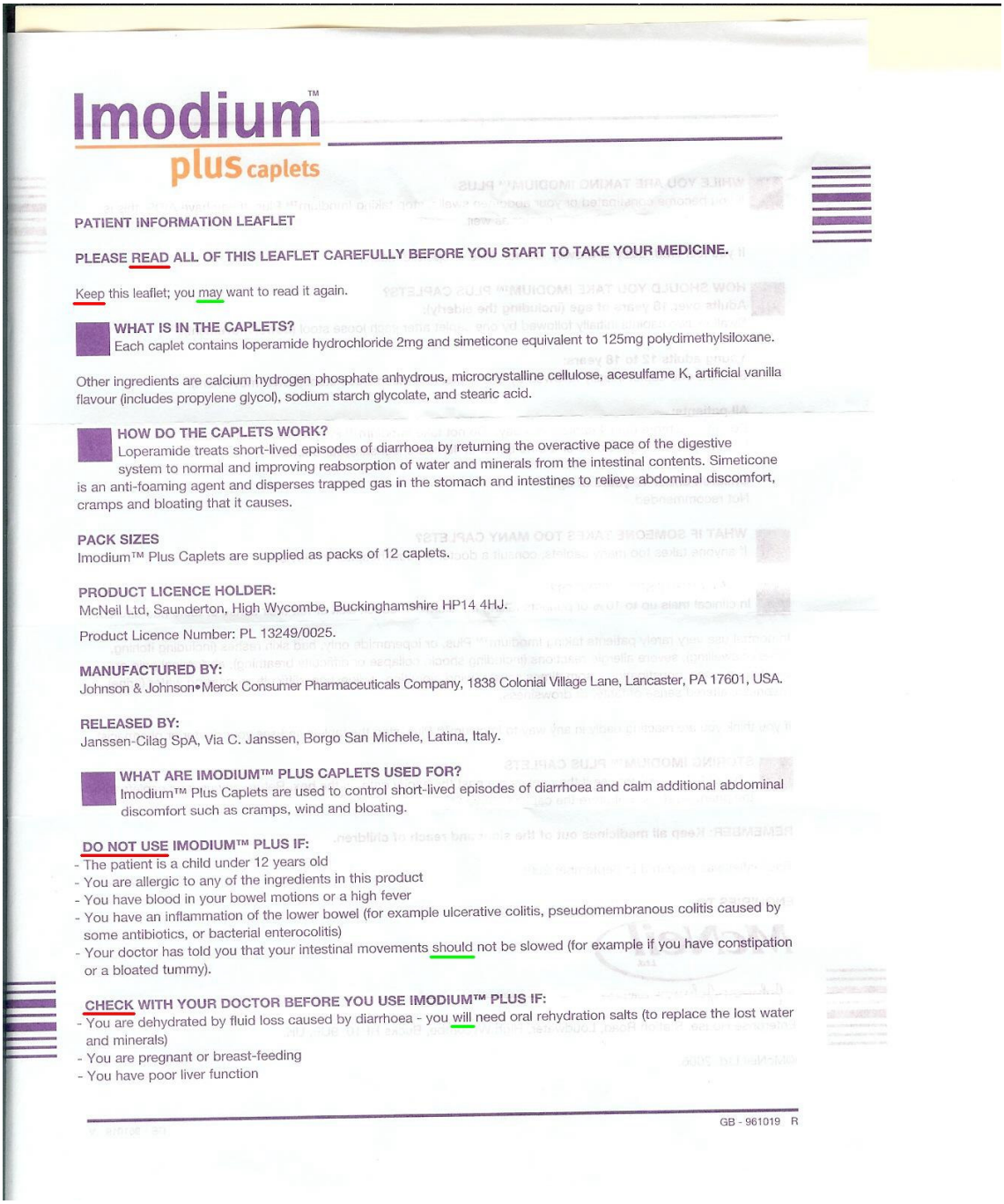
**Rx only**

*Distributed by*
**Pfizer Labs**
Division of Pfizer Inc, NY, NY 10017

LAB-0328-3.0
May 2006

# Appendix 5

## Imodium, patient information leaflet



Imodium™
plus caplets

PATIENT INFORMATION LEAFLET

PLEASE READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR MEDICINE.

Keep this leaflet; you may want to read it again.

**WHAT IS IN THE CAPLETS?**
Each caplet contains loperamide hydrochloride 2mg and simeticone equivalent to 125mg polydimethylsiloxane.

Other ingredients are calcium hydrogen phosphate anhydrous, microcrystalline cellulose, acesulfame K, artificial vanilla flavour (includes propylene glycol), sodium starch glycolate, and stearic acid.

**HOW DO THE CAPLETS WORK?**
Loperamide treats short-lived episodes of diarrhoea by returning the overactive pace of the digestive system to normal and improving reabsorption of water and minerals from the intestinal contents. Simeticone is an anti-foaming agent and disperses trapped gas in the stomach and intestines to relieve abdominal discomfort, cramps and bloating that it causes.

**PACK SIZES**
Imodium™ Plus Caplets are supplied as packs of 12 caplets.

**PRODUCT LICENCE HOLDER:**
McNeil Ltd, Saunderton, High Wycombe, Buckinghamshire HP14 4HJ.

Product Licence Number: PL 13249/0025.

**MANUFACTURED BY:**
Johnson & Johnson•Merck Consumer Pharmaceuticals Company, 1838 Colonial Village Lane, Lancaster, PA 17601, USA.

**RELEASED BY:**
Janssen-Cilag SpA, Via C. Janssen, Borgo San Michele, Latina, Italy.

**WHAT ARE IMODIUM™ PLUS CAPLETS USED FOR?**
Imodium™ Plus Caplets are used to control short-lived episodes of diarrhoea and calm additional abdominal discomfort such as cramps, wind and bloating.

**DO NOT USE IMODIUM™ PLUS IF:**
- The patient is a child under 12 years old
- You are allergic to any of the ingredients in this product
- You have blood in your bowel motions or a high fever
- You have an inflammation of the lower bowel (for example ulcerative colitis, pseudomembranous colitis caused by some antibiotics, or bacterial enterocolitis)
- Your doctor has told you that your intestinal movements should not be slowed (for example if you have constipation or a bloated tummy).

**CHECK WITH YOUR DOCTOR BEFORE YOU USE IMODIUM™ PLUS IF:**
- You are dehydrated by fluid loss caused by diarrhoea - you will need oral rehydration salts (to replace the lost water and minerals)
- You are pregnant or breast-feeding
- You have poor liver function

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## WHILE YOU ARE TAKING IMODIUM™ PLUS

If you become constipated or your abdomen swells, stop taking Imodium™ Plus. If you have AIDS, this is especially important - see your doctor as well.

If you feel tired, dizzy or drowsy, do not drive or operate machinery.

## HOW SHOULD YOU TAKE IMODIUM™ PLUS CAPLETS?

**Adults over 18 years of age (including the elderly):**
Swallow two caplets initially followed by one caplet after each loose stool (bowel movement).

**Young adults 12 to 18 years:**
Swallow one caplet initially followed by one caplet after each loose stool (bowel movement).

**All patients:**
Do not take more than 4 caplets in a day. Do not take Imodium™ Plus for more than 2 days.
If your symptoms get worse or are no better in 48 hours, consult your doctor.

**Children under 12 years of age:**
Not recommended.

## WHAT IF SOMEONE TAKES TOO MANY CAPLETS?

If anyone takes too many caplets, consult a doctor or local hospital for advice.

## WHAT ABOUT SIDE EFFECTS?

In clinical trials up to 10% of patients taking Imodium™ Plus felt sick or felt their sense of taste had altered.

In normal use very rarely patients taking Imodium™ Plus, or loperamide only, had skin rashes (including itching, hives or swelling), severe allergic reactions (including shock, collapse or difficulty breathing), abdominal pain or bloating, nausea, constipation – sometimes severe, wind, vomiting, indigestion, difficulty in passing water (urine), dizziness, altered sense of taste, or drowsiness.

If you think you are reacting badly in any way to Imodium™ Plus, stop the tablets and see your doctor or pharmacist.

## STORING IMODIUM™ PLUS CAPLETS

"Use by" date: Do not use if the caplets are past the expiry date on the box. Return any unused caplets to the pharmacist. Do not store the caplets above 25°C.

**REMEMBER: Keep all medicines out of the sight and reach of children.**

This leaflet was prepared in September 2005.

**ENQUIRIES TO:**

McNeil Ltd.
a Johnson & Johnson company
Enterprise House, Station Road, Loudwater, High Wycombe, Bucks HP10 9UF, UK.



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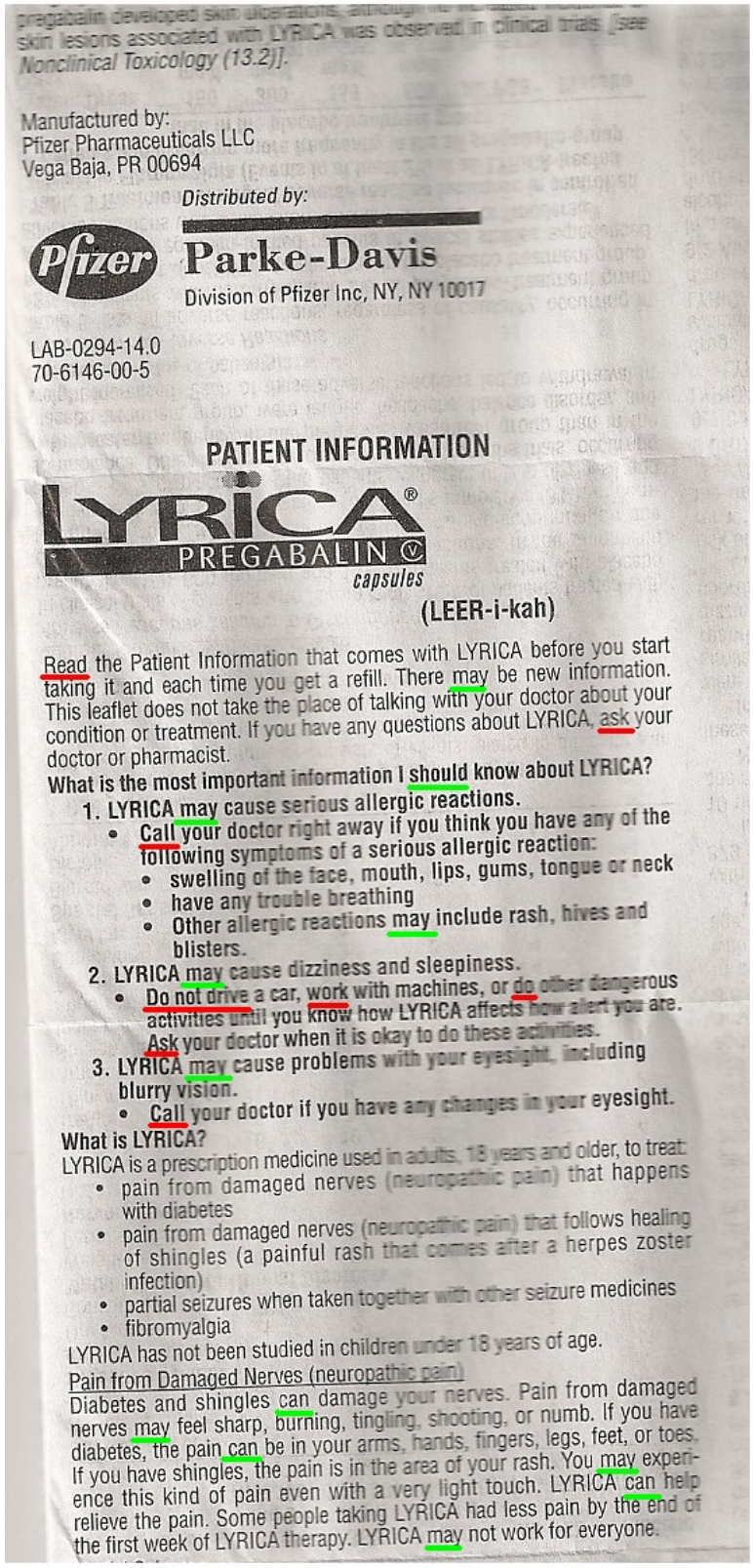
# Appendix 6

**Lyrica, patient information leaflet**



pregabalin developed skin ulcerations, among [illegible] skin lesions associated with LYRICA was observed in clinical trials [see *Nonclinical Toxicology (13.2)*].

