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TRABAJO DE FIN DE GRADO

Are Patient Information Leaflets (PILs) a New Medical Genre? Analysis and Translational Commentaries

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ABSTRACT

This dissertation provides a rhetorical, linguistic, and translation analysis of different Patient Information Leaflets (PILs) with the aid of two corpus tools: *AntConc* and *TermoStat*. In this sense, we have chosen the PILs of 10 medicines serving different purposes in order to consider as many types as possible (10 in English and 10 in Spanish). Previous studies have shown that PILs have been undervalued when they actually stand for one of the most important types of medical texts because of how potentially influential they are on patients. Our aim has been to analyse the language, to establish the genre of PILs, and to answer the hypotheses of whether they have been translated from English into Spanish and whether the popularity of PILs influences when identifying them as translations.

Keywords: Medicines**,** PILs, language, medical, translation, patient.

RESUMEN

En este trabajo de fin de grado, hemos llevado a cabo un análisis a nivel retórico, lingüístico y de traducción de varios prospectos médicos con la ayuda de dos herramientas de análisis del corpus: *AntConc* y *TermoStat*. De este modo, hemos seleccionado los prospectos médicos de 10 medicamentos con fines diferentes para abarcar tantos tipos como nos fuera posible. A través de estudios anteriores, hemos comprobado la escasa importancia que se ha dado a los prospectos médicos cuando en realidad representan uno de los tipos de texto más importantes del ámbito médico debido a la gran influencia que ejercen sobre el paciente. Por esta razón, hemos realizado este estudio con el objetivo de analizar el lenguaje, establecer el género del prospecto médico y responder a las hipótesis de si nuestros textos se han traducido de inglés a español y si la popularidad de los medicamentos es determinante a la hora de identificarlos como traducciones.

Palabras clave: Medicamentos, prospectos médicos, lengua/lenguaje, médico/a, traducción, paciente.

CONTENTS

LIST OF ACRONYMS

AdjP: Adjectival Phrase

CMS: Committee on Safety of Medicines

JRV: Journalistic Reported Version

LGP: Language for General Purposes

LSP: Language for Specific Purposes

NHS: National Health System

NP: Noun Phrase

OCU: Organización de Consumidores y Usuarios

PIL(s): Patient Information Leaflet(s)

POS: Part of Speech

PP: Prepositional Phrase

SS: Seguridad Social

UK: United Kingdom

URL: Uniform Resource Locator

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1. INTRODUCTION

In our undergraduate dissertation, we want to comment on, and analyse, the language of the proposed Patient Information Leaflets (PILs). Experts like Ghaemi and Sheibani report that researchers of the field of medicine have mostly paid attention to medical research articles, ignoring other medical genres such as PILs or medical brochures. In this way, they assert that the analysis of PILs is relevant due to the "large number of intended audience and the importance of their content" which makes PILs to be considered "one of the most important text types in the field of medicine" (50-51). Moreover, we can find some examples of scientific popularized texts –such as PILs– as those that Nwogu refers to when he claims that they are focused on their lexicon and syntax because these are "rewritten for different audiences", so the content is not as scientific as the medical field generally represents (111). For this reason, our intention is to analyse the similarities and/or differences between the PILs and the medical domain and the importance of them to establish the genre of PIL.

On this basis, one of our purposes is to establish the genre of PILs by showing its main characteristics that will probably arise from this dissertation. The second purpose of this study is based on the discussion whether our PILs have been translated from one of the languages involved into the other. In this regard, we hypothesise that our English PILs have been translated from the Spanish versions, or at least some of them. Moreover, our last hypothesis is that the probability of the PIL being a translation has to do with the popularity of the medicine.

In this sense, we will use two corpora and consider them parallel and comparable in order to analyse if the texts are translations or not. To confirm or reject the hypotheses, we will establish a comparison between the PILs in both Spanish and English by carrying out a translation analysis focusing on the frequency of equivalents and translation procedures. In order to develop a more exhaustive analysis, we will carry out two further analyses. On the one hand, a linguistic analysis, focusing on three different levels: the grammatical one –Part of speech (POS) and study of frequency of lexical words– the syntactic one –types of sentences and verb tenses– and the semantic one –words of special interest regarding their meaning, ambiguity, lexical fields… On the other hand, we will propose a rhetorical analysis in order to observe how these texts are usually structured, and how the information is organized in them.

This dissertation is divided into fourth sections. The first section is focused on theoretical aspects of PILs such as their characteristics or other theoretical information applied to the analyses. The second section deals with the methodology where we explain in detail the different analyses, the corpora, and corpus tools used to carry out the analyses. The third section is focused on the empirical analyses and results, which consists in three main parts: the rhetorical, the

linguistic, and the translational one in which we will display the analyses and their results. Finally, the fourth section is dedicated to the discussion, where we will summarise and discuss the main results as well as resolve the hypotheses of the study.

2. THEORETICAL BACKGROUND

In this section, we will define some characteristics of PILs as well as present information that we have used for the analyses. First, we have focused on the definition of the PIL. Here, we have determined the subject field and nature of the PIL, and its impact on readers. Second, we have established the similarities and differences between the 'typical' medical language and the language of PILs, including their characteristics, and the hierarchies in the medical domain. Third, we have focused on the textual and communicative characteristics of our PILs. Concerning the textual ones, we have discussed the macro-genre, genre, and function of PILs; and regarding the communicative ones, we have discussed the communicative situations of the scientific/medical field –more general– and then the communicative situations of the medical field/PILs genre –more specific. Finally, we have included information about some concepts necessary for each of the analyses before carrying them out.

2.1. What is a PIL (Patient Information Leaflet)

Informally speaking, we can define a Patient Information Leaflet as a piece of text which is generally included in a medicine package and contains all the information you need about the medicine and its characteristics. In words of the Committee on Safety of Medicines (1), PILs "provide the essential information which patients need to enable them to use the medicine safely and gain the most benefit". This is understood in the sense that patients use the PIL in order to know how to take a medicine and to get the most out of it without compromising their health. We can also find PILs along with other pharmaceuticals that are not necessarily medicines such as anti-aging creams. However, our project is not dedicated to the latter, but to the medicines and the PILs contained in them.

Apart from that, the Committee on Safety of Medicines asserts that the role of the PIL is to make the patients "able to access information to enable them to make informed decisions about their health." (8). This means that it is important for patients to know how a medicine works and then decide if they can or cannot take it, regardless of their reason –any allergy, too many side effects… etc. In this way, patients need to be informed because one of the most important factors in anyone's life is health.

Medicines are regulated differently in Europe depending on the country. For this reason, it is important to mention some ideas about the health systems in Spain and UK concerning the acquisition of pharmaceuticals. In Europe, we can establish two different models that regulate the national health systems: the Beveridge model and the Bismarck model. The OCU (Organización de Consumidores y Usuarios) states that the Beveridge model is based on the British health system and was later adopted by other countries such as Spain. Moreover, it is financed by the government through taxes, is committed to providing universal health protection, and it only includes pharmaceutical co-payment[1]. Finally, it regulates the price of those medicines to facilitate patients access to them. On the other hand, the Bismarck model works in countries like Germany or France. The system is based on the payment of monthly premiums according to the age, health, and sex of the person. In other words, the first model offers an –almost– free health care while the second model does not (n.p.). As we are interested in Spain and UK, we cannot find huge differences towards the health systems in these two countries since both belong to the same health system model in Europe, that is the Beveridge model.

Besides, the Committee on Safety of Medicines claims that "unlike other sources of information, the patient information leaflet is highly regulated." (1). In this sense, as stated by the European Commission, there is an EU legal framework for the pharmaceuticals which "guarantees high standards of quality and safety." (n.p.) This legal framework "is based on the principle that medicinal products may be placed on the market only following a marketing authorisation granted by the competent authorities." (n.p.) This means that the marketed medicines suffer a strict control in order to provide medicines of the highest possible quality to avoid any probable failure, since the health system's premise is the good condition of the patient.

Along these lines, we noted that the pharmaceuticals are not always defrayed by the government, but by their users in both countries. In Spain, the system of Seguridad Social (SS) is prevalent. It is the main social protection system of the nation, including the health sector, which means that the government is the body in charge of paying for the healthcare costs of those people affiliated with the SS. However, medicines are not usually included in the service provided by the SS except for exceptional cases such as severe illnesses of high cost or for lack of economic means.

[1] A co-payment is a concept included in the medical domain which defines the amount of money that a person has to pay for a service compared to the actual cost of that service. The government of the country defrays the difference of those costs.

In the UK, the institution responsible for providing a proper healthcare system is the National Health System (NHS). It works in a similar way as in Spain, so the medicines are normally paid by the patient. However, the funds allocated to the provision of health services come from the taxes collected from workers registered for these institutions, so health care costs are not directly paid by the Government. In the case of private health insurance, only those who have a pharmacy coverage included in their insurance policy can access almost-free medicines. However, these insurances involve costs that not everyone can afford.

Due to their peculiar characteristics, complicated sentences, technical expressions, and ambiguous terms are very common in this type of texts. For this reason, it is sometimes very difficult to fully understand what is written in these papers. Before starting with the analysis, we need to consider some of the peculiarities of our PILs. Once we know what is a PIL, its origin, how the healthcare systems work, and the cost of medicines in Spain and UK, it is necessary to focus our attention on the linguistic aspects of this text type.

2.1.1. **Scientific text: medical subject field (LSP)**

Medicines are scientific products since they have been developed in laboratories, particularly in the pharmaceutical sector. For this reason, it is assumed that the language contained in the PILs belongs to a scientific medical domain as it describes the characteristics of these medicinal products. In this way, the language of PILs belongs to the medical subject field that is studied within the Language for Specific Purposes (LSP) perspective. Thus, this perspective means that the medical domain of PILs is not only a variety of language spoken and common to experts in the area, but also it should be also adequate to the specific purpose of informing the patient.

2.1.2. **Influences on the patient's decision: how to take a medicine**

The Committee on Safety of Medicines (CSM) asserts that "patients naturally want to be involved in decisions relating to their health". Moreover, patients feel more confident to choose a treatment when they have been told the advantages or disadvantages of taking a medicine or not (33). This means that the more the patients are informed, the better for them. For this reason, an adequate communication between the medical doctor, supposedly the writer of the PIL[2], and the patient is very important. Even if a PIL should never replace a diagnosis made by a doctor, the point of writing these documents is that patients may be able

[2] Bowler states that "professional scientists were not the only authors writing for a general audience, of course. There were still many writers who specialised in this area, often because they had some links with academic or industry-based scientists" (n.p.). In this sense, we see that the medical doctor, which is a professional scientist, is not the only possible person able to write PILs. However, we have referred to the writer of PILs as medical doctor or medical writer in order to avoid confusions.

to take the medicines on their own without medical support. This is particularly important when taking non-prescription medicines. In addition, the reading of PILs contributes to avoiding, when possible, the risk of health problems when the patients make improper use of medication. The CSM defines it as "risk information". This not only implies that the information is well presented and adequate for the patient, but also the need for trustable sources from which getting the PILs such as governments or pharmaceutical companies. (33). This is the main reason why we have selected our PILs from the Spanish and English government websites in order to get reliable texts. Even if PILs are subject to strict controls, their quality is sometimes affected particularly when they are translated.

2.2. Medical language vs. language of PILs: similarities and differences

We can establish clear differences between the medical language in general and the language we find in PILs. As we have seen before, the PIL is included in the medical domain, but this domain is too broad. What characterizes a PIL is that it is a peculiar text sample of this subject field, since it is a text addressed to laymen, when the usual communicative situation of the medical subject field is based on the relationship expert to expert. All the medical genres included in the expert to layperson communicative situation are called popularized medical texts. In words of Nwogu (111), "the tendency for previous studies to concentrate on the syntax and vocabulary of popularized science texts might be due to the fact that more attention tends to be paid to lexical and syntactic changes when scientific texts are being rewritten for different audiences, as evidence from the *NewScientist* shows." Even if Nwogu referred to texts other than medical, these are also representative of the scientific popularisation domain whose function is spreading knowledge to laymen in an easier language as it is the case of PILs. This would support our analysis since this type of texts contains different lexical and syntactic aspects which result from simplifying more complex medical texts for a non-expert audience, as in the case of our PILs or the NewScientist articles mentioned above.

2.2.1. Highly-specialized language of typical medical texts, and specialized but simpler language of PILs

The most-known model of the medical language is usually considered as a highly specialized domain, which means that a minimum of linguistic competence and subject knowledge –medical field– is required to understand its texts. However, it is also true that PILs do not comply with this model because they do not contain such a technical and restricted language as most of the genres typical of the medical domain.

In line with this, García Izquierdo asserts that unlike more specialized medical informational genres, PILs have a less conventional fixation. This is because the PIL includes characteristics that are specific to the genre of dissemination rather than to the specialized medical genre as such (*Divulgación médica y traducción* 13-14; my translation). This can be understood as a difference in the sense that the medical language is more scientific-oriented than the language of PILs.

Finally, one of the similarities between the language of PILs and the medical language in general is their purpose. Doval reports that the primary goal of medicine is to achieve health or cure diseases (84). In this sense, we can establish a common point since both look for the patient to overcome an illness.

2.2.2. **Hierarchies in the medical domain**

The relationship between the medical domain and the PIL can be understood in a hierarchical way taking into account the task carried out by each person involved. First, we find the expert-to-expert relationship, in which doctors communicate each other through a highly-specialized medical language. Regarding this communicative situation, Bowler states that scientists, in our case doctors, engage in debates about the wider implications of their work in order to create new theories, new medicines, etc. (n.p.). This idea is contrary to what we have seen with the language of PILs and the communicative situation in which they are included.

Second, once doctors have defined their specialized language, medical writers use those complex medical texts and adapt them proposing a language that is appropriate for the communicative situation of expert to layman. This is the case of the informative language we find in the PILs called medical popularization. As reported by Arora (6), "the language of PILs is fairly simple while avoiding medical jargon so as to ensure a comprehensive understanding by the consumers/patients." In this sense, the language of PILs is characterized by its –supposedly– low technical level, so that the patient can acquire the information in an adequate and efficient way. The result of these expert-to-layman texts is what Bowler claims by saying that "the professional scientific community remain aloof from the public and rely on science writers to disseminate a simplified report of their research findings." (n.p.). Once again, this means that scientific writers, in our case medical writers, provide simpler texts of experts' findings in order to make it possible that the public have access to it, being the PIL a clear example of this.

2.3. Textual and communicative characteristics of PILs

In this section, we are going to discuss the most relevant textual and communicative characteristics present in PILs. For the textual aspects, we have considered the macro-genre, the genre, and the function of the texts; then for the communicative, we have defined the main communicative situations present in the medical domain, and particularly that of PILs.

In words of García (Traducción de textos especializados 22; my translation), the translator of medical texts has not a doctor's level of expertise, so the translator may be more interested in the textual and communicative aspects rather than the specialized content. We disagree with the author since we think the task of the translator is concerned with both the communicative aspect and the specialized terminology because even if the translator has not the expertise level of the doctor in the medical field –expert– it is necessary for him to have a minimum level of expertise in the same field to understand those medical texts –semi-expert. Unlike other specialized domains, a peculiarity of the medical language, as it is the case of the language of PILs, is that it has characteristics in common not only with LSP, but also with the language for general purposes (LGP).

2.3.1. **Macro-genre: informational and scientific/medical popularization**

We have already seen that the language of PILs is included in the medical field, but different macro-genres can be found in that field depending on the characteristics of those texts and their purpose. PILs are said to belong to an informative macro-genre, but it is necessary to clarify some aspects before going ahead with further explanations.

In words of Álvarez Angulo, "the definition of the informative text often appears alongside qualifications as expository" (15; my translation). Moreover, Álvarez Angulo claims that the concept of information is too general and vague and that informative and expository types are overlapped, making the distinctions between them actually complex. However, according to the English classification of typology of texts, these two types are the ones we find in our PILs: expository and informative types. They are often referred to the same type because they serve to similar purposes: the expository type aims at showing information through clear examples while the informative type not only conveys information in an accurate way, but it is also concerned with the understanding of those texts. As we can see, these types do also overlap in English.

Going back to the macro-genre of PILs, García Izquierdo approaches it in a more scientific and specialized way saying that this type of texts has to be considered as *divulgativo* (Divulgación médica y traducción 35; my translation), a type that provides information about something in an accessible and familiar language, understandable not just by experts, but by

everyone. In English, this term is referred to as informative once again. Álvarez Angulo supports this same idea by asserting that one of the most reliable and representative examples of informative/expository texts is scientific popularization or *divulgación científica* (16; my translation). One example of this is the patient information leaflet text type within the medical domain, the one we have studied in this project. Texts about *divulgación científica* are known in English as popularized science texts. In the same way, Nwogu defines the popularized text in the medical domain as a "rewriting of medical research reports for lay audiences." (113). This means that an expert simplifies the language contained in that scientific domain to make it easier and accessible for everybody.

Furthermore, the proposed definition of *divulgación* perfectly suits the aim of our chosen texts: they give information about various medicines in a familiar and accessible language so that everyone is able to access that information and not only medical specialists such as doctors.