Manufactured by:
Pfizer Pharmaceuticals LLC
Vega Baja, PR 00694

*Distributed by:*

Pfizer **Parke-Davis**
Division of Pfizer Inc, NY, NY 10017

LAB-0294-14.0
70-6146-00-5

**PATIENT INFORMATION**

**LYRICA®**
**PREGABALIN** Ⓒ
*capsules*
**(LEER-i-kah)**

Read the Patient Information that comes with LYRICA before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment. If you have any questions about LYRICA, ask your doctor or pharmacist.

**What is the most important information I should know about LYRICA?**

1. **LYRICA may cause serious allergic reactions.**
   - **Call your doctor right away if you think you have any of the following symptoms of a serious allergic reaction:**
     - **swelling of the face, mouth, lips, gums, tongue or neck**
     - **have any trouble breathing**
     - **Other allergic reactions may include rash, hives and blisters.**
2. **LYRICA may cause dizziness and sleepiness.**
   - **Do not drive a car, work with machines, or do other dangerous activities until you know how LYRICA affects how alert you are. Ask your doctor when it is okay to do these activities.**
3. **LYRICA may cause problems with your eyesight, including blurry vision.**
   - **Call your doctor if you have any changes in your eyesight.**

**What is LYRICA?**

LYRICA is a prescription medicine used in adults, 18 years and older, to treat:

- pain from damaged nerves (neuropathic pain) that happens with diabetes
- pain from damaged nerves (neuropathic pain) that follows healing of shingles (a painful rash that comes after a herpes zoster infection)
- partial seizures when taken together with other seizure medicines
- fibromyalgia

LYRICA has not been studied in children under 18 years of age.

Pain from Damaged Nerves (neuropathic pain)

Diabetes and shingles can damage your nerves. Pain from damaged nerves may feel sharp, burning, tingling, shooting, or numb. If you have diabetes, the pain can be in your arms, hands, fingers, legs, feet, or toes. If you have shingles, the pain is in the area of your rash. You may experience this kind of pain even with a very light touch. LYRICA can help relieve the pain. Some people taking LYRICA had less pain by the end of the first week of LYRICA therapy. LYRICA may not work for everyone.

relieve the pain. Some people taking LYRICA had less pain by the end of the first week of LYRICA therapy. LYRICA may not work for everyone.

Partial Seizures

Partial seizures start in one part of the brain. A seizure can make you fearful, confused, or just feel "funny". You may smell strange smells. A seizure may cause your arm or leg to jerk or shake. It can spread to other parts of your brain, make you pass out, and cause your whole body to start jerking.

LYRICA can lower the number of seizures for people who are already taking seizure medicine.

Fibromyalgia

Fibromyalgia is a condition which includes widespread muscle pain and difficulty performing daily activities. LYRICA can help relieve the pain and improve function. Some people taking LYRICA had less pain by the end of the first week of LYRICA therapy. LYRICA may not work for everyone.

**Who Should Not Take LYRICA?**

**Do not take LYRICA if you are allergic to any of its ingredients.** The active ingredient is pregabalin. See the end of this leaflet for a complete list of ingredients in LYRICA.

**What should I tell my doctor before taking LYRICA?**

**Tell your doctor about all your medical conditions, including if you:**

- **have any kidney problems or get kidney dialysis**
- **have heart problems including heart failure**
- **have a bleeding problem or a low blood platelet count**
- **are pregnant or plan to become pregnant.** It is not known if LYRICA may harm your unborn baby. You and your doctor will have to decide if LYRICA is right for you while you are pregnant.
- **are breastfeeding.** It is not known if LYRICA passes into breast milk and if it can harm your baby. You and your doctor should decide whether you should take LYRICA or breastfeed, but not both.

**Tell your doctor about all the medicines you take including prescription or non-prescription medicines, vitamins or herbal supplements.** LYRICA and other medicines may affect each other. Especially tell your doctor if you take:

- angiotensin converting enzyme (ACE) inhibitors. You may have a higher chance for swelling and hives if these medicines are taken with LYRICA. See "What is the most important information I should know about LYRICA?"
- Avandia®(rosiglitazone) or Actos®(pioglitazone) for diabetes. You may have a higher chance of weight gain or swelling if these medicines are taken with LYRICA. See "What are the possible side effects of LYRICA."
- any narcotic pain medicine (such as oxycodone), tranquilizers or medicines for anxiety (such as lorazepam). You may have a higher chance for dizziness and sleepiness if these medicines are taken with LYRICA. See "What is the most important information I should know about LYRICA?"
- any medicines that make you sleepy

Know all the medicines you take. Keep a list of them with you to show your doctor and pharmacist each time you get a new medicine.

**Tell your doctor if you plan to father a child.** Animal studies showed that pregabalin, the active ingredient in LYRICA, made male animals less fertile and caused sperm abnormalities. Also, in animal studies, birth defects occurred in the offspring of male animals who were treated with pregabalin. It is not known if these effects would happen in people.

**How should I take LYRICA?**

- Take LYRICA exactly as prescribed. Your doctor may adjust your dose during treatment. Do not change your dose without talking to your doctor.
- Do not stop taking LYRICA suddenly without talking to your doctor. If you stop taking LYRICA suddenly, you may have headaches, nausea, diarrhea or trouble sleeping. Talk with your doctor about how to slowly stop LYRICA.
- LYRICA is usually taken 2 or 3 times a day, depending on your medical condition. Your doctor will tell you how much LYRICA to take and when to take it. Take LYRICA at the same times each day.
- LYRICA may be taken with or without food.
- If you miss a dose by a few hours, take it as soon as you remember. If it is close to your next dose, just take LYRICA at your next regular time. **Do not** take two doses at the same time.
- If you take too much LYRICA, call your doctor or poison control center or go to the nearest emergency room right away.

**What Should I Avoid While Taking LYRICA?**

- **Do not drive a car, work with machines, or do other dangerous activities until you know how LYRICA affects how alert you are.** See "What is the most important information I should know about LYRICA?"
- **Do not drink alcohol while taking LYRICA.** LYRICA and alcohol can affect each other and increase side effects such as sleepiness and dizziness. This can be dangerous.

**Do not take other medicines without talking to your doctor.** Other medicines include prescription and non-prescription medicines, vitamins, and herbal supplements. LYRICA and other medicines may affect each other and increase the side effects of swelling, sleepiness and dizziness. Be especially careful about medicines that make you sleepy (such as sleeping pills, anxiety medicines, tranquilizers and some antihistamines, pain relievers and seizure medicines).

**What are the possible side effects of LYRICA?**

**LYRICA may cause side effects including:**

- **allergic reactions.** See "What is the most important information I should know about LYRICA?"

- **weight gain and swelling of the hands and feet (edema).** Weight gain may affect the management of diabetes. Weight gain and swelling can also be a serious problem for people with heart problems.
- **dizziness and sleepiness.** See "What is the most important information I should know about LYRICA?"
- **eyesight problems.** See "What is the most important information I should know about LYRICA?"
- **unexplained muscle problems, such as muscle pain, soreness, or weakness.** If you develop these symptoms, especially if you also feel sick and have a fever, tell your doctor right away.

**The most common side effects of LYRICA are:**

- dizziness
- blurry vision
- weight gain
- sleepiness
- trouble concentrating
- swelling of hands and feet
- dry mouth

LYRICA caused skin sores in animals. Although skin sores were not seen in studies in people, if you have diabetes, you should pay extra attention to your skin while taking LYRICA and tell your doctor of any sores or skin problems.

LYRICA may cause some people to feel "high." Tell your doctor, if you have abused prescription medicines, street drugs, or alcohol in the past.

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the side effects of LYRICA. For more information, ask your doctor or pharmacist.

**How should I store LYRICA?**

- Store LYRICA at room temperature, 59 to 86° F (15 to 30° C) in its original package.
- Safely throw away LYRICA that is out of date or no longer needed.
- **Keep LYRICA and all medicines out of the reach of children.**

**General information about LYRICA**

Medicines are sometimes prescribed for conditions other than those listed in patient information leaflets. Do not use LYRICA for a condition for which it was not prescribed. Do not give LYRICA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about LYRICA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about LYRICA that is written for health professionals.

You can also visit the LYRICA website at www.LYRICA.com or call 1- 866- 4LYRICA.

**What are the ingredients in LYRICA?**

**Active ingredient:** pregabalin

**Inactive ingredients:** lactose monohydrate, cornstarch, talc;

**Capsule shell:** gelatin and titanium dioxide; Orange capsule shell: red iron oxide; White capsule shell: sodium lauryl sulfate, colloidal silicon dioxide. Colloidal silicon dioxide is a manufacturing aid that may or may not be present in the capsule shells.

**Imprinting ink:** shellac, black iron oxide, propylene glycol, potassium hydroxide.

Manufactured by:
Pfizer Pharmaceuticals LLC
Vega Baja, PR 00694

LAB-0299-5.0

Avandia is a registered trademark of GlaxoSmithKline.
Actos is a registered trademark of Takeda Chemicals Industries, Ltd. and used under license by Takeda Pharmaceuticals of America, Inc. and Eli Lilly and Co.
June 2007

# Appendix 7

## Zmax, patient information leaflet

**17 PATIENT COUNSELING INFORMATION**

*See FDA-approved Patient Labeling (17.2)*

**17.1 General Patient Counseling**

- Patients should be instructed to take Zmax on an empty stomach (at least 1 hour before or 2 hours following a meal).
- To ensure accurate dosing for children, use of a dosing spoon, medicine syringe, or cup is recommended.
- Patients should be told that Zmax needs time to work, so the patient may not feel better right away. If the patient's symptoms do not improve in a few days, the patient or their guardian should call their doctor.
- Patients should be instructed to immediately contact a physician if any signs of an allergic reaction occur.
- Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.
- Patients who vomit within the first hour should contact their health care provider about further treatment.
- Keep bottle tightly closed. Store at room temperature. Use within 12 hours of constitution. Shake bottle well before use. Adult patients should consume the entire contents of the bottle; pediatric patients should take the recommended dose and MUST discard any unused portion.
- Patients should be advised that Zmax may be taken without regard to antacids containing magnesium hydroxide and/or aluminum hydroxide.

Patients should be counseled that antibacterial drugs including Zmax should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). Not taking the complete prescribed dose may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by Zmax or other antibacterial drugs in the future.

**17.2 FDA-approved patient labeling**

Read the Patient Information that comes with Zmax® carefully before you or your child take it. This leaflet does not take the place of talking with your doctor about you or your child's medical condition or treatment. Only your doctor can decide if Zmax is right for you or your child.

**What is Zmax?**

Zmax is an antibiotic that kills certain bacteria. Zmax is dosed differently from other antibiotics.

You take **just one dose, one time**.

- Day 1: Take Zmax in one dose. Zmax starts working.
- Days 2 – 3: As with most antibiotics, you may not feel better right away.
- After Day 3: Zmax continues to work over time. If your symptoms are not better, call your doctor.

Zmax is used in adults and in children over the age of 6 months against bacteria to treat certain kinds of pneumonia (lung infections)

Zmax is used in adults against bacteria to treat sinus infections.

Zmax only works against bacteria. It does not work against viruses, like the common cold or flu.

Zmax has not been studied in children under 6 months of age.