2.3.2. **Genre: Patient Information Leaflet (PIL) or *Prospecto Médico***

The analysis of genre is very important in our dissertation. In this sense, Calvi and Mapelli reported that the concept of genre leads us to go beyond the typical classification – argumentation, description, narration, etc.– because it allows considering texts as a whole instead of something composed of different sections (37). This is the reason why genres are considered as rhetorical structures since texts contain considerable characteristics regarding the arrangement and organization of their elements. In addition, they claim that specialized knowledge is created from the various genres and serves in the task of creating a particular social reality. This means that texts can be classified in more particular ways as the great variety of text typologies demands, and each text typology is concerned with different social situations as it is the case of PILs.

According to Trosborg (6), "texts used in a particular situation for a particular purpose may be classified using everyday labels such as a guidebook, a poem, etc. Such categories are referred to as genres." In this way, García Izquierdo claims that genre is applicable to any communicative situation which results from a particular communicative circumstance and, therefore, any conventionalized text form can be considered as a genre (Traducción de textos especializados 22; my translation). This means that any element related to communication can be analysed from the point of view of genre and any text that follows a series of accepted standards from the point of view of culture can be accepted as a genre; in this regard, we can interpret a PIL as a genre itself. In translation studies, we can find many different fields of

expertise and each of them has particular standards or rules to regulate them, so it would be of great importance to analyse which are those norms that regulate the medical field.

The adapting of any scientific language into a popularize one, as the case of the language of PILs, may lead to difficulties when considering their inclusion in specialized genres and their aim for information –informative texts. Nwogu declares that "there is a tendency for information in most JRV texts to be organized according to an identifying pattern or schema" (120), being the Journalistic Reported Version –JRV– texts examples of popularized journal scientific texts. Even if Nwogu is dealing with journalistic texts, he is still talking about scientific popularization, so the same idea can be found in our PILs and, therefore, in any text included in the scientific popularization type. However, Nwogu claims that this does not mean that all popularized texts follow the same schema since the scope of this scientific field is too broad to restrict it to a single pattern (121). In this regard, our PILs follow the same idea proposed by Nwogu in the sense that PILs' main aim is to inform by following a specific pattern or schema. This pattern is particularly different from that of scientific journalistic texts because the nature of this type of texts is clearly different than that of the PILs. As we can see in the rhetoric analysis section, all PILs, whatever their origin, are structured in the same way to facilitate patients their understanding. In addition, this type of texts has a specific informational objective since PILs "conform to the demands of a 'five-W' beginning" which means that the first sentences of the texts are based on the relative clauses of 'who – what – where- when – and – why' and need to be answered (120).

2.3.3. **Function: functional and informative texts**

We have said that the main objective of the PIL is informing the patient about a medicine. Pander Maat and Lentz state that the main functions are to promote "the health of the population" as well as "educating patients about health problems" in order to make a proper use of medicines (quoted in Bongaart 6). In this way, patients are informed in the sense that they receive an education on how to deal with health issues. Nevertheless, in words of Wright (1999:85, quoted in Divulgación médica y traducción 37), the aim is not only informing the patient and promoting health, but also influencing on his/her decision making, so the way in which the writer informs is essential for this type of texts. In this sense, the writer recommends and makes suggestions to the readers so that they are influenced by the opinion of an expert in the medical field. In this sense, Maes, Ummelen, and Hoeken (quoted in Bongaart 6) assert that patients consult PILs to "weigh up the medicine's pros and cons and decide if the medicine is suitable in their situation". However, García Izquierdo claims that the PIL should always be complementary information and should never replace doctor-

patient communication (Divulgación médica y traducción 38). Thus, patients use the PIL if direct communication with the doctor is not possible or if they need more precise information from the one the doctor has provided to them.

2.3.4. **Communicative situations in the scientific/medical field**

In the LSP domain, the approach applied to the notion of medical language has been adopted from the sociolinguistic point of view instead from the functional one, which would explain that the guiding principle to define this 'scientific English' language is the consideration of the different communicative situations within the medical domain (Trosborg, 159).

In words of Calvi and Mapelli, there are three different types of communicative situation implying the sender and the receiver within the specialized language: the communication between the specialists, in which we can find the highest lexical density in specialized texts; the transmission of knowledge from experts to semi-experts or training experts; and the dissemination, characterised by a low-density vocabulary and highly related to LGP (37). The characteristics regarding the communicative aspects we want to consider can be seen through the communicative situations of the medical field affecting its language.

Medical language is often categorized as the expert-to-expert communicative situation, being this the reason why it can be considered as a specialized language. The genre of PIL implies the necessity of adapting the medical language to a form in which laymen are able to understand it, and the result is a non-systematic, subjective language rather than the systematicity and objectivity of the authentic medical language, which leads to actual variations in the production and interpretation of LSP.

2.3.5. **Communicative situations in the medical field/PILs genre**

As we have discussed, our PILs are included in the macro-genre of popularization or dissemination because they are written by medical experts, but they are presented in a familiar language so that everyone can understand them. In this way, the contents are supposed to be explained by means of definitions, reformulations, or paraphrasis oriented to the audience according to its level of expertise, which is that of laymen in our case.

As we have seen before, we can find a clear hierarchy in the analysis of the different communicative situations applied to the writing of PILs. In the highest position, we find the medical doctors, who are the experts in the medical communicative situation. They propose the theories or findings which have been later disseminated to the readers. In the second rank,

we find the scientific writers, or medical writers in our case. They are intermediaries between the medical doctors and the audience responsible for adapting the formal, expert register into a more informal, non-expert register so that it is accessible for the public audience. At the lower rank, we find the readers or patients. They are the lay public who seek information to cure a disease.

However, the reality may be far from this because there are situations where the pharmaceutical experts are the ones who write the PILs, mainly to save costs. Groenewoud talks in his work about different non-specialized genres of the medical domain, including the PIL. He claims that "the authors who write them [the PILs and other non-specialized genres] […] are generally the same specialists who work for pharmaceutical companies. It seems that institutions do not hire external staff to write the texts." (23; my translation). Let us remember that, even if the pharmaceutical industry is concerned with people's health, it is still a profit-oriented industry. This may be one of the reasons why PILs contain highly technical expressions that even people that have received an average education may not understand. Even if medical doctors are experts in developing a specialized medical language, they may not be skilled in transmitting those concepts in a simpler or *popularized* language. Those ideas may explain the lack of legibility that Calvi and Mapelli show because PILs seem more likely to be aimed at an expert audience rather than a lay audience due to their complexity (35).

2.4. Structural, linguistic and translation features relevant for the analysis

In this section, we have included information necessary for understanding some aspects relevant in the analysis section.

2.4.1. Rhetorical features: superstructure and macrostructure.

A rhetorical analysis aims at deconstructing a text in different parts to get information about the main ideas included in it regarding the author and the text itself. There are two textual characteristics to consider in a rhetorical analysis: cohesion and coherence. The idea of cohesion is very important in the rhetorical section because the ideas included in our PILs, i.e. cohesion, help us identify the different parts of the text. Moreover, this idea goes hand in hand with that of coherence because it is necessary to understand the ideas implicit in those texts.

The classification and analysis of the different sections of a text are carried out by the two following structures: the **superstructure and macrostructure**. In words of Van Dijk (1977, 1978, 1980; quoted in Macroestructura Textual; my translation), "the superstructure

represents the way information is organized in the text, i.e. the formal structure of a text", while the macrostructure can be defined as "the semantic structure of the text as a whole". The medical field, among others, is characterised by basic structural models for each text type, as the case of PILs. On the one hand, the superstructure of the PILs can be defined as the order of, and the relationships between, the constituent parts of the PILs. On the other hand, the macrostructure deals with the ideas present in texts that help to transmit its content. Along these lines, the macrostructure is the subject matter of PILs, that is the semantic approach applied to them. It provides information about PILs' usefulness and other features of the medicines regarding their meaning.

While the superstructure is concerned with cohesion, the macrostructure has to do with coherence. The principle of coherence is to establish a logical relationship between two or more different ideas so that they do not contradict each other. The structuring of texts such as the ones we have analysed is not likely to cause problems regarding the issue of coherence.