**Who should not take Zmax?**

- You or your child should not take Zmax if allergic to:
  - anything in Zmax. See the end of this leaflet for a complete list of ingredients in Zmax.
  - antibiotics like erythromycin or telithromycin (Ketek®).

Talk with your doctor or pharmacist if you have questions about your medicine allergies.

**Before you start Zmax…**

**Tell your doctor about all your or your child's medical problems** including if you or your child:

- have liver problems.
- have kidney problems.
- have myasthenia gravis.
- are pregnant, or might be pregnant. It is not known if Zmax could harm your baby.
- are breast-feeding.

**Tell your doctor about all the medicines you take,** including prescription and non-prescription medicines, vitamins and herbal supplements. Especially tell your doctor if you or your child are taking warfarin (Coumadin®, Jantoven)

Know the medicines you take. Keep a list of your medicines and show it to your doctor or pharmacist when you get a new prescription.

**Do I need to prepare Zmax?**

- If you get Zmax in **liquid form, it is ready to take.**
- If you get Zmax as **dry powder, you must add water to the bottle before you take it.** To prepare Zmax:
  1. Open the bottle: To open the bottle, press down on the cap and twist.
  2. Use a measuring cup to add 60 mL (1/4 cup) water to the Zmax bottle.
  3. Tightly close the bottle and shake to mix it.

**How do I take Zmax?**

- Keep Zmax at room temperature between 59ºF to 86ºF (15º to 30ºC).
- Shake the bottle well before using.
- Take Zmax or give it to your child within 12 hours after it has been prepared by the pharmacy or you add water to the powder.
- Take Zmax or give it to your child exactly how your doctor prescribes it. This will help to treat you or your child's infection and decrease the chance that Zmax or other antibiotics will not work to treat infections in the future.
  - Adults: take all the medicine in the bottle.
  - Children: give your child the amount of Zmax prescribed by your doctor and throw away the rest of the medicine.
  - To be sure that you give your child the right dose of Zmax, use a dosing spoon, medicine syringe, or cup.
- Take Zmax on an empty stomach (at least 1 hour before eating or 2 hours after eating).
- You can take antacids with Zmax.
- If you or your child throws up (vomits) within one hour of taking Zmax, call your doctor right away to see if more medicine is needed. Do not give your child more Zmax unless your doctor tells you to.
- If your child takes too much Zmax, call your doctor right away or go to the nearest hospital emergency room.

**How will I know Zmax is working?**

Zmax needs time to work, so you or your child may not feel better right away. If you or your child's symptoms do not get better in a few days, call your doctor.

**What are possible side effects of Zmax?**

Zmax may cause serious side effects. These happened in a small number of patients. Call your doctor right away or get emergency treatment if you or your child have any of the following:

- **Serious allergic reaction or serious skin reaction:** Get emergency help right away if you or your child has:
  - Hives, skin rash, sores in your mouth, or your skin blisters and peels
  - Trouble swallowing,
  - Swelling of your face, eyes, lips, tongue or throat
  - Wheezing or trouble breathing

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**These symptoms could go away and then come back.**

- **Diarrhea:** Call your doctor right away if you have diarrhea that does not go away, is severe, watery, or has blood in it. Diarrhea can occur as late as two or months after you take an antibiotic such as Zmax.
- **Abnormal heart rhythm.** Tell your doctor right away if you or your child feel your heart beating in your chest or an abnormal heart beat, get dizzy or faint. This has been seen with other antibiotics like Zmax.

The most common side effects in **adults** are:

- Diarrhea/loose stools
- Nausea
- Stomach pain
- Headache
- Vomiting

The most common side effects in **children** are:

- Vomiting
- Diarrhea/loose stools
- Nausea
- Stomach pain

Tell your doctor if you have any side effects that bother your or your child, or that does not go away.

These are not all of the possible side effects with Zmax. For a list of all reported side effects, ask your doctor or pharmacist.

**General information about Zmax**

Doctors sometimes prescribe medicines for conditions that are not in the patient leaflets. Do not use Zmax for anything other than what your doctor prescribed. Do not give it to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet is a summary of the most important information about Zmax. For more information, talk with your doctor. You can ask your doctor or pharmacist for information about Zmax that is written for healthcare professionals. For more information, go to our website at www.zmaxinfo.com or call 1-800-438-1985.

**What is in Zmax?**

Active ingredient: azithromycin dihydrate

Inactive ingredients: glyceryl behenate, poloxamer 407, sucrose, sodium phosphate tribasic anhydrous, magnesium hydroxide, hydroxypropyl cellulose, xanthan gum, colloidal silicon dioxide, titanium dioxide, artificial cherry flavor, and artificial banana flavor



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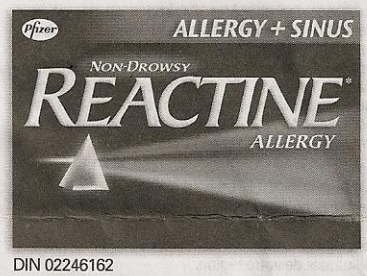
**LAB-0384-2.0**
**Revised October 2008**

# Appendix 8

## Reactine, patient information leaflet




DIN 02246162

**Antihistamine – Decongestant Extended Release Tablets**

Cetirizine Hydrochloride 5 mg – Pseudoephedrine Hydrochloride 120 mg

**Why Take Reactine Allergy & Sinus?**

For fast, long lasting relief of itchy watery eyes, sneezing, runny nose and nasal congestion caused by seasonal allergies (hay fever, trees, grass, pollen and ragweed) and perennial allergies (dust mites, animal dander and molds).

**Directions:**

Adults and children 12 years of age and over: The recommended dose of Reactine Allergy & Sinus is one tablet every 12 hours. May be taken with or without food.

Adults 65 years of age and over and in patients with moderate hepatic and/or renal impairment: a dose of one tablet once daily is recommended. Do not exceed recommended dosage unless directed by a doctor. Prolonged use only as directed by a doctor.

**CAUTION:**

Do not take this product if you are allergic to cetirizine hydrochloride or pseudoephedrine hydrochloride or any of the non-medicinal ingredients (see list on the outer carton). Talk to a doctor before using this product if you are pregnant, breast-feeding, or if you have liver or kidney disease. Talk to a doctor before using this product if you have any of the following conditions: narrow-angle glaucoma, urinary retention due to prostate gland enlargement, severe hypertension (high blood pressure), severe coronary artery disease (heart disease), thyroid disease, diabetes, receiving a monoamine oxidase (MAO) inhibitor or within 14 days of stopping such treatment, or are taking any prescription drugs. Some people can experience drowsiness due to allergies or antihistamine use. If drowsiness does occur, do not drive or operate machinery and do not use Reactine Allergy + Sinus with sedating substances such as alcohol and some other medications. Keep this and all medications safely out of reach of children.

Store between 15 °C and 30 °C.

**What causes my allergy?**

Your allergy symptoms are simply your body's over reaction in trying to protect you from allergens such as dust, ragweed, grass and tree pollen, animal dander or mold. When allergens are detected, your body rushes a substance called histamine to the histamine receptor sites in your skin and tissues. The resulting reaction causes itchy, watery eyes, sneezing and runny nose. Reactine helps relieve your allergy symptoms by blocking these receptor sites before histamine binds there.

**What other things can I do for my allergies?**

**Keep pollens out.** Keep windows closed. Use an air conditioner.

**Stay informed** about pollen seasons and levels in your region.

**Plan outdoor activities.** Stay inside on warm and windy days. Most plants pollinate in the morning. Stay indoors until later.

**Stay away from big pollen producers** like birch, ash, maple, oak and walnut trees.

**Hire someone to cut your grass.**

**Remove pets if possible.** Keep them out of bedrooms.

**Keep a dust-free home.** Remove carpets, keep furnace ducts clean and vacuum often.

**Control dust mites.** Encase your mattress in a proper dust mite barrier and wash bedding often in very hot water.

**Stay away** from those foods, medications, insects, or even dyes and plants, that may cause itchy, irritating rashes called hives (urticaria).

**What causes my nasal congestion?**

Typically a cold or prolonged allergy attacks will be the cause of nasal congestion, however, other causes include: exposure to tobacco smoke; dust or airborne pollutants; swimming in polluted water or overuse of non-prescription nasal sprays.

**What other things can I do for nasal congestion?**

**Stay away from airborne irritants:** cigarette smoke and other air pollutants.

**Avoid alcohol intake** as it can cause sinus membranes to swell.

**Avoid swimming in pools treated with chlorine** as it can irritate the lining of the nose and sinuses.

**Beware of situations** which can result in sinus pressure, such as flying, due to low cabin pressure.

**Adopt sleeping positions** that are either slightly propped up or on one side or the other.

**Medicinal Ingredients:** Each tablet contains cetirizine hydrochloride 5 mg, in an immediate release layer and pseudoephedrine hydrochloride 120 mg in an extended release layer.

**Non-Medicinal Ingredients:** celluloses, lactose, magnesium stearate, polyethylene glycol, silicon dioxide, sodium carboxymethylcellulose, titanium dioxide.

**Questions about Reactine Allergy & Sinus?**

**1-87-REACTINE**

www.reactine.ca

Product monograph available to doctors and pharmacists upon request.

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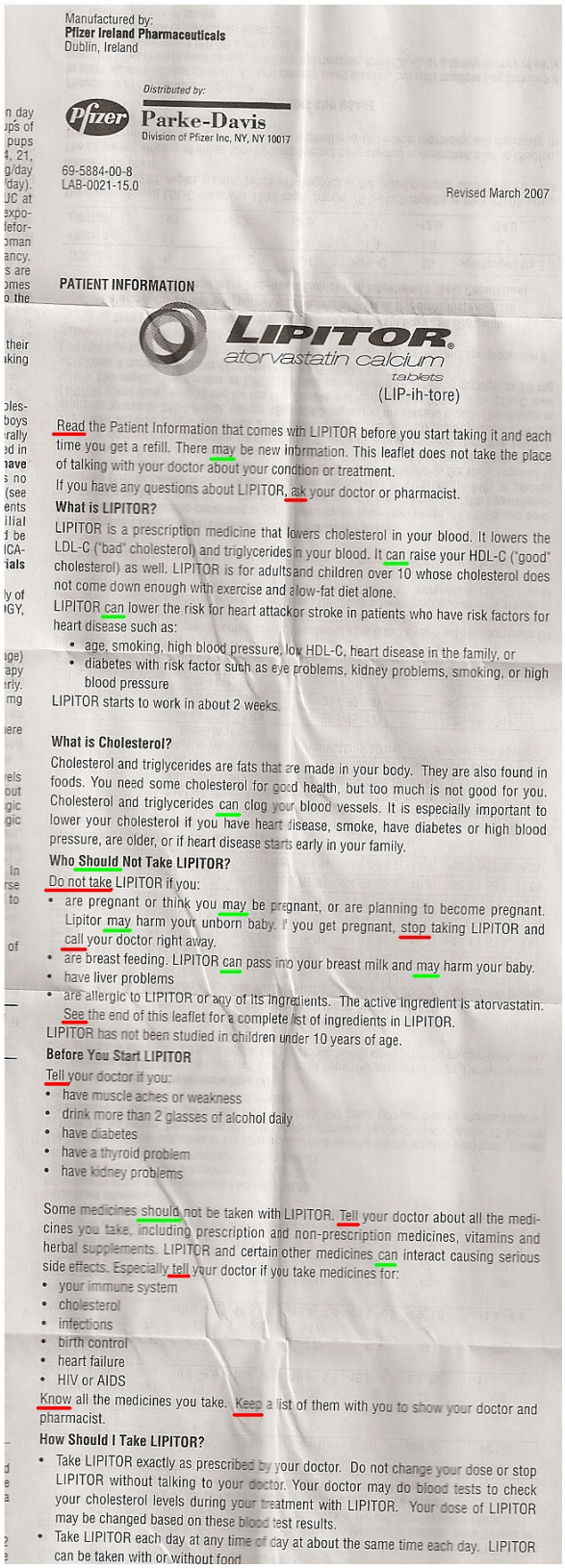
# Appendix 9

## Lipitor, patient information leaflet



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Revised March 2007

**PATIENT INFORMATION**

**LIPITOR®**
atorvastatin calcium
tablets
(LIP-ih-tore)

Read the Patient Information that comes with LIPITOR before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment.

If you have any questions about LIPITOR, ask your doctor or pharmacist.

**What is LIPITOR?**

LIPITOR is a prescription medicine that lowers cholesterol in your blood. It lowers the LDL-C ("bad" cholesterol) and triglycerides in your blood. It can raise your HDL-C ("good" cholesterol) as well. LIPITOR is for adults and children over 10 whose cholesterol does not come down enough with exercise and a low-fat diet alone.

LIPITOR can lower the risk for heart attack or stroke in patients who have risk factors for heart disease such as:

- age, smoking, high blood pressure, low HDL-C, heart disease in the family, or
- diabetes with risk factor such as eye problems, kidney problems, smoking, or high blood pressure

LIPITOR starts to work in about 2 weeks.

**What is Cholesterol?**

Cholesterol and triglycerides are fats that are made in your body. They are also found in foods. You need some cholesterol for good health, but too much is not good for you. Cholesterol and triglycerides can clog your blood vessels. It is especially important to lower your cholesterol if you have heart disease, smoke, have diabetes or high blood pressure, are older, or if heart disease starts early in your family.

**Who Should Not Take LIPITOR?**

Do not take LIPITOR if you:

- are pregnant or think you may be pregnant, or are planning to become pregnant. Lipitor may harm your unborn baby. If you get pregnant, stop taking LIPITOR and call your doctor right away.
- are breast feeding. LIPITOR can pass into your breast milk and may harm your baby.
- have liver problems
- are allergic to LIPITOR or any of its ingredients. The active ingredient is atorvastatin. See the end of this leaflet for a complete list of ingredients in LIPITOR.

LIPITOR has not been studied in children under 10 years of age.

**Before You Start LIPITOR**

Tell your doctor if you:

- have muscle aches or weakness
- drink more than 2 glasses of alcohol daily
- have diabetes
- have a thyroid problem
- have kidney problems

Some medicines should not be taken with LIPITOR. Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. LIPITOR and certain other medicines can interact causing serious side effects. Especially tell your doctor if you take medicines for:

- your immune system
- cholesterol
- infections
- birth control
- heart failure
- HIV or AIDS

Know all the medicines you take. Keep a list of them with you to show your doctor and pharmacist.

**How Should I Take LIPITOR?**

- Take LIPITOR exactly as prescribed by your doctor. Do not change your dose or stop LIPITOR without talking to your doctor. Your doctor may do blood tests to check your cholesterol levels during your treatment with LIPITOR. Your dose of LIPITOR may be changed based on these blood test results.
- Take LIPITOR each day at any time of day at about the same time each day. LIPITOR can be taken with or without food.

- HIV or AIDS

Know all the medicines you take. Keep a list of them with you to show your doctor and pharmacist.

**How Should I Take LIPITOR?**

- Take LIPITOR exactly as prescribed by your doctor. Do not change your dose or stop LIPITOR without talking to your doctor. Your doctor may do blood tests to check your cholesterol levels during your treatment with LIPITOR. Your dose of LIPITOR may be changed based on these blood test results.
- Take LIPITOR each day at any time of day at about the same time each day. LIPITOR can be taken with or without food.
  Don't break LIPITOR tablets before taking.
- Your doctor should start you on a low-fat diet before giving you LIPITOR. Stay on this low-fat diet when you take LIPITOR.
- If you miss a dose of LIPITOR, take it as soon as you remember. Do not take LIPITOR if it has been more than 12 hours since you missed your last dose. Wait and take the next dose at your regular time. **Do not take 2 doses of LIPITOR at the same time.**
- If you take too much LIPITOR or overdose, call your doctor or Poison Control Center right away. Or go to the nearest emergency room.

**What Should I Avoid While Taking LIPITOR?**

- Talk to your doctor before you start any new medicines. This includes prescription and non-prescription medicines, vitamins and herbal supplements. LIPITOR and certain other medicines can interact causing serious side effects.
- Do not get pregnant. If you get pregnant, stop taking LIPITOR right away and call your doctor.

**What are the Possible Side Effects of LIPITOR?**

**LIPITOR can cause serious side effects. These side effects have happened only to a small number of people. Your doctor can monitor you for them. These side effects usually go away if your dose is lowered or LIPITOR is stopped. These serious side effects include:**

- **Muscle problems.** LIPITOR can cause serious muscle problems that can lead to kidney problems, including kidney failure. You have a higher chance for muscle problems if you are taking certain other medicines with LIPITOR.
- **Liver problems.** LIPITOR can cause liver problems. Your doctor may do blood tests to check your liver before you start taking LIPITOR, and while you take it.

**Call your doctor right away if you have:**

- muscle problems like weakness, tenderness, or pain that happen without a good reason, especially if you also have a fever or feel more tired than usual
- nausea and vomiting
- passing brown or dark-colored urine
- you feel more tired than usual
- your skin and whites of your eyes get yellow
- stomach pain

Common side effects of LIPITOR include headache, constipation, diarrhea, gas, upset stomach and stomach pain, rash, and muscle and joint pain. These side effects are usually mild and may go away.

Talk to your doctor or pharmacist if you have side effects that bother you or that will not go away.

These are not all the side effects of LIPITOR. Ask your doctor or pharmacist for a complete list.

**How do I store Lipitor?**

- Store LIPITOR at room temperature, 68 to 77°F (20 to 25°C).
- Do not keep medicine that is out of date or that you no longer need.
- **Keep LIPITOR and all medicines out of the reach of children.** Be sure that if you throw medicine away, it is out of the reach of children.

**General Information About LIPITOR**

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use LIPITOR for a condition for which it was not prescribed. Do not give LIPITOR to other people, even if they have the same problem you have. It may harm them.

This leaflet summarizes the most important information about LIPITOR. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about LIPITOR that is written for health professionals. Or you can go to the LIPITOR website at www.lipitor.com.

**What are the ingredients in LIPITOR?**

**Active Ingredient:** atorvastatin calcium

**Inactive Ingredients:** calcium carbonate, USP; candelilla wax, FCC; croscarmellose sodium, NF; hydroxypropyl cellulose, NF; lactose monohydrate, NF; magnesium stearate, NF; microcrystalline cellulose, NF; Opadry White YS-1-7040 (hypromellose, polyethylene glycol, talc, titanium dioxide); polysorbate 80, NF; simethicone emulsion.

**Rx Only**

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**Manufactured by**
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**Dublin, Ireland**

LAB-0348-3.0
June 2006

# Appendix 10

## Temodar, patient information leaflet

# TEMODAR®
# (temozolomide)
## Capsules

PATIENT INFORMATION

### What is TEMODAR?

TEMODAR (temozolomide) is used to treat certain cancerous tumors in the brain of adult patients. Your doctor has prescribed TEMODAR (temozolomide) as part of your cancer treatment. TEMODAR is a drug you take by mouth that interferes with cell growth, especially in cells that are growing rapidly, such as cancerous cells. TEMODAR has been shown to help slow the growth of certain cancerous tumors. When given to patients with brain cancer, TEMODAR has been shown to reduce the size of the tumor in some patients.

### Who should not take TEMODAR?

You should not take TEMODAR Capsules if you have had an allergic reaction to DTIC-Dome (dacarbazine), a different treatment for cancer. If you have had an allergic reaction before to drugs such as DTIC-Dome, be sure to tell your doctor before taking TEMODAR. If you are allergic to drugs similar to TEMODAR, you may also have an allergic reaction to TEMODAR.

### How should I take TEMODAR?

Take each day's dose of capsules at one time, with a full glass of water. **DO NOT** open or split the capsules. If the capsules are accidentally opened or damaged, you should be extremely careful to avoid inhaling the powder in the capsules or getting it on your skin or mucous membranes (eg, in nose or mouth). Flush the area with water if contact occurs. The medication should be kept away from children and pets. They should be swallowed whole and **NEVER CHEWED**. If capsules are vomited, do not take a second dose. New capsules should not be taken until the next planned dose. The medicine is used best by your body if you take it at the same time every day in relation to a meal. To reduce nausea, try to take TEMODAR on an empty stomach or at bedtime. Your doctor may also have prescribed antinausea or other medications to relieve the side effects associated with TEMODAR. Antinausea medications should be taken as directed by your doctor.

It is important that you continue to see your doctor regularly to check your progress. Your doctor can uncover side effects of treatment that you might not notice.

Because TEMODAR Capsules is a drug you take by mouth, you can take it at home. There are two different dosing schedules for taking TEMODAR. Be sure you follow the one that your doctor has prescribed for you. One schedule you may be prescribed is, TEMODAR for 42 days (up to 49 days) with radiotherapy. Another schedule should be taken for 5 consecutive days only then you must **STOP** taking TEMODAR for the next 23 days. This total period of 5 days on TEMODAR and 23 days off TEMODAR is called one treatment cycle. Your dose is based on your height and weight, and the number of treatment cycles will depend on how you respond to and tolerate this treatment.

TEMODAR comes in different strength capsules (shown on the outer label in mg). Each strength has a different color band. Depending on the dose of TEMODAR that your doctor prescribes, you may have to take several capsules on each dosing day of a treatment cycle (Day 1 through Day 5, followed by 23 days with no capsules) or the 42 days (up to 49 days) of consecutive treatment schedule with radiotherapy.

- Be sure you understand exactly how many capsules you need to take of each strength. Ask your doctor or pharmacist to write down the number of each strength (include color) that you need to take each dosing day.
- Be sure you know exactly which days are your dosing days.
- Be sure to review the dose with your health care provider each time you start a new cycle. Sometimes the dose or the mix of capsules you need to take will be different from the last cycle.
- Once you take the medicine home, if you are confused or unsure about how to take your dose, contact your doctor or pharmacist immediately.



Your doctor may have prescribed a treatment regimen that is different from those discussed in this information sheet. If so, make sure you follow the specific instructions given to you by your doctor. You should talk to your doctor about what to do if you miss a day. If you take more than the prescribed amount of medicine, contact your doctor right away. It is important that you understand your dosage regimen; it is also important that you do not take more than the amount of TEMODAR prescribed for you. Overdoses can lead to serious outcomes including severe low blood counts and possible death.

### How is TEMODAR supplied?

TEMODAR Capsules contain a white capsule body with a color cap and the colors vary based on the dosage strength. The capsules are available in six different strengths.

| TEMODAR Capsule Strength | Color |
|---|---|
| 5 mg | Green Cap |
| 20 mg | Yellow Cap |
| 100 mg | Pink Cap |
| 140 mg | Blue Cap |
| 180 mg | Orange Cap |
| 250 mg | White Cap |

### What should I avoid while taking TEMODAR?

There are no limitations on what you may eat or drink while taking TEMODAR. However, to ease nausea, try to take TEMODAR on an empty stomach.

TEMODAR may cause birth defects. Therefore, male or female patients who take TEMODAR should use effective birth control. Female patients should avoid becoming pregnant while receiving this drug. You should not breast-feed an infant while taking TEMODAR. It is not known whether TEMODAR passes into breast milk. Because many drugs do pass into breast milk, there is the possibility of serious harm to nursing infants.

### What are the possible or reasonably likely side effects of TEMODAR?

Nausea and vomiting are the most common side effects associated with TEMODAR. Your doctor can prescribe medicines that may help reduce some of these. Other common side effects include headache, feeling tired, loss of appetite, hair loss, and constipation.