2.4.2. Linguistic features: syntactic and semantic types of sentences

Regarding the **syntactic section**, we can find different types of sentences. Arroyo asserts that there is a distinction between *oraciones compuestas coordinadas* and *oraciones compuestas subordinadas* in Spanish. The first ones include *oraciones copulativas, disyuntivas, distributivas, adversativas, explicativas*, while the second ones contain *oraciones sustantivas, adjetivas, and adverbiales*, and within the *oraciones adverbiales*, we can find *oraciones adverbiales propias de lugar, tiempo y modo, causales, finales, concesivas, consecutivas, comparativas, y condicionales* (54-55; my translation). The classification of the English sentences is very similar to the Spanish one. The English equivalent of the *oración coordinada* is the compound sentence –two independent clauses– which includes the same sub-classification that in Spanish, i.e. copulative, disjunctive, distributive, adversative, and explicative sentences, while the *oración subordinada* would be called complex sentence in English –one independent clause along with one or more embedded subordinate clauses. In general, there are several types of complex clauses which occur in a similar way as the Spanish classification: nominal clause, adjectival clause, and the adverbial clause. The adverbial clause includes the following types: causal –because–, comparative –such as–, concessive –although–, conditional –if–, consecutive –so–, purpose –to, in order to, for–, result –so…that–, and place –where–, manner –as–, and time –after/before, when.

Regarding the **semantic section**, Lynn states that we can find four types of sentences in English according to their meaning: the declarative sentence, which is used to "make

statements", the imperative sentence, which "makes demands or requests", the exclamatory sentence, which is concerned with "making important or excited statements", and the interrogative, which "asks questions" (37). On the other hand, Arroyo asserts that there are six types of simple sentences in Spanish to which Rabuñal proposes a translation (52-53; my translation). In words of Rabuñal, we can find the statement sentence which refers to the English declarative sentence, the imperative sentence, the exclamatory, and the interrogative. We can find two more types that do not appear in the English classification: the desiderative sentence, which expresses the speaker's wish, and the doubt sentence, which expresses the speaker's doubt. (n.p.)

2.4.3. Translation features: borrowings

We can comment about the origins of **borrowings** in English, which are very common in the medical domain. In this way, Répás states that "although medical terms have been drawn from many languages, a large majority are from Greek and Latin". In addition, he asserts that "terms of Greek origin occur mainly in clinical terminology, while Latin terms make up the majority of anatomical terminology" (5). In Spanish, they are more typical because this language derives from Latin, but English does not. What many people do not know is that "Greek medicine migrated to Rome at an early date, and many Latin terms crept into its terminology", as Répás claims (5), so the importance of Latin in the medical domain is because of Greek influence. Conversely, English comes primarily from the Germanic languages. Nevertheless, there is an important trace of Latin when England was under the Roman empire. In words of Répás (5), "Latin was the language of science up to the beginning of the 18th century". For this reason, the use of Latin words in English is typical of texts with a specialized language such as the medical language.

3. METHODOLOGY

3.1. Aim of the study and types of analysis

Due to the minor importance given to the PIL from a research point of view and the great relevance of this type of texts in terms of health information, we have carried out an empirical analysis in order to establish the characteristics of the new genre of PILs, to discover if our texts have been translated, and to know if the popularity of a medicine is inversely proportional to the likelihood that it is a translation. Our study is composed of three types of analysis: the rhetoric, the linguistic, and the translation ones. The rhetoric analysis is focused on how this particular type of texts is structured and the ideas it contains; the linguistic analysis is centred on the grammatical, syntactic, and semantic features of the PIL as a genre and equivalents in

Spanish and English; and the translation analysis aims at showing the frequency of words of relevant terms and their equivalents as well as the most common translation procedures. Each analysis has been explained at the beginning of their respective section.

3.2. Corpora: types and characteristics

According to the typology and selection of the corpora, we have compiled two monolingual corpora in electronic format (pdf files), one in Spanish and another in English that have helped us to carry out the analysis. They can be considered comparable and parallel: comparable because each corpus may have been made of independent texts in each language, and parallel because we have presumed the English PILs have been translated from the Spanish ones, so they may be dependent since the Spanish PILs have been all developed by *Kern Pharma*.

It is important to mention that the corpora tools have not been used for all the analysis. The use of these tools only allows the formal analysis, which refers to how the genre is applied from the verbal point of view, excluding the rhetoric section. In the rhetoric analysis, texts have been analysed manually, that is to say, we have analysed them one by one without the aid of a corpus tool. For the linguistic analysis, we have considered the corpora as comparable as they are analysed independently. In the translation analysis, we considered them as parallel since we have presumed that the Spanish texts have been translated into English. Finally, the Spanish and English texts have been compared and commented in all the analyses.

3.2.1. PILs for different medicines: types and sources

To compile the corpora, we have chosen ten different medicines together with their corresponding PILs, all of them serving to a different purpose, except for the first two medicines which we particularly selected due to their popularity (*Paracetamol* and *Ibuprofen*). In this way, the selected texts refer to the following medicines[3]:

- Analgesic and antipyretic: *Paracetamol e Ibuprofen (Ibuprofeno)*
- Antacid and antiulcerous: *Omeprazole (Omeprazol)*
- Antibiotic: *Amoxicillin (Amoxicilina)*
- Antitussive and mucolytic: *Acetylcysteine (Acetilcisteína)*

[3] Due to the difficulty of getting a hard copy of the selected PILs, we opted for getting them from trustworthy and updated websites developed by the governments of the respective countries: the United Kingdom and Spain. For further information, both websites can be found at the end of this project –see websites in the appendix.

- Anxiolytic and anticonvulsant: *Diazepam (Diazepan)*
- Antiviral: *Aciclovir*
- Anti-inflammatory and nonsteroidal anti-rheumatic: *Glucosamine (Glucosamina)*
- Treatment of Alzheimer's disease: *Memantine (Memantina)*
- Antihypertensive: *Valsartan (Valsartán)*

3.3. Corpora tools

As we mentioned before, the rhetorical analysis has been done manually on the texts since corpora tools were not useful. For this purpose, the linguistic and translation analyses have been done manually and on the basis of two different tools: *TermoStat* and *AntConc*. These corpus tools have organized our texts' data and given us information not only concerning grammatical, syntactic, and semantic features of the terms –concordancing software: frequency of words, collocations, syntactic patterns, etc., relevant for the linguistic analysis, but also about translation aspects such as the analysis of translation procedures to identify transpositions, omissions, additions, and borrowings, among others.

Each tool has been used for different purposes. *TermoStat* has been used to identify the most used words and their frequency –grammatical analysis– since this tool only shows lexical words. It has also been used to look for equivalents in the other language for the most frequent lexical words –Spanish/English–, and to show some contexts of use –see Image 1: word *compensar*, p. 28. Meanwhile, *AntConc* has been used to extract examples of use of verb tenses, sentence types –syntax and semantics– examples of the different translation procedures, and to look for contexts of use to validate the sense of a word in the account of the frequency of equivalents in Spanish and English. Finally, the types of verb tenses and sentence types along with their frequency –syntax and semantic levels– and the semantic fields have been analysed manually.

4. EMPIRICAL ANALYSIS AND RESULTS

4.1. Rhetorical analysis

4.1.1. Superstructure and macrostructure

As we have seen before, there are two ideas to consider in this section: the superstructure and the macrostructure. First, we can consider the superstructure, which is referred to as the

arrangement of the information of a text and from which we can see different patterns depending on the text type.

In this way, we have considered the pattern of the PIL. In Europe, the patterns of PILs are regulated by the European Commission through the European legal framework –Community Directive– in the section of *Public Health (Medicinal Products): Information to Patients - Legislative Approach*. Hence, the structure of PILs may be similar if not the same in Spain and Great Britain because both countries belong to the European Commission. European Commission's aim is to promote access to information on medicines of the highest possible quality. The superstructure of PILs can be seen in Table 1:

Table 1. Superstructure of PILs in Spanish and English[4]. Source: my creation[5]

SPANISH	ENGLISH
1. Qué es X y para qué se utiliza	1. What X is/are and what it/they is/are used for
2. Qué necesita saber antes de empezar a tomar X	2. What you need to know before you take X
3. Cómo tomar X	3. How to take X
4. Posibles efectos adversos	4. Possible side effects
5. Conservación de X	5. How to store X
6. (Contenido del envase) e información adicional	6. Contents of the pack and other information/Further information

As we have said before, the sections we find in the PILs are the same in Spanish and English. This superstructure always follows the specific order indicated Table 1, which helps demonstrate cohesion all throughout the text. Cohesion is usually created by the use of discursive markers which organize the text in different sections and the ideas included in each one, but we have seen that PILs are characterised by an absence of discursive markers. Cohesion in PILs has been created not by the use of particular linguistic units, but by typographical elements and the structure itself: paragraphs, number schemes, bold type,

[4] The information that is contained in round brackets appears only in some of the PILs as well as that which occurs after the forward slash.
[5] All tables included in the present project have been created and written by me.

capital letters, indexation, etc. Furthermore, this type of cohesion provides readers with the information they need, so that it is easier for them as they have not to read the whole PIL.