TEMODAR also can reduce the number of certain types of blood cells, which can have serious effects. White blood cells are needed to fight infections. Lowering of white blood cells could result in a serious infection with a potential outcome of death. Platelets are needed in the normal course of blood clotting. Lowering of platelets does not allow your blood to clot normally, which can result in bleeding episodes. Therefore, it is important that your doctor check your blood periodically while you are taking TEMODAR to see if these side effects are occurring. Patients age 70 or older, women, and patients who have had chemotherapy or radiation therapy may be more likely to have their blood cells affected.

There are other side effects associated with TEMODAR. They are included in a longer, more technical information leaflet written for health care providers that you can get from your doctor or pharmacist.

### General information about the use of prescription drug products.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Package Insert. You should contact your health care professional regarding any concerns you may have about using TEMODAR. TEMODAR should not be used for a condition for which it was not prescribed, and it should not be given to other persons.

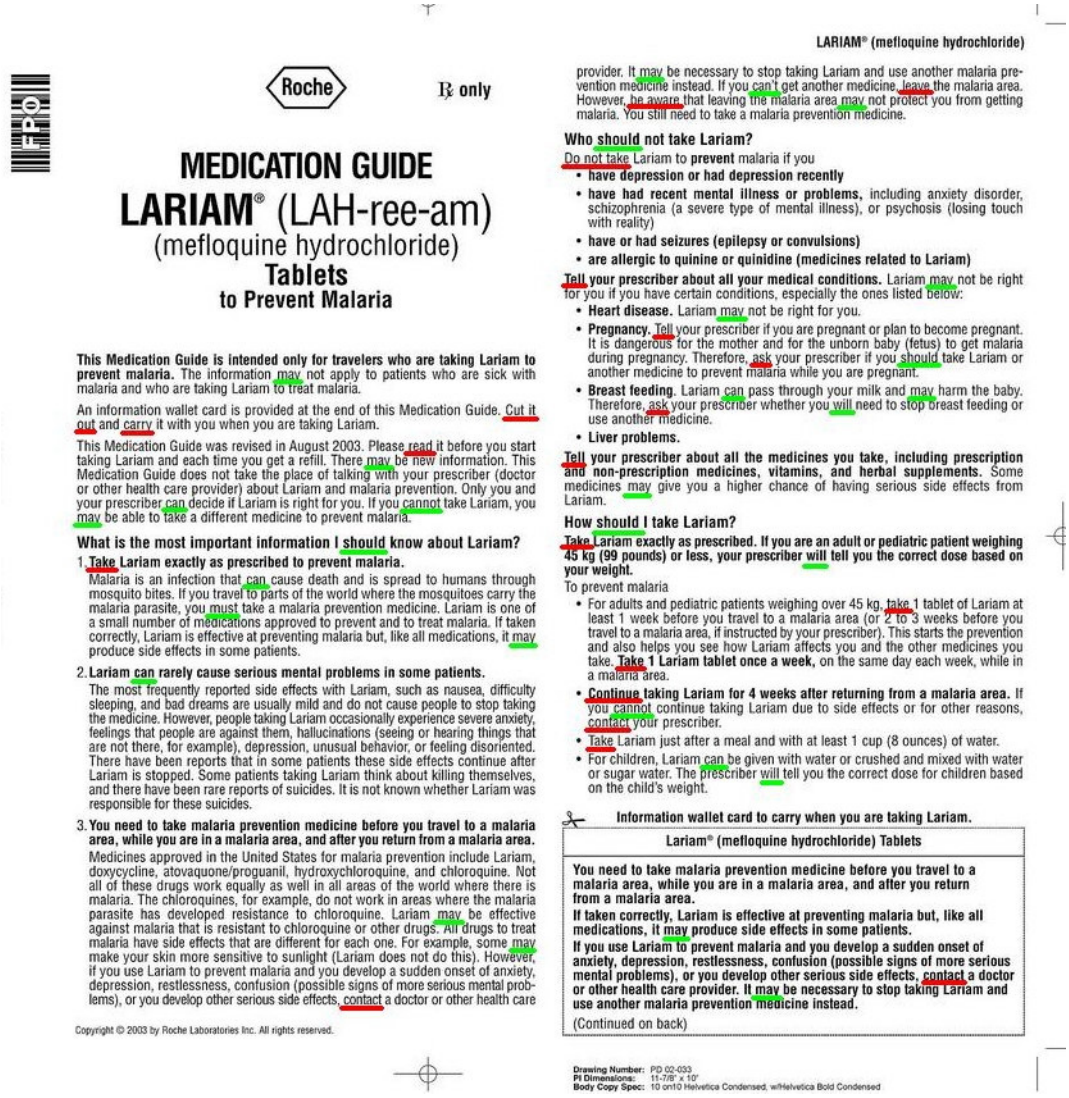
U.S. Patent No. 5,260,291.



Rev. 3/07 30984412T

# Appendix 11

## Lariam, patient information leaflet



Roche

℞ only

# MEDICATION GUIDE

# LARIAM® (LAH-ree-am)
(mefloquine hydrochloride)
**Tablets**
**to Prevent Malaria**

**This Medication Guide is intended only for travelers who are taking Lariam to prevent malaria.** The information may not apply to patients who are sick with malaria and who are taking Lariam to treat malaria.

An information wallet card is provided at the end of this Medication Guide. Cut it out and carry it with you when you are taking Lariam.

This Medication Guide was revised in August 2003. Please read it before you start taking Lariam and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your prescriber (doctor or other health care provider) about Lariam and malaria prevention. Only you and your prescriber can decide if Lariam is right for you. If you cannot take Lariam, you may be able to take a different medicine to prevent malaria.

### What is the most important information I should know about Lariam?

1. **Take Lariam exactly as prescribed to prevent malaria.**
Malaria is an infection that can cause death and is spread to humans through mosquito bites. If you travel to parts of the world where the mosquitoes carry the malaria parasite, you must take a malaria prevention medicine. Lariam is one of a small number of medications approved to prevent and to treat malaria. If taken correctly, Lariam is effective at preventing malaria but, like all medications, it may produce side effects in some patients.

2. **Lariam can rarely cause serious mental problems in some patients.**
The most frequently reported side effects with Lariam, such as nausea, difficulty sleeping, and bad dreams are usually mild and do not cause people to stop taking the medicine. However, people taking Lariam occasionally experience severe anxiety, feelings that people are against them, hallucinations (seeing or hearing things that are not there, for example), depression, unusual behavior, or feeling disoriented. There have been reports that in some patients these side effects continue after Lariam is stopped. Some patients taking Lariam think about killing themselves, and there have been rare reports of suicides. It is not known whether Lariam was responsible for these suicides.

3. **You need to take malaria prevention medicine before you travel to a malaria area, while you are in a malaria area, and after you return from a malaria area.**
Medicines approved in the United States for malaria prevention include Lariam, doxycycline, atovaquone/proguanil, hydroxychloroquine, and chloroquine. Not all of these drugs work equally as well in all areas of the world where there is malaria. The chloroquines, for example, do not work in areas where the malaria parasite has developed resistance to chloroquine. Lariam may be effective against malaria that is resistant to chloroquine or other drugs. All drugs to treat malaria have side effects that are different for each one. For example, some may make your skin more sensitive to sunlight (Lariam does not do this). However, if you use Lariam to prevent malaria and you develop a sudden onset of anxiety, depression, restlessness, confusion (possible signs of more serious mental problems), or you develop other serious side effects, contact a doctor or other health care provider. It may be necessary to stop taking Lariam and use another malaria prevention medicine instead. If you can't get another medicine, leave the malaria area. However, be aware that leaving the malaria area may not protect you from getting malaria. You still need to take a malaria prevention medicine.





### Who should not take Lariam?

Do not take Lariam to **prevent** malaria if you

- **have depression or had depression recently**
- **have had recent mental illness or problems,** including anxiety disorder, schizophrenia (a severe type of mental illness), or psychosis (losing touch with reality)
- **have or had seizures (epilepsy or convulsions)**
- **are allergic to quinine or quinidine (medicines related to Lariam)**

**Tell your prescriber about all your medical conditions.** Lariam may not be right for you if you have certain conditions, especially the ones listed below:

- **Heart disease.** Lariam may not be right for you.
- **Pregnancy.** Tell your prescriber if you are pregnant or plan to become pregnant. It is dangerous for the mother and for the unborn baby (fetus) to get malaria during pregnancy. Therefore, ask your prescriber if you should take Lariam or another medicine to prevent malaria while you are pregnant.
- **Breast feeding.** Lariam can pass through your milk and may harm the baby. Therefore, ask your prescriber whether you will need to stop breast feeding or use another medicine.
- **Liver problems.**

**Tell your prescriber about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.** Some medicines may give you a higher chance of having serious side effects from Lariam.

### How should I take Lariam?

**Take Lariam exactly as prescribed. If you are an adult or pediatric patient weighing 45 kg (99 pounds) or less, your prescriber will tell you the correct dose based on your weight.**

To prevent malaria

- For adults and pediatric patients weighing over 45 kg, take 1 tablet of Lariam at least 1 week before you travel to a malaria area (or 2 to 3 weeks before you travel to a malaria area, if instructed by your prescriber). This starts the prevention and also helps you see how Lariam affects you and the other medicines you take. **Take 1 Lariam tablet once a week,** on the same day each week, while in a malaria area.
- **Continue taking Lariam for 4 weeks after returning from a malaria area.** If you cannot continue taking Lariam due to side effects or for other reasons, contact your prescriber.
- Take Lariam just after a meal and with at least 1 cup (8 ounces) of water.
- For children, Lariam can be given with water or crushed and mixed with water or sugar water. The prescriber will tell you the correct dose for children based on the child's weight.

**Information wallet card to carry when you are taking Lariam.**

**Lariam® (mefloquine hydrochloride) Tablets**

**You need to take malaria prevention medicine before you travel to a malaria area, while you are in a malaria area, and after you return from a malaria area.**

**If taken correctly, Lariam is effective at preventing malaria but, like all medications, it may produce side effects in some patients.**

**If you use Lariam to prevent malaria and you develop a sudden onset of anxiety, depression, restlessness, confusion (possible signs of more serious mental problems), or you develop other serious side effects, contact a doctor or other health care provider. It may be necessary to stop taking Lariam and use another malaria prevention medicine instead.**

(Continued on back)

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# Appendix 12

## Codeine, patient information leaflet

### CODEINE PHOSPHATE 15 mg, 30 mg and 60 mg TABLETS BP

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you take these tablets. It briefly outlines the most important things you need to know. If you want to know more about this medicine, or you are not sure about anything, ask your doctor or your pharmacist.

*The name of your medicine is*
**Codeine Phosphate 15 mg, 30 mg or 60 mg Tablets BP.**

#### WHAT IS CODEINE ?

Codeine Tablets contain 15, 30 or 60 mg of codeine phosphate. They also contain dextrin, lactose and magnesium stearate.

The product is available in a pack size of 28 tablets. See outer packaging or the pharmacy label for contents i.e. the number of tablets.

Codeine is a pain killer which also acts as a cough suppressant and anti-diarrhoeal agent.

The Marketing Authorisation holder and company responsible for manufacture is TEVA UK Limited, Eastbourne, BN22 9AG.

#### WHAT IS CODEINE USED FOR ?

Codeine Tablets are used to treat mild or moderate pain, diarrhoea and troublesome cough. Ask your doctor or pharmacist for additional information.

#### BEFORE YOU TAKE CODEINE

Are you sensitive to any of the ingredients in the medicine, listed above ?
Do you have a high alcohol intake ?
Do you have problems with your kidneys or liver ?
Do you suffer from asthma, chronic bronchitis or other breathing difficulties ?
Do you have low blood pressure ?
Do you suffer from fits ?
Do you suffer from colitis (inflammation of the colon) ?
Do you have any problems with your prostate and have difficulty passing urine ?
Have you recently had a head injury or do you suffer from raised pressure in your head (this may cause vomiting, headache and changes in behaviour) ?
Do you have problems with your thyroid gland ?
Do you have diarrhoea which is known to be caused by an infection ?
Are you taking metoclopramide, domperidone, flecainide or mexiletine ?
Are you taking antipsychotics (medicines used to treat mental disorders) e.g. chlorpromazine ?
Are you taking ciprofloxacin, ritonavir or cimetidine ?
Are you taking any sleeping pills, tranquillisers or antidepressants ?
Have you had stomach surgery, a stomach injury, inflammation of the pancreas or other stomach problems recently ?
Are you taking, or have you taken a monoamine oxidase inhibitor within the past 14 days ?
Are you pregnant or breast-feeding ?

**If the answer to any of these questions is YES, do not take Codeine before talking to your doctor or pharmacist.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

These tablets may make you feel drowsy. Do not drive or operate machinery until you are used to the medication.

Alcohol should be avoided as it may affect you more than usual.

#### TAKING CODEINE

The tablets should be swallowed with a drink of water.

The usual dosage instructions are given below:

**Adults:**
**Pain relief:**
30 - 60 mg every four hours when necessary, up to a maximum of 240 mg in 24 hours.
**Treatment of diarrhoea:**
30 mg three to four times daily.
**Treatment of cough:**
15 - 30 mg three to four times daily.

**Elderly:**
A reduced adult dosage as prescribed by your doctor.

**Children aged 1 to 12 years:**
The dosage depends on the weight of the child.
**Pain relief:**
The usual dose is 3 mg/kg bodyweight daily in 4 to 6 divided doses.
**Treatment of cough:**
The usual dose is 1 - 2 mg/kg bodyweight daily in 4 to 6 divided doses.
**Treatment of diarrhoea:**
Not recommended.

**Children under 1 year of age:**
Not recommended.

The dosage will be reduced if you have liver or kidney problems.

Your doctor has decided the dose which is suited to you. Always follow your doctor's instructions and those which are on the pharmacy label. If you do not understand these instructions, or you are in any doubt, ask your doctor or pharmacist.

You should continue to take these tablets for as long as your doctor tells you to. If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Never take two doses together. Take the remaining doses at the correct time.

If you see another doctor or go into hospital, let him or the staff know what medicines you are taking.

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has accidentally swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.


## AFTER TAKING CODEINE

Codeine, like many other medicines may cause side effects in some people. These may include drowsiness, nausea, breathing difficulties, low blood pressure (dizziness or fainting), vomiting, a sensation that your surroundings are spinning either up or down or from side to side, headache, dry mouth, sweating, reddening or flushing of the face, change in heart rate (either faster or slower) and palpitations. Other side effects include low body temperature, hallucinations, a general feeling of restlessness, uneasiness or of being unwell, mood changes, pinpoint pupils, rashes, itching, nettle rash, reduced sex drive, impotence, abdominal and back pain, problems passing urine and constipation. In the elderly in particular, impaction of the faeces may occur which could lead to incontinence, unexplained diarrhoea, abdominal pain and in rare cases, obstruction of the intestine.

If you have these or any other effects whilst taking Codeine, tell your doctor.

In prolonged use, tolerance of the drug may occur so that increasingly higher doses are required to achieve the desired effect. If used for extended periods, Codeine can become habit-forming.

## STORING CODEINE

Do not use this medicine after the expiry date shown on the outside packaging.
These tablets should be stored in a dry place below 25°C and protected from light in the package or container supplied. Do not transfer them to another container. **Keep them in a secure place where children cannot get at them.** This medicine is for you ONLY, do not give it to anyone else. Unless your doctor tells you to, do not keep these tablets for longer than you need. Return all unused medicines to your pharmacist for safe disposal.

## FURTHER INFORMATION

If you are travelling abroad you may require a letter from your doctor explaining why you need to take these tablets.

This leaflet only gives a brief outline of some of the more important points about Codeine. If you want to know more about these tablets or their effects, please ask your doctor or pharmacist.

Revised: August 2005

Distributed by TEVA UK, Leeds LS27 0JG.

TEVA UK Limited

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# Appendix 13

## Flonase, patient information leaflet

Flonase®

(fluticasone propionate aqueous nasal spray)

GlaxoSmithKline

***Information for the Consumer***

Please read this leaflet carefully before you start to take your medicine. For further information or advice, ask your doctor or pharmacist.

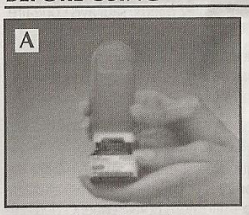
### The name of your medicine

The name of your medicine is FLONASE® (fluticasone propionate aqueous nasal spray). This is one of a group of medicines called corticosteroids.

FLONASE® Aqueous Nasal Spray can only be obtained on the prescription of a doctor.

### Instructions for use of your FLONASE® Aqueous Nasal Spray

***BEFORE USING***





**A.** Shake the bottle gently, then remove the dust cover by gently squeezing the ribs between your finger and thumb and lifting off.

**B.** Hold the spray as shown with your forefinger and middle finger on either side of the nozzle and your thumb underneath the bottle.

**C.** If using FLONASE® Aqueous Nasal Spray for the first time or if you have not used it for a week or more test the spray as follows: with the nozzle pointing away from you, press down several times as shown until a fine mist comes out of the nozzle.

***USING THE SPRAY***



- Tell your doctor if you notice that any discharge from your nose is yellow or green, if you have not already done so.
- Make sure that your doctor knows what other medicines you are taking (such as those for allergies, nervousness, depression, migraine, etc.), including those you can buy without a prescription as well as herbal and alternative medicines.
- Due to the interaction between Ritonavir (a medicine used to treat HIV infection or AIDS) with either intranasal or inhaled fluticasone propionate, it is important that your doctor knows that you are taking Ritonavir.
- It is important that you inhale each dose through the nose as instructed by your doctor or nurse. The label will usually tell you how many doses to take and how often. If it does not, or if you are not sure, ask your doctor or pharmacist.

  **For adults:** The usual dose is 2 sprays (2 x 50 micrograms) into each nostril, once a day, in the morning. Your doctor may advise you to increase this to 2 sprays (2 x 50 micrograms) into each nostril, twice a day.

  **For children aged 4-11 years:** The usual dose is one spray (50 micrograms) into each nostril, once a day in the morning. Your doctor may advise you to increase this to 2 sprays (2 x 50 micrograms) into each nostril, once a day.
- DO NOT inhale more doses or use your nasal spray more often than your doctor advises.
- It takes a few days for this medicine to work. **IT IS VERY IMPORTANT THAT YOU USE IT REGULARLY. DO NOT STOP** treatment even if you feel better unless told to do so by your doctor.
- If your symptoms have not improved after three weeks of treatment with FLONASE® Aqueous Nasal Spray, tell your doctor.

### About your medicine

FLONASE® Aqueous Nasal Spray is used to treat seasonal allergic rhinitis (including hay fever) and perennial rhinitis. Symptoms of these conditions include pain and pressure around the nose and eyes (sinuses), itching, a blocked up feeling in the nose and excessive sneezing. FLONASE® Aqueous Nasal Spray reduces the irritation and inflammation in the lining of the nose and nasal passages and so it relieves the pain and pressure around the nose and eyes, the blocked up feeling in the nose, the runny nose, itching and sneezing.

### The use of this medicine during pregnancy and breast feeding

Please tell your doctor if you are pregnant, likely to become pregnant or if you are breast feeding a baby. Your doctor may decide not to prescribe this medicine in these circumstances.

### Adverse reactions

- Occasionally you may sneeze a little after using this spray but this soon stops. You may experience an unpleasant taste or smell.
- If your nose or throat becomes painful or if you have a severe nose bleed after using the nasal spray tell your doctor as soon as possible.

D. Blow your nose gently.

E. Close one nostril as shown in the diagram and put the nozzle in the other nostril. Tilt your head forward slightly and keep the spray upright.

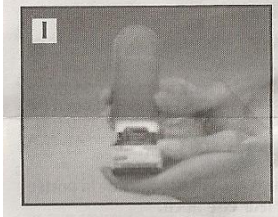
F. Start to breathe in through your nose and WHILE BREATHING IN press down with your fingers ONCE to release one spray.



G. Breathe out through your mouth. If a second spray in that nostril is required repeat steps F and G.

H. Repeat E, F, and G for the other nostril.

## *AFTER USE*




I. Wipe the nozzle with a tissue or handkerchief and replace the cover.

## *CLEANING*

J. Gently pull off the nozzle. Wash it in warm water.

K. Shake off excess water and allow to dry in a warm place but avoid excessive heat.

L. Gently push the nozzle back on top of the brown bottle. Replace the dust cover.

M. If the nozzle becomes blocked it can be removed as above and left to soak in warm water. Rinse under a cold tap, allow to dry and refit. Do not try to unblock the nozzle by inserting a pin or other sharp objects.

## Important points to remember

Follow the INSTRUCTIONS FOR USE described above. If you have any problems tell your doctor or pharmacist.

- Have you ever had to stop taking other medicines for this illness because you were allergic to it or it caused problems? If the answer is YES, tell your doctor or pharmacist as soon as possible, if you have not already done so.
- If you have any problems with your eyes such as pain or blurred vision, tell your doctor as soon as possible.
- If you feel unwell or have any other problems tell your doctor and follow the advice given.
- Some people can be allergic to medicines. If you have any of the following symptoms soon after using the nasal spray, **STOP** taking this medication and tell your doctor immediately.
  - Sudden wheeziness and chest pain or tightness
  - Swelling of the eyelids, face or lips
  - Lumpy skin rash or "hives" anywhere on the body

## What to do if an overdose is taken

Tell your doctor if you use more than you were told.

## What to do if you miss a dose

If you miss a dose do not worry; take a dose when you remember and take the next dose when it is due.

## What to do if you stop your medicine

If your doctor decides to stop your treatment, do not keep any left over medicine unless your doctor tells you to.

## Storage of your medicine

- **Keep your nasal spray in a safe place where children cannot reach it. Your medicine may harm them.**
- **Keep your nasal spray between 4° C and 30° C.**

## A reminder

**REMEMBER** this medicine is for **YOU**. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

## FURTHER INFORMATION

**If you have questions or are not sure about anything, then you should ask your doctor or the pharmacist.**

You may want to read this leaflet again. Please DO NOT THROW IT AWAY until you have finished your medicine.



**GlaxoSmithKline Inc.**
Mississauga, Ontario; Montreal, Quebec

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# Appendix 14

**Comparative texts**

## Dolphin at a Glance

Coryphaena hippurus
By Frank Sargeant, Projects Editor

The dolphin is the wood duck of pelagic fishes, so spectacularly colorful that it seems impossible it could have evolved by accident. The back and head are iridescent, glowing neon blue and chartreuse green. The sides and belly are gold, sprinkled with bright blue spots. And, like some other pelagics, the fish has the ability to "light up" with shimmering waves of color across its body, almost as if its skin were embedded with moving lights.

In fact, biologists say the fish's color is the result not only of pigment, but of microscopic structures in the skin, which the fish can manipulate to change its color. The color changes could have evolved for spawning selection, or perhaps as a camouflage when approached by predators, as with many bottom creatures. In any case, the spectacular color in life leaves no doubt when a dolphin dies; the skin almost instantly turns an ugly, blotchy gray-silver or dull yellow.

Dolphins are found in the Atlantic, Pacific and Indian oceans, anywhere that the water remains at 70 degrees or warmer throughout the winter. In U.S. waters they migrate seasonally, following bait northward along the Atlantic coast to Virginia and beyond in spring, back toward the Keys in winter, but good numbers remain in Florida waters throughout the summer as well.

The dolphin is unique among pelagic fishes in that the mature males have a distinctly different shape than the females; the forehead of an adult "bull" is high and blunt, while the "cow" has a more typical, streamlined forehead. (The males look just like the females until they approach adulthood.) There are no reports of the male using this head as a battering ram in mating battles, but it's pretty clearly a secondary sexual characteristic.