Second, we can comment on the macrostructure we find in our PILs. It refers to the ideas contained in the PILs. In this sense, we should now consider the information contained in each section of a PIL. The title of each section briefly describes its content. In the first section, named *Qué es X y para qué se utiliza* in Spanish, and *What X is/are and what it/they is/are used for* in English, we can find data about a particular medicine and its purpose, primarily in a simple language.

The second section, called *Qué necesita saber antes de empezar a tomar X* in Spanish, and *What you need to know before you take X* in English, is concerned with some indications and precautions that patients should follow, especially if they have any allergies, suffer from a particular disease, or are taking any medicine. Patients are warned particularly in this section in order to avoid any possible thing that endangers their health.

The third section, named *Cómo tomar X* in Spanish, and *How to take X* in English, focuses on the dosage of a medicine for each patient, which changes depending on the age of that patient, or on particular conditions such as an illness. The time of dosage taking is also specified, that is how a medicine should be distributed on a day and the alternatives if you forget to take a dose. This is one of the sections that includes the most redundancy, which can be seen in detail in the semantic section.

The fourth section, called *Posibles efectos adversos* in Spanish, and *Possible side effects* in English, deals with the possible side effects that the patient may suffer and their level of frequency. Moreover, in each package leaflet, the contact information of an institution dedicated to dealing with matters of pharmacological nature is mentioned in case of reporting new side effects in order to make the information as accurate as possible.

The fifth section, named *Conservación de X* in Spanish, and *How to store X* in English, concerns the conservation of the medicine, which may or may not require special storage conditions. This section is the most similar one in all the PILs since the recommendations included are recurrent in all of them, that is they appear in the same way. Some of these examples are *Mantener fuera del alcance y de la vista de los niños* and *Keep this medicine out of the sight and reach of children*; or *Do not use this medicine after the expiry date* and *No utilice este medicamento después de la fecha de caducidad*.

Finally, the last section, called *(Contenido del envase) e información adicional* in Spanish, and *Contents of the pack and other information/Further information* in English, includes data

about the ingredients –active substances and excipients–, physical appearance –e.g. colour and shape–, contents –e.g. size and number of tablets in each pack– of the medicine, and sometimes, about the flavour of the medicine if it is taken orally. Moreover, we can see information about the laboratories that are responsible for manufacturing and marketing of the medical products, sometimes two different companies. Moreover, this section provides information about the pharmaceutical laboratories responsible for the production and commercialisation of each of the medicines. This information may help us to know if our PILs are translations or not.

4.1.2. Relevance of the sixth section

In this regard, we thought that laboratories included in the sixth section would provide us with a hint to know if the texts have been translated or not. First, we have observed that most of the PILs have been developed by different laboratories, except for *Omeprazole*, *Memantine*, and Glucosamine. Even if all the Spanish PILs have been commercialised by the Spanish laboratory *Kern Pharma*, the manufacturing laboratory may have been a different one. In this sense, *Omeprazole* has been manufactured by the same laboratory in the case of the Spanish and English PILs, which is the Spanish Laboratorios Dr. Esteve S.A., located in Barcelona. By observing these two PILs, they are structured in exactly the same way and containing each idea in the same place, something unusual for PILs that have not been translated.

Second, there are some peculiarities that we can comment about *Memantine* PILs. The Spanish version has been developed and commercialised by *Kern Pharma*, but the English PIL has been manufactured in Malta and commercialised by an Irish company. The point is that the structure of both PILs is very similar, almost the same, but it is unlikely that the texts are translations. However, we tend to think that the Spanish version has been translated from English since we have identified some calques and literal translation, e.g. *su médico puede tener que ajustar la dosis del medicamento* instead of *es posible que su médico le ajuste la dosis del medicamento*, or *respiración difícil* instead of *dificultad para respirar*. Finally, Glucosamine PILs are not likely to be translations. Even though the English PIL manufacturer is from Spain, Alcala Farma S.L., it is different from the Spanish PIL manufacturer, which is *Kern Pharma*. Moreover, the language and structure of each PIL of Glucosamine are completely different. For instance, the sentences from the English PIL are much shorter than those from the Spanish PIL; what is more, we find informational contradictions from one PIL to the other: *This medicinal product does not require any special temperature storage conditions* in English, while in Spanish it says *Conservar por debajo de 25ºC.*

To conclude, our PILs follow a clear and organized pattern –cohesion– so the ideas included in them are properly brought together and, therefore, we find an evident coherence in our texts. However, we find some inconsistencies when comparing the English and Spanish PILs, e.g. contradictions.

4.2. Linguistic analysis

In this section, we have analysed particular characteristics regarding the language of our PILs. In this way, this section is dedicated to analysing the characteristics of PILs to formalize these texts as a genre, that is, to consider the Patient Information Leaflet as a genre itself. For this aim, we have considered three main aspects in the PILs: grammar, semantics, and syntax. Moreover, we have presented the analysis together with the results.

Along these lines, we have discussed the different **grammatical** categories or POS making up the texts, specifically nouns, verbs, and adjectives –because they are the ones that have meaning by themselves– and their frequency of use throughout the texts. To carry out this task, we have needed the compiled corpora, so as to make comparisons between the two languages.

For the **syntactic** analysis, we have considered the main structures of the sentences in both languages and some syntactic elements such as the analysis of verb tenses, types of sentences –coordination or subordination–, and their frequency in order to establish a comparison between these features in regard to the Spanish and English PILs. Furthermore, we have used the compiled corpora and two corpora subtypes: the comparable and the parallel ones. As stated before, in this linguistic analysis, we have focused on the interpretation of corpora as comparable in order to observe the characteristics of the texts in Spanish and English as independent texts instead of translated texts.

Finally, in the **semantic** analysis, we have focused on sentence semantics, particularly the category of modality, and some words, particularly those related to the LSP, that is those specific of a medical domain. Thus, the different semantic fields have been investigated. Moreover, we have investigated the presence of ambiguity and redundancy, which are often related, and the consequences these may bring.

4.2.1. **Grammar**

As we have mentioned before, we have analysed nouns, verbs, and adjectives contained in the PILs selected because they are the ones that convey information, that is to say, words that have meaning by themselves. In table 2, we can see the most used verbs of our Spanish and English PILs:

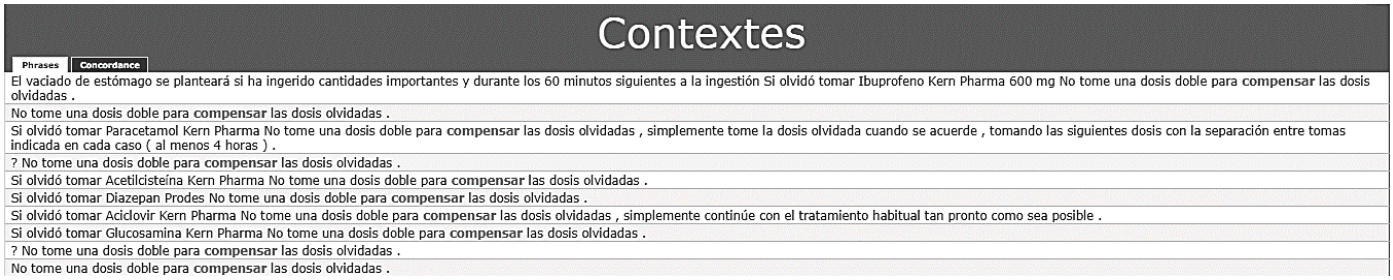
Table 2. Spanish and English most frequently used verbs. Source: *TermoStat*.

	SPANISH	ENGLISH
	Poder (273)	Take (344)
	Tomar (195)	Use (131)
TERMS	Consultar (82)	Do (85)
	Prospectar (79)	Tell (66)
	Envasar (75)	Treat (63)
	Total: 704	Total: 689

As we can see in Table 2, the total count of verbs differs from Spanish and English, but this difference is not very significant –704 verbs in Spanish, and 689 verbs in English. This can be seen by comparing the Spanish and English results. The variety of verbs in Spanish is higher than in English and this is why the frequency of each verb is lower. The contrary occurs in English because there is a fewer variety of verbs, thus their frequency is higher. This supports the idea that English verbs tend to be polysemic, while the Spanish are not likely to, which means that an English verb contained in the PILs has several equivalents in the Spanish patient leaflets.

By looking at the frequency of some verbs, we realised that some of them appear only 10 times in the whole corpus, which coincides with the number of medicines we have. This may mean that some verbs have been used once in each of the Spanish/English PILs. In this case, we need to remember that the corpora work independently, so we have found ten results in the Spanish corpus, and other ten results in the English one. In addition, this gives us a relevant cue for the rhetoric structure analysis because it may mean that there is a given structure that is repeated in each of the PILs. This is the case of the Spanish verb *compensar*. Its context reveals it is a word that appears once in each of the leaflets and is contained in the same section in all the cases, that is in the Spanish PILs –section 3: *Cómo tomar X*. The contexts of the verb *compensar* can be seen in Image 1:

Image 1. Contexts of the word *compensar*. Source: *TermoStat*.