Dolphin reportedly can reach speeds up to 50 mph, and sometimes run down flyingfish in the air, though more commonly they race along just under the surface, watching a flyer and eating it the second it touches down. They also eat lots of squid, small bonito and other pelagic bait.

There's a second species of dolphin in Florida waters known as the pompano dolphin, Coryphaena equisetis. It's less elongated than the larger cousin, and never reaches sizes much over two feet long and weights of 5 pounds. If you get into a big school of "chicken" dolphin, they are probably pompano dolphin-some scientists believe they're more common than the "common" dolphin. One sure way to tell which species you have in hand is to check the anal fin. Common dolphin has a notch near the front, but pompano dolphin does not. For regulatory purposes, Florida considers them one species, with no separate bag limit. (The dolphin limit is 10 daily, with no minimum or maximum size.)

Dolphin grows very fast, reaching 10 pounds in three years. The Florida record is 76 pounds, 8 ounces for a fish taken out of Lake Worth Inlet, while the all-tackle mark is 87 pounds even, from the Exumasin the Bahamas.

Like cobia, dolphins are attracted to all sorts of floating objects, from the smallest to the largest. Weedlines have a natural attraction for them, but they seem particularly interested in the debris of civilization; pieces of wood, plastic sheets, barrels and wrecked docks have all been reported as dolphin attractors.

Little is known about dolphin mating or juvenile life, but they apparently spawn April to August. The larval fish live in the sargassum that provides the only cover in the open sea until they're big enough to run down prey in open water. The body shape is similar to adults, but the colors are gold/orange with black stripes, probably giving them a better chance of escaping predators as they hide in the sargassum. They're attracted to partyboat lights at night; if you want a miniature, take along a long-handled dipnet.

They're also called dorado, the golden fish, in Spanish, and mahi-mahi in Hawaii and in expensive restaurants. Whatever you call them, they're delicious on the table, and a delight on the hook.

*(Thanks to scientists at Dauphin Island Sea Lab and the National Marine Fisheries Service for information included in this report.)*

**FS**

## The Monkey and the Crocodile

Retold from the Panchatantram by Rohini Chowdhury

Once there lived a monkey in a jamun tree by a river. The monkey was alone - he had no friends, no family, but he was happy and content. The jamun tree gave him plenty of sweet fruit to eat, and shade from the sun and shelter from the rain.

One day a crocodile came swimming up the river and climbed on to the bank to rest under the monkey's tree. 'Hello', called the monkey, who was a friendly animal. 'Hello', replied the crocodile, surprised. 'Do you know where I can get some food?' he asked. 'I haven't had anything to eat all day - there just don't seem to be any fish left in the river.'

'Well,' said the monkey, 'I don't eat fish so I wouldn't know - but I do have plenty of ripe purple jamuns in my tree. Would you like to try some?' He threw some down to the crocodile. The crocodile was so hungry that he ate up all the jamuns even though crocodiles don't eat fruit. He loved the sweet tangy fruit and shyly asked whether he could have some more. 'Of course', replied the monkey generously, throwing down more fruit. 'Come back whenever you feel like more fruit', he added when the crocodile had eaten his fill.

After that the crocodile would visit the monkey every day. The two animals soon became friends - they would talk and tell each other stories, and eat as much of the sweet jamuns as they wanted. The monkey would throw down all the fruit the crocodile wanted from his tree.

One day the crocodile began talking about his wife and family. 'Why didn't you tell me earlier that you had a wife?' asked the monkey. 'Please take some of the jamuns for her as well when you go back today.' The crocodile thanked him and took some of the fruit for his wife.

The crocodile's wife loved the jamuns. She had never eaten anything so sweet before. 'Imagine', she said, 'how sweet would be the creature who eats these jamuns every day. The monkey has eaten these every day of his life - his flesh would be even sweeter than the fruit.' She asked her husband to invite the monkey for a meal - 'and then we can eat him up' she said happily.

The crocodile was appalled - how could he eat his friend? He tried to explain to his wife that he could not possibly eat the monkey. 'He is my only true friend', he said. But she would not listen - she must eat the monkey. 'Since when do crocodiles eat fruit and spare animals?' she asked. When the crocodile would not agree to eat the monkey, she pretended to fall very sick. 'Only a monkey's heart can cure me', she wailed to her husband. 'If you love me you will get your friend the monkey and let me eat his heart.'

The poor crocodile did not know what to do - he did not want to eat his friend, but he could not let his wife die. At last he decided to bring the monkey to his wife.

'O dear friend', he called as soon as reached the jamun tree. 'My wife insists that you come to us for a meal. She is grateful for all the fruit that you have sent her, and asks that I bring you home with me.' The monkey was flattered, but said he could not possibly go because he did not know how to swim. 'Don't worry about that', said the crocodile. 'I'll carry you on my back.' The monkey agreed and jumped onto the crocodile's back.

The crocodile swam with him out into the deep wide river. When they were far away from the bank and the jamun tree, he said, 'My wife is very ill. The only thing that will cure her is a monkey's heart. So, dear friend, this will be the end of you and of our friendship.' The monkey was horrified. What could he do to save himself? He thought quickly and said 'Dear friend, I am very sorry to hear of your wife's illness and I am glad that I will be able to help her. But I have left my heart behind on the jamun tree. Do you think we could go back so that I can fetch it for your wife?'

The crocodile believed the monkey. He turned and swam quickly to the jamun tree. The monkey leaped off his back and into the safety of his tree. 'False and foolish friend,' he called. 'Don't you know that we carry our hearts within us? I will never trust you again or ever give you fruit from my tree. Go away and don't come back again.'

The crocodile felt really foolish - he had lost a friend and a supply of good sweet fruit. The monkey had saved himself because he had thought quickly. He realised that a monkey and a

crocodile could never be true friends - crocodiles preferred to eat monkeys rather than be friends with them.

## Of Love and War

Reviewed by Nicholas Gage
Sunday, October 17, 2004

BIRDS WITHOUT WINGS
By Louis de Bernières

Ever since the invasion of Troy, convulsions in the eastern Mediterranean -- from the Persian wars to Alexander's conquests to the Battle of Lepanto in 1571 -- have provided the raw material for epic tales of struggle and sacrifice. In the 20th century, the upheaval that continued that tradition and promised to produce more than one great literary work was the collapse of the Ottoman Empire and the rise of Turkish nationalism under Mustafa Kemal Atatürk.

Here you had it all: hedonism and decay as the old order crumbled; persecution and genocide as Turkish extremists sought to drive out and destroy millions of Christians in their midst; invasion and occupation as Greek forces, spurred on by their European allies, occupied Smyrna and pushed deep into Anatolia; reversal and resurgence as Kemal revived the battered Turks and drove the invaders back to the sea; betrayal and slaughter as the Europeans abandoned the Christians to the fury of their attackers; and loss and sacrifice as 1.5 million Christians were forced to abandon their ancestral homelands in Anatolia for Greece.

For almost a century, many writers, from Franz Werfel (The Forty Days of Musa Dagh) to Elia Kazan (The Anatolian), have tried to use this intensely dramatic material to create a literary work worthy of the historical events. It was natural that Louis de Bernières, a master storyteller who knows the eastern Mediterranean well and achieved his greatest success with a novel set in the region, Corelli's Mandolin, should turn to this subject to try to produce an epic novel that would do the turbulent era justice.

His new book, Birds Without Wings, to which he has devoted a decade of his writing life, does not quite achieve that goal, but it is a fascinating, evocative work written on a grand scale not much seen today. Despite its flaws, it is as rich and compelling as any novel written about the Anatolian upheaval.

Birds Without Wings and Corelli's Mandolin share the same theme -- a peaceful, sun-drenched community shattered by the horrors of war. They also share one character, Drosoula Drapanitikos, the refugee from Anatolia who runs the local taverna in the earlier novel and is the mother of the rebel leader, Mandras.

Birds takes Drosoula back to her youth and her ancestral home, Eskibahçe, a town on the Lycian coast known as Paleoperiboli (Old Orchard) in Byzantine times. In this seaside Eden, Christians and Muslims live convivially together, sharing holidays, customs and superstitions and even intermarrying. Although Drosoula has her own tragic story to tell, she serves primarily as the vehicle for recounting the main romance in the novel, the love affair of her childhood friend, the beautiful Christian girl Philothei, and the Muslim goatherd Ibrahim.

Drosoula is only one of many narrators in this mosaic of a novel, and Philothei's doomed love affair is only one of several interconnected stories. There is Rustem Bey, the rich landlord, proud of his Circassian mistress but tortured by his love for the unfaithful wife he tried to have stoned to death; the ascetic Greek schoolteacher Leonidas, who spends his nights fomenting plots and writing messages to irredentist groups; the potter Iskander and his son, Karatavuk, who winds up on the Turkish defense line at Gallipoli and witnesses the crushing defeat of Allied forces.

But while there are several brilliant set pieces -- the battle of Gallipoli, the expulsion of Christians from their ancestral homes -- as well as enough major characters and story lines to fill three novels, Birds Without Wings does not hang together well enough to be the master work the author intended. For one thing, there are so many characters and interconnected story lines that confusion and repetition are the inevitable byproducts. For another, many of the major characters are so endearing, so knowing, so full of folk wisdom that they are simply not believable. It is hard to accept, for example, that an illiterate potter,

thoughtful as he might be, would come up with such an insight as "Destiny caresses the few, but molests the many, and finally every sheep will hang by its foot on the butcher's hook." To add to the confusion, de Bernières scatters throughout the book 22 chapters on the life and career of Kemal Atatürk, the military leader who forged the modern Turkish nation, that have little connection to the other stories he recounts and produce a portrait that verges on hagiography. As a result, the mosaic he has created does not emerge as the grand vision it could have been with tighter editing and a less diffuse narrative.
Nevertheless, in his compassionate portrayal of simple people struggling against sweeping historical forces and his vivid descriptions of the cruelties of war, de Bernières has reached heights that few modern novelists ever attempt. While Birds Without Wings can be confusing and meandering at times, it offers a thrilling ride through a whirlwind of history that changed forever a pivotal part of our world.

## Introducing Madagascar

Forget Hollywood fripperies, Madagascar is like no place else on earth. In fact, all things considered, it barely qualifies as part of Africa: the two are separated by hundreds of kilometres of sea and 165 million years of evolution – long enough for Madagascar's plants and animals to evolve into some of the weirdest forms on the planet. Nowhere else can you see over 70 varieties of lemur, including one that sounds like a police siren, the world's biggest and smallest chameleons, and the last stomping ground of the elephant bird, the largest bird that ever lived. Near Ifaty in Southern Madagascar you will see forests of twisted, spiny 'octopus' trees and in the west, marvel at the bottle-shaped baobabs, especially the Avenue du Boabab near Morondava. And be on the look out for the carnivorous pitcher plant found around Ranomafana, there are over 60 varieties of them. Not for nothing is Madagascar regarded as the world's number one conservation priority.
And the people are no less interesting: arriving here some 2000 years ago along the Indian Ocean trade routes, they grow rice in terraced paddies, and speak a language that has more in common with their origins in Southeast Asia than with the African continent. Their culture is steeped in taboo and magic, imbuing caves, waterfalls, animals and even some material objects with supernatural attributes. Hill peoples live in traditional multistoried brick houses with carved balconies and, in some areas, dance with their dead ancestors in the 'turning of the bones' ceremony.
Throw in a soupçon of pirate history, coastlines littered with shipwrecks, great regional cooking, some of the world's longest place names, and unfailingly polite and friendly people, and you'll experience a refreshing take on the overused 'unique' tag.