Considering now the grammatical category of nouns, we can see the most used nouns of our Spanish and English PILs in table 3:

Table 3. Spanish and English most frequently used nouns. Source: *TermoStat*.

	SPANISH	ENGLISH
	Medicamento (323)	Medicine (223)
	Pharma (257; ignored)	Ø
TERMS	Médico (228)	Doctor (214)
	Dosis (145)	Tablet (160)
	Efecto (134)	Side (157)
	Tratamiento (130)	Effect (153)
	Total: 960	Total: 907

If we take a look at Table 3, we cannot see huge differences in terms of frequency of the most frequently used nouns contained in the PILs –960 nouns in Spanish, and 907 in English. The Spanish superiority regarding the frequency of nouns may occur because these substantives appear rather as verbs instead of nouns in the English texts.

The Spanish LSP contained in this type of texts is generally characterised by an important use of nouns, while in English, we find more verbs. When translating from English into Spanish, the English verbs become nouns by a process called nominalization. When looking at the equivalents of some of the most used nouns, there is a considerable difference in terms of frequency of the results, as we can see with words such as *tratamiento* (130) and *treatment* (35). The same occurs with other terms such as *administración* (22) and *administration* (1), *duración* (11), *duration* (2), etc. Nevertheless, we have identified many nominalizations in both languages as well as a high number of nouns in both cases. This may support the notion that the English texts have been translated from Spanish. However, the discussion about nominalization can be seen in the translation analysis.

Finally, we are focused on the last table within this grammatical analysis in which we can see the most used adjectives of our Spanish and English PILs:

Table 4: Spanish and English most frequently used adjectives. Source: *TermoStat*.

	SPANISH	ENGLISH
	Posible (52)	Severe (35)
	Grave (49)	Allergic (32)
TERMS	Frecuente (37)	High (26)
	Raro (35)	Pregnant (25)
	Siguiente (30)	Usual (24)
	Total: 203	Total: 142

In Table 4, we can note that the English adjectives are not as frequent as the Spanish ones and tend to collocate with the same word(s), as in the case of *usual*, whose context reveals that it is mostly used preceding the noun *dose*. Moreover, the English adjectives are less varied: according to *TermoStat*, we have 145 different adjectives in Spanish –9% of the whole Spanish corpus–, and 71 different adjectives in English –6% of the whole English corpus.

Unlike English adjectives, the Spanish ones are both more numerous and occur more frequently in the texts. In the same way as with the English adjectives, we can see that the Spanish ones tend to collocate with given constructions such as *posible*, which collocates with the verb *es* resulting in the construction *es posible que*, or it is included in the NP *efectos adversos*, resulting in *posibles efectos adversos*. By observing these results, we can state that their frequency is twice that of the English adjectives, which is reflected in longer texts in Spanish than in English. The difference of frequency in adjectives may be caused by the different grammatical categories that are used in each of the languages. In this way, while the Spanish PILs use adjectives, the pre-modification of English nouns is mainly done by the past participle and -ing constructions, which are actually interpreted as verbs. These two verbal constructions tend to appear only once or twice in the PILs, so that is the reason why their frequency is particularly low: *existing factors*, *spinning feeling, lacking energy, breathing difficulties, increased risk, blocked artery, film coated tablet, delayed serious liver damage,* etc. Although there is a great variety of these, they cannot be considered as adjectives, which explains the low presence of English adjectives in the PILs.

4.2.2. **Syntax**

The following section of this linguistic analysis is focused on the analysis of some syntactic elements: the principal verb tenses and types of sentences –according to syntax–,

and their frequency in the selected PILs. This aspect has been crucial for us in the translation analysis section to confirm or reject that the English texts are actual translations.

With reference to **verb tenses in Spanish**, we have identified nine tenses in our corpus: periphrastic verb forms, present simple –indicative mood–, present simple –subjunctive mood–, present simple –imperative mood–, impersonal constructions, passive verbs, preterit perfect, non-inflected forms –infinitive, gerund, and participle–, and the future imperfect[6].

It is relevant to define and comment on some of the Spanish tenses that appear in the PILs since they differ significantly from those from the English texts. First, the periphrastic verb form does not exist in English. It usually consists in a structure of two –or three– verbs in which the first one is inflected, while the second one –or the remaining ones– is non-inflected, particularly in infinitive form or included in a clause with the relative *que*. The last verb of this structure is the one which carries the meaning, e.g. *debe tomar*, or *tener que mantener*. Unlike the English language, the Spanish grammar differentiates between simple and compound tenses. A simple tense consists in one verb taking the appropriate inflections of its tense, while the compound tense consists in the inflected verb *haber* followed by another verb in the participle form which carries the meaning. In this way, the preterit perfect is the compound designation for the past form of verbs which indicates an action that has already finished, e.g. *ha sufrido*. Finally, the future imperfect refers to the simple tense designation for the future tense.

Even if some tenses do not exist in the other language, we can find clear differences when comparing the verb tenses included in the PILs between the two languages. For this reason, we have identified seven main **English verb tenses** in that corpus: modal verbs, passive verbs[7], present simple –indicative mood–, present simple –imperative mood–, non-inflected forms, present perfect, and future.

Thus, each tense has its equivalent in the other language in these texts: the periphrastic verb forms refer to the modal verbs in English, the passive is often translated as impersonal constructions and sometimes as passive verbs in Spanish, and the future tense is expressed in Spanish as the future imperfect. The English equivalent for the preterit perfect is the present perfect, while the Spanish non-inflected verb forms –infinitive, gerund, and participle– are referred in English with the same name, but including the infinitive, -ing forms, and the past

[6] The designation of the Spanish verb tenses is taken from the Spanish verbal system contained in the *Gramática de la Lengua española* (RAE), quoted in Rallides (11-12).

[7] We know that the passive voice is not a tense but a grammatical voice, as it is the case with other structures such as the periphrastic verb forms, which are not tenses as such. Nevertheless, we decided to include them in the section of tenses in order to simplify the presentation of information in the analysis.

participle constructions, respectively. We can also find few instances of the present continuous in English, whose Spanish equivalent is the present progressive. The most commonly used verbs of this tense are the following: *are suffering*, *are taking*, and *are planning* in English, and *está tomando* or *está utilizando* in the case of Spanish.

Regarding the modality of verbs, the present tense has been found in the three moods in Spanish: indicative, subjunctive, and imperative, while in English we have only found the indicative and imperative moods. As the subjunctive mood is extremely rare in English, we have not found it in the English PILs. For this reason, we have identified the indicative mood as the English equivalent for the Spanish subjunctive mood.

Let's analyse now the most frequently used verb tenses in each language. Table 5 contain information about the different verb tenses discussed above along with different examples of each tense. To this end, we have selected only the most representative examples for each tense. Moreover, each Spanish tense is aligned with its English equivalent.

Table 5: Spanish and English verb tenses with examples. Source: *AntConc* and my creation.

Impersonal constructions	***Se utiliza, se recomienda, se trata, se deben***		
Passive verbs	*Ser afectado por, está provocada por, están formadas por, es absorbido por*	Passive verbs	*Are used to, is described, is based on, may be associated, can be increased, should be avoided, has been prescribed*
Non-inflected verb forms	Infinitivo: *mantener, conservar, utilizar, tratar* Gerundio: *incluyendo, provocando, causando* Participio: *incluido/a, utilizado/a, producido/a, denominado/a*	Non-inflected verb forms	Infinitive: *to take, to treat, to store, to know* Past Participle: *used, called* -ing forms: *taking, including, causing, feeling*
Future imperfect	*Indicará, decidirá, dependerá, informará*	Future tense	*Will help, will decide, will advise*
Periphrastic verb forms	*Puede producir, puede tener que, puede perjudicar, debe dar, debe tomar, contribuir a proporcionar, tener que volver, sospecha estar, tendrá que mantener*	Modal verbs	*May cause; may be; may need; can be; can cause; can help; should be; should check*
Present simple (imperative mood)	*Consulte, utilice, suspenda, pregunte, tome*	Present simple (imperative mood)	*Keep, talk, ask, seek, stop, drink, put, use*
Present simple (indicative mood)	*Indica, pertenece, sirve, afecta, altera, produce*	Present simple (indicative mood)	*Are, get, include, belong to, relieve, suffer from, have, see, contain, start*
Present simple (subjunctive mood)	*Necesite, presente, experimente*		
Preterit perfect	*Ha sufrido, ha tomado, ha indicado, ha utilizado, ha ingerido*	Present perfect	*Have had, have taken, have forgotten*

At a glance, we have seen that the most used tense in Spanish is the periphrastic verb form, while in English it is the modal verb. However, it is important to mention that some of the results are deceiving because if we do not look at the whole context, we cannot properly identify the actual tense of the results provided by *AntConc*. This is the case of the modal verbs *may, can,* and *must,* which collocate with the verb *to be* resulting in *may be, can be,* and *must be*. When looking at the context of those constructions, we realised that they are in fact instances of passive constructions: *may be associated, may be considered, can be increased, can be divided*, *should be swallowed,* and *should be avoided*.