***Travel Alert:*** *The political situation is unpredictable in Madagascar and travellers should exercise caution. Refer to the BBC for news updates or the Safe Travel for current government warnings.*

## Hit The Floor -- A True Story
Friday, April 13, 2001

On a recent weekend in Atlantic City, a woman won a bucketful of quarters at a slot machine. She took a break from the slots for dinner with her husband in the hotel dining room.
But first she wanted to stash the quarters in her room.' I'll be right back and we'll go eat,' she told her husband and she carried the coin-laden bucket to the elevator.
As she was about to walk into the elevator she noticed two men already aboard. Both were black. One of them was big... very big... an intimidating figure. The woman froze. Her first thought was: These two are going to rob me. Her next thought was: Don't be a bigot, they look like perfectly nice gentlemen. But racial stereotypes are powerful, and fear immobilized her. She stood and stared at the two men. She felt anxious, flustered, and ashamed. She hoped they didn't read her mind, but knew they surely did; her hesitation about joining them

on the elevator was all too obvious. Her face was flushed. She couldn't just stand there, so with a mighty effort of will she picked up one foot and stepped forward and followed with the other foot and was on the elevator.
Avoiding eye contact, she turned around stiffly and faced the elevator doors as they closed. A second passed, and then another second, and then another. Her fear increased. The elevator didn't move. Panic consumed her.
'My God, she thought, I'm trapped and about to be robbed' Her heart plummeted. Perspiration poured from every pore. Then ...one of the men said, "Hit the floor." Instinct told her: Do what they tell you. The bucket of quarters flew upwards as she threw out her arms and collapsed on the elevator carpet. A shower of coins rained down on her. Take my money and spare me, she prayed.
More seconds passed. She heard one of the men say politely, 'Ma'am, if you'll just tell us what floor you're going to, we'll push the button.'
The one who said it had a little trouble getting the words out. He was trying mightily to hold in a belly laugh. She lifted her head and looked up at the two men. They reached down to help her up. Confused, she struggled to her feet. 'When I told my man here to hit the floor,' said the average sized one, 'I meant that he should hit the elevator button for our floor. I didn't mean for you to hit the floor, ma'am.' He spoke genially. He bit his lip. It was obvious he was having a hard time not laughing.
She thought: 'My God, what a spectacle I've made of myself.' She was too humiliated to speak. She wanted to blurt out an apology, but words failed her. How do you apologize to two perfectly respectable gentlemen for behaving as though they were going to rob you? She didn't know what to say.
The 3 of them gathered up the strewn quarters and refilled her bucket. When the elevator arrived at her floor, they insisted on walking her to her room. She seemed a little unsteady on her feet, and they were afraid she might not make it down the corridor. At her door they bid her a good evening. As she slipped into her room she could hear them roaring with laughter while they walked back to the elevator. The woman brushed herself off. She pulled herself together and went downstairs for dinner with her husband.
The next morning flowers were delivered to her room-a dozen roses. Attached to EACH rose was a crisp one hundred-dollar bill. The card said: 'Thanks for the best laugh we've had in years'

It was signed,
Eddie Murphy & Michael Jordan

## Cops shoot dead police killer

By VINCE SOODIN
Published: Today

***POLICE say they have shot dead a man suspected of gunning down four officers in Seattle.***

Pierce County sheriff's spokesman Ed Troyer said Maurice Clemmons was shot early this morning.
Clemmons, 37, who had chillingly boasted to pals to watch TV news because "I am going to kill some cops" — was let out on bail just six days before Sunday's horror.
Last night more than 300 police were hunting the mentally-unstable and violent criminal.
SWAT teams stormed a house in Seattle, Washington state, at dawn after a tip-off that the killer was holed up inside. They fired tear gas and hurled in grenades but there was no sign of Clemmons.
His victims were named as Tina Griswold, 40, Sgt Mark Renninger, 39, Ronald Owens, 37, and Greg Richards, 42.
The uniformed officers were completing paperwork in the coffee shop in Tacoma, Washington, as they prepared to start their shift.
Clemmons opened fire without warning, shooting two of them in the back of the head execution style.
Another of the officers managed to shoot Clemmons in the stomach as the gunman fled into the car park.

The cop later died from his wounds. Mr Troyer said yesterday Clemmons may not have got far. He said: "If he didn't get a ride out of there he could still be in the area."
Detectives do not know why the gunman - described in court papers as delusional and unstable - targeted the officers.
Clemmons faced child rape and police assault charges. He was controversially freed by Arkansas Governor Mike Huckabee in 2000 after serving 11 years of a 95-year sentence for robbery.
Huckabee said he met the conditions for parole.

## Nokia N93 Cell Phone

Decisions, decisions, decisions. Now that the new Nokia N93 has been announced, I have been stuck with a very peculiar dilemma: whether to go for the N93 or the N91. Did I just say Nokia N93? That's right kids: the N93 is an all-new phone incorporating camcorder capabilities boasting a 3.2 megapixel camera, Carl Zeiss optics and 3x optical zoom.
If what Nokia claims is true, then consumers can look forward to DVD-like video capture, and later view it on a standard television thanks to the TV-out option. The bundled Adobe Premiere Elements 2.0 software will further assist in burning your high-quality home videos onto DVDs. This is virtually a camcorder with a phone attached. Videos can be captured in MPEG4 format at 30 fps.
Like the N90, simply unfold and twist the main display and presto: you get a full-screen color viewfinder in landscape mode. It's that simple, really. The primary screen is a spanking 2.4" high-definition Active-Matrix display with a wide 160° viewing angle running at 320x240 pixel resolution and 262k colors, while the secondary is 1.1" offering 65k colors. Bluetooth 2.0 makes an appearance but is lost in all the other great features.
The Nokia N93 is based on S60 3rd Edition - the same as Nokia N91 - with 50MB internal memory and support for miniSD cards (expandable up to 2GB). This one's also a 3G phone, supporting WCDMA 2100MHz with simultaneous voice/packet data, and integrated 802.11b/g wireless LAN connectivity. What's more, with its TV-out capability, you can even browse the web, work on your office documents and even play games on the TV.
With Adobe Premiere Elements, you can play with your videos inserting various effects and transitions, and burn 'em onto DVDs or convert them to a web-suitable format for streaming. Oh and if the videos ever get boring, there's always good old radio to fall back on: the N93 also has an integrated stereo FM receiver. Or how about the digital music player?
Priced at €550, expect the Nokia N93 to hit the markets in July this year. Grab details from Nokia or check the extended entry for specs.

## Resin rules on Beads, Baubles and Jewels

Earlier this year I went to Cleveland to tape a few segments for Beads, Baubles, and Jewels. I brought three cute tops, moisturized my hands, cleaned and painted my fingernails, put anti-frizz gunk in my hair, and let the makeup artist do her thing so I could look like the perfect TV Barbie doll next to BBJ's wonderful host, Katina Forte. Truth be told, I really panic when I'm on television. I'm used to blabbing my head off in front of a crowd of rowdy beaders when I teach classes, but it's quite another thing to be a talking head in a quiet studio with a bunch of expressionless guys in headphones pointing cameras at you. But, by my third segment I was more relaxed, knew the names of the camera crew, and forgot about my hair. So, I feel the third segment was my best one. I talked about resin beads and how versatile they are. Judy Thomsky of Natural Touch Beads was nice enough to lend me a ton of her beautiful work so I looked like I knew what I was doing.  Here's a sneak preview of my resin bead segment.
These resin beads are made in a cottage industry in Java, Indonesia. They're made in small batches by pouring liquid resin into molds, then they're hand cut and sanded. Don't these new opaque colors remind you of antique Bakelite? I can see a world of Art Deco designs just waiting in those cuffs.

Want to make these delicious-looking beads even more tasty? Rub a bit of hand lotion or olive oil over the surface and you'll achieve a beautiful luster.
Ever tried stamping resin? A stamp dabbed with permanent ink turns a plain bead into an exciting one very quickly. You can also wirework resin beads, work beadwork over them, or use interesting stringing materials like leather, yarn, and silk to string them.
Remember when we used to make beaded beads over wooden beads? Use a resin bead instead of wood, and the finished piece just glows.
You don't need to stop at round beads when beading over this pretty material. For my latest over-the-top jewelry creation, *Festivus*, (I swear, my next stop is Vegas) I used resin donuts as the base for the starbursts. I could have just skipped that part when I was designing, but the resin lends a pretty luminescence, not to mention body, to the necklace. And guess what? The instructions for this necklace will be in the December/January issue of Beadwork magazine! I want to see all of you wearing one at your holiday parties, okay?
Do you get ideas from all the materials you see on Beads, Baubles and Jewels, like resin beads? Share your comments here.

## Rufus Wainwright

By Caryn Ganz
Photography Daniel Jackson

After releasing six albums, appearing in a handful of films, and single-handedly resurrecting the songbook of Judy Garland, Rufus Wainwright took the next logical step: He spent three years writing a two-hour opera. But *Prima Donna*, which will premiere this July at the Manchester International Festival in England, isn't the only bizarre career move Wainwright has taken lately. He just wrapped up work in Berlin on a musical adaptation of Shakespearean sonnets with director Robert Wilson. On that project, his feelings are mixed: "It was a bit like World War II over there," he laughs, "which is to be expected, I guess, because that's where World War II took place." But Wainwright considers it "a good booster shot" for what he'll experience once he unveils *Prima Donna*. The opera's main character is Régine Saint Laurent, a diva who disappears for six years following a tragedy on the night of a premiere. The story begins on the morning of her return to the stage. Saint Laurent is seizing her moment, much like the 35-year-old Wainwright, a lifelong opera buff who accelerated his artistic plans once his mother became sick with cancer. "Once illness strikes, you realize there's not a lot of time for you to do what you really need to do," he says. "And there's no time like the present."

CARYN GANZ: The star of your opera is literally a diva. Were you drawing on anyone specific?

RUFUS WAINWRIGHT:Well, the closest one would be [*Sunset Boulevard*'s] Norma Desmond, or actual old silent-movie stars who had it all taken away from them. I suppose one could argue that there were Madonna moments. Some peoplethink my opera is about her early career in Detroit or something—like, *Pre-Madonna*.

GANZ: Divas loom large in high culture, but also in low culture like reality shows. Did both sides of that persona inspire you?

WAINWRIGHT: There is actually a great book called *Prima Donna* by Rupert -Christiansen that deconstructs the myth. In fact, many of the women who were prima donnas were feminists and incredible forces for their time. You had to be an over-the-top, demanding, dramatic figure in order to progress as a woman in Europe over the last few hundred years. Now people say, "You're being such a prima donna," meaning you're being hard to deal with or crazy. It's a bit sexist.

GANZ: Did you set out to write a feminist opera?

WAINWRIGHT: It's funny, now that you mention it—I didn't set out to do that. But I was keenly aware that I didn't want to draw on too many typically doomed aspects of the fated singer. Whether it's Judy Garland or Norma Desmond, there is this tragic quality to older women that one can revel in, and you want it to be more three-dimensional than that. So it was important for the character to be strong and resilient, because there are so many victims in opera.

GANZ: The opera also lasers in on the idea of the comeback, which, from Mickey Rourke to Britney Spears, is one of the most compelling tropes in our culture right now.

WAINWRIGHT: Well, in a way I'm kind of making my own comeback. I've been in the business now for 20 years. I've had my ups and downs, and I definitely have a sense—in America, especially—that once you've made your mark and gotten your *Rolling Stone* piece and your Grammy nomination, that they're on to the next piece of meat, and they don't necessarily like to follow the twistsand turns of an artistic career. Throwing an opera at them is something they have to notice. There's nothing subtle about it. I don't know if it will be my big comeback, but I think it is a statement—that I am a self-sustaining, vibrant, long-term artist, and I'm not going away! And if you don't give me credit, then the musical gods will!

GANZ: As everything about the music industry gets more digital, you're moving in the opposite direction—opera and Shakespeare . . .

WAINWRIGHT: I definitely have a Luddite's approach to what's going on. I find that as I get older, I get stupider. For me, the iPhone is harder than reading Faust. I've been hanging out a bit with Lou Reed, and he's the complete opposite. He's into technology and is kind of like a toddler, compared to me, who's like an old 19th-century widow or something.