We are dealing with texts full of complex structures like the ones we have just mentioned, which make the text very dense and not only in English, but also in Spanish. In this way, we can find many diverse examples of the periphrastic verb form as it is the most repeated Spanish tense. In our corpus, this Spanish tense is used in such a variety of ways that we cannot cover all the different types included in the texts; for that reason, we have selected the most common ones: *puede producir, puede tener que, puede perjudicar, debe dar, debe tomar, contribuir a proporcionar, tener que volver*, etc. Furthermore, we can also observe even more complex constructions such as *contribuir a proporcionar*. As we have said before, this tense represents the Spanish equivalent for the modal verb since they cover a similar structure and meaning as far as both tenses express modality such as possibility, necessity, or obligation: e.g. *puede producir,* and its English equivalent *may cause.* These constructions lead to a dense, heavy language that complicates the legibility of the PIL, thus provoking a lack of interest in the reader. Another verb construction that is characteristic of the English PILs is the passive verb. Even if it is not commonly used in Spanish, we can find some instances of it in our corpus, e.g. *ser afectado por*, *está provocada por, es absorbido por,* or *están formadas por*.

Analysing the PILs, it is very difficult that the two Spanish and English PILs of the same medicine contain identical information. One of the reasons may be the language style, which changes depending on the laboratory in charge of developing the medicine and, consequently, the medical doctor responsible for writing the PIL. Nevertheless, by considering these results, we reached the conclusion that there are certain sections that contain exactly the same information in the Spanish and English PILs, as we have seen in the rhetoric analysis, even in those PILs that have been demonstrated as not being translations from the other language involved. Just as in passive constructions, the presence of verb tenses/constructions that are not commonly used in a particular language occurs especially in given sections of the PIL which are likely to be translated from other languages. This is why the presence of passive verbs makes us think that the Spanish PILs are translated from English, contrary to what we

hypothesised at the beginning when we said that the English PILs were translated from Spanish. Moreover, this may be caused by the use of the specialized language, particularly the medical language, which is more likely to be literally translated. This is done to maintain the passive construction, or any other tense, even if they are not as commonly used in Spanish.

To illustrate this, we can mention the first structure that appears at the beginning of the fourth section called *Possible side effects* or *Posibles efectos adversos.* The English sentence at issue is the following: *Like all medicines, this medicine can cause side effects, although not everybody gets them*. This structure appears in the same position and contains exactly the same information in all the English PILs, as well as in the Spanish ones with the sentence *Al igual que todos los medicamentos, este medicamento/X puede producir efectos adversos, aunque no todas las personas los sufran*.

Passive verbs have another equivalent form in Spanish, which appears more frequently than the Spanish passive verb: the impersonal construction, e.g. *se utiliza, se recomienda, se trata, se deben*, etc. In addition, we can also find even more complex constructions such as *se ha observado,* which is a tense that combines the Spanish impersonal construction and the preterit perfect. This combination of verb tenses proves once more the complexity of the language contained in these PILs.

Similarly, another typical tense that appears in both languages is the present simple in imperative mood: *keep, talk, ask, seek, stop* in English, and *consulte, utilice, suspenda, pregunte, tome* in Spanish.

In words of Mercado (n.p.; my translation), the PIL's issuer is a health professional, while the directors of the laboratory where the medicines are manufactured are responsible for the information written on the package leaflets. The recipient is the patient to whom the medication is prescribed. This means that the information contained in the PIL is arranged by the laboratory directors, but the actual intermediary is the health professional. In this way, the act of communication through the PIL can be considered as a way in which a health professional or medical doctor orders, requests, or asks the patient to do a particular action. However, we can clearly see that s/he is rather giving orders than asking or advising the patient to act in a specific way, which can be seen by looking at the examples of the present simple tense in imperative mood. This attitude that the health professional adopts by using the imperative mood creates an authoritative perspective of the language included in the texts, which may be negative for the patient since s/he is already in a weak position. Nevertheless, this language is softened at some point through the use of modal verbs and periphrastic verb

forms, which we have already mentioned. To illustrate this, we propose the following example:

Table 6: Example of the use of language in PILs. Source: *AntConc*

Exhortative language (present simple: imperative mood)	*Do not stop taking your medicine without talking to your doctor first even if you feel better. / No deje de tomar el medicamento a menos que se lo indique su médico.*
Softened language (modal verb/impersonal construction)	*If you notice any changes* […] *you should stop taking these tablets immediately. / Si aparecen estos síntomas, se recomienda interrumpir el tratamiento y acudir al médico.*

In the first example of Table 6, we can see the medical professional's attitude towards the patient in which s/he seems to obligate the patient to not stop taking the medicine in both English and Spanish. In the second case, we present an example in which the medical professional is rather advising the patient to stop taking the medicine. In this sense, we consider the second example to be the most appropriate way of addressing patients since they do not feel the authoritative phrasing of the professional and avoid the negative impact that the imperative mood of verbs may evoke, as we mentioned above. However, this negative impact is reduced in the first Spanish example due to the level of formality when addressing the patient: *No deje de tomar*.

Finally, the last tense that we consider as characteristic of the language of PILs is the use of the Spanish present simple tense in subjunctive mood, whose equivalent in English is the present simple in indicative mood: *necesite, presente, experimente.* The first thing we appreciate from the use of this tense is the high level of formality of the Spanish texts since the reader is addressed in a formal, obsolete way. In addition, this way of addressing patients has an effect of keeping a distance with them, which may make the reader feel uncomfortable.

Not only verb tenses help us identify whether the texts are translations or not, but also the other syntactic elements provide relevant information about this. We have found that PILs contain complex constructions at a verb level, and the same applies to the structure and typology of the sentences. In this sense, we can establish the analysis of sentences at two levels, semantic and syntactic.

First, the semantic level of sentences has been analysed in the following semantic section. Second, we have focused on the types of sentences according to syntax for the syntactic level of sentences, which is how sentences are constructed following particular syntactic patterns.

As we have said before, there are several types of sentences in English and in Spanish and we have maintained the Spanish names because they are very similar to the English ones.

In Table 7, our results have been displayed together with an example taken from the PILs in both English and Spanish, and then we have commented on them:

Table 7: Comparison of Spanish and English syntactic sentence types[8]. Source: *AntConc* and my creation.

	Spanish		**English**
O. Coordinada Copulativa	*Interrumpa el tratamiento y acuda de inmediato a su médico*	**Copulative Coordinate clause**	*What Ibuprofen Tablets are and what they are used for*
O. Coordinada Adversativa	*Sirve para fraccionar y facilitar la deglución pero no para dividir…*	**Adversative Coordinate Clause**	*The medicine is …, but within the leaflet it will be referred as Valsartan Tablets*
O. C. Disyuntiva	*Si tiene más de 60 años o necesita tomar el medicamento de forma prolongada*	**Disjunctive C. C.**	*… a lot of the tablets all together, or if you think a child has swallowed…*
O. Subordinada sustantiva	*Es posible que se produzcan reacciones alérgicas*	**Nominal subordinate clause**	*It is possible that the levels of magnesium…*
O. Subordinada adjetiva	*Infecciones causadas por bacterias en distintas partes del cuerpo*	**Adjectival subordinate clause**	*A drug used to lower cholesterol*
O. Subordinada adverbial propia	*Qué necesita saber antes de empezar a tomar Omeprazol*	**Time and place adverbial s.c.**	*… shortness of breath when exercising or lying flat*
O. Subordinada adverbial causal	*No suspenda el tratamiento antes, ya que entonces no se obtendrían los resultados*	**Causal adverbial s.c.**	*Your doctor has prescribed Amoxicillin capsules because it can treat a wide range of…*
O. S. A. Consecutiva	*… cantidades de Paracetamol en la leche maternal, por lo tanto, se recomienda…*	**Consecutive adverbial s.c.**	*It may occasionally interfere with other medicines, so it is important that…*
O. S. A. Final	*… más tiempo del necesario para controlar sus síntomas*	**Final adverbial s.c.**	*Do not take a double dose to make up for a forgotten dose*
O. S. A. Concesiva	*Debe ser tenido en cuenta por su médico, aunque no sea necesario…*	**Concessive a.s.c.**	*Aciclovir can cause side effects, although not everybody gets them*
O. S. A. Condicional	*Swetiene alguna duda, consulte a su médico*	**Conditional a.s.c.**	*Do not take it if you have a peptic ulcer*

[8] We decided to maintain the Spanish naming for the types of sentences because it is very similar to that of English and does not pose any problem regarding their meaning.

In Table 7, we can see equivalents in both languages between the syntactic sentence types. We can establish differences according to the frequency of use of each syntactic type in its respective language. The Spanish most used one is the *oración subordinada adverbial condicional* as well as in English –the conditional adverbial subordinate clause. This may be explained because our PILs are full of conditional situations in which the patient may be or may not be included, e.g. *if s/he suffers from a particular illness.* The most-used second type is the *oración subordinada adjetiva*, which also coincides with the English adjectival subordinate clause, being the most frequently used type that of the past participle form –in Spanish, *adjetiva de participio*. These two structures may make us think that the texts have been translated from one language to the other because the frequency and typology of sentences coincide in both languages. However, opposed ideas have arisen when analysing the next syntactic sentence types because they do not coincide in the two languages.

In this way, the Spanish third type is the *oración coordinada copulativa*, while in English it is the final adverbial subordinate clause. The fourth place is also shared by both languages with the *adverbial propia* or the adverbial clause of time, place, and manner, particularly that of time with the constructions of *antes de/después de* and its equivalent in English before/after. Finally, the fifth place in English is occupied by the *oraciones subordinadas sustantivas,* and by the disjunctive coordinate clause in English, specifically the constructions with "que" in Spanish, e.g. *es importante que utilice la dosis más pequeña que alivie/controle el dolor*, and the typical use of the conjunction *or* in this type of sentence in English, e.g. *if you are suffering from or have a history of repeated stomach ulcers or other gastric complain*.

4.2.3. **Semantics**

By analysing the language contained in our PILs, we have observed that it consists of an objective medical language characterised by a devoid of emotions which follows a structure similar to that of a manual. However, a controlled, delicate, and clear language would be expected in the sense of keeping in mind the situation of the patients and considering their health. In words of Pérez García, a PIL should be characterised by a tone that demonstrates seriousness and reliability, without compromising the patient's health who needs to be well informed, and for whom improvement is ensured (n.p.; my translation). The problem with many of these PILs is that they reach a point where they are illegible, i.e. the information they contain is not clear enough and there are cases of ambiguity which may cause misinterpretations. This may have serious consequences when making a contraindicated use of the medicine.

The use of continuous repetitions of structures that have been found in the Spanish and English PILs is also worth mentioning. A good example of this is the unceasing use of conditional sentences when patients have been warned –in case of doubt– to avoid taking a medicine if they suffer from a disease which is contraindicated in the use of a certain medicine, etc. This refers to repetitions of certain paragraphs, which lead to repetitions of content. Thus, we can also find redundancy in terms of content, in which certain information of the PIL is repeated. One example is the one of the English *Paracetamol* leaflet. In this leaflet, section 3 called *how to take Paracetamol film coated tablets* says not to take more than 4 tablets in 24 hours, that is the prescribed dose, and immediately after it says not to take more than the prescribed dose, so the same information is repeated.

Along these lines, the constant repetitions of both structure and content in the PILs result in a language with repetitive patterns. The repetitive patterns in this type of texts may be positive or negative. When the use of repetitive patterns is positive, these are called didactic repetitions. In this medical texts, these positive repetitive patterns aim at having a positive impact on the patients so that they understand and acquire new information from the PIL regarding a disease, particularly from the most important sections. Nevertheless, the outcome is not always like this and results in a redundant language that negatively affects the patient, as in the case of our PILs –negative repetition. It is actually an overly insistent language that may make the patient choose not to read the whole PIL or just some sections ignoring the rest of the leaflet.

We have found other strategies that help the reader understand the texts, such as the avoidance of synonymy, particularly in English. In this strategy, the writer employs the same words all along the PIL avoiding as much as possible the use of synonyms. That may be one of the reasons why the frequency of some words is so high: *medicine, dose, doctor, talk, take,* etc. By analysing the PILs, however, we realised that the use of synonymy in each language depends on the grammatical category to which we refer. In the PILs, Spanish is more likely to contain synonyms for nouns and adjectives, while English contains more synonyms for verbs through the use of modal verbs. We have done a further analysis of the idea of synonyms and equivalents of words below.

On the other hand, we have also found certain peculiarities in the use of repetitions at the sentence level, such as modal repetitions. It is not based on repetition of sentences as such, but on the modality of those sentences. In this regard, we find different types of sentences in terms of meaning, particularly of modality, with clear differences between Spanish and English. We approached this sentence classification in a very superficial way in the previous section calling it sentence semantic level, so we have proposed it in detail below. As we have stated, there are

four English types of sentences to a semantic level, particularly modality, while in Spanish there are six types.

Going back to the issue of repetition and related to the idea of modality, we have found clear instances in the PILs of both languages. Along these lines, we have identified an imperative modality all throughout the PIL, which can be clearly identified by the constant use of present simple in the imperative mood. Here, the medical writer is transmitting an order to the patient to do something through the use of different imperative sentences, e.g. *tell your doctor if you are taking other medicines.* This imperative modality is often combined with conditional sentences –*if* in English, and *si* in Spanish– that can be understood as a doubt modality since hypothetical situations that can happen or not are presented, such as when the patient is said to be pregnant or not. Finally, the other modality that we can find is that of the interrogative sentence. This interrogative sentence appears in indirect speech, while in Spanish it is just called indirect interrogative sentence, e.g. *How to store Acetylcysteine Effervescent Tablets,* or *Cómo tomar Amoxicilina Kern Pharma.* In this type of sentences, patients ask for information and the medical doctor provides it to them through the PIL. In addition, we also considered the interrogative sentence as partial because the patient is looking for specific information, e.g. how to use the medicine, relevant information before taking it, its dosage, or the way to store it.

Conversely, it is also relevant to talk about to the lexical fields that we have found in the PILs as they are also part of the LSP. In our case, we have found words that are typical of the medical domain. As we dealt with popularized scientific texts, we assumed that we would not find highly technical words. Instead, we expected simpler structures to refer to those terms, which derives from the conversion of the technical lexicon of scientific discourse into a semi-technical lexicon, so that the lay audience can understand it. Moreover, those terms or expressions which cannot be replaced by simpler terms are accompanied by small and expository definitions: *Clopidogrel (used to prevent blood clots (thrombi)).*

At a first sight, we can establish different hyperonyms[9]. The first hyperonym is that of *medicine* in which we can include several hyponyms such as the different medicines of the PILs –*Paracetamol*, *Ibuprofen*, Amoxicillin, etc. –, the components of those medicines –*gelatin, maize starch, titanium dioxide*, etc. –, along with other words such as *dosage, dose, mixture,* etc. The second hyperonym is *disease,* and we can include here a lot of hyponyms: *peptic ulcer, blood disorder, jaundice,* etc. The third semantic field is that of the hyperonym

[9] Here, we are only referring to English terms included in the English PILs ignoring the Spanish ones because the results are the same in both cases, so we found it unnecessary.

including parts and organs of the human body such as *liver, mouth, skin, legs,* etc. since the medicines may have an impact on any of these. The fourth semantic field is that of words meaning cause and consequence, particularly verbs: *cause* and all its variants, *history, condition, circumstances, result* and all its variants, *effect,* etc., which are mainly referred to the situation of the patient before, during, and after taking the medicine. The fifth semantic field is that related to people according to their age, so we can find words such as *elder, children, adult, years old, aged,* etc. Finally, the sixth semantic field found is that of colours, which may be referred to many different things such as the look of the tablets or some illnesses that change the colour of different parts of the patient's body: *yellowing, purplish-red, pink, white, black,* etc.

4.3. Translation analysis

In this section, we have discussed the hypothesis of our texts being translations or not and if our PILs have been translated from Spanish into English. The Spanish PILs were taken from *Kern Pharma*. Moreover, the English PILs were selected without considering the laboratory in which they were created and commercialised, so it is possible that at least some of the English PILs are translated from Spanish. To this end, we have analysed two main features.

First, we have considered the frequency of equivalents. From the point of view of corpus-based translation studies, the study of the frequency of words has been relevant, but in a different way as it was in the linguistic analysis. In this sense, we were interested in recovering the most used words and comparing their frequency with that of their equivalents in the other language, which we have done by using the corpora. Second, we have analysed the principal translation procedures we find when comparing the texts: formality/informality, transposition, borrowing, description, calque, literal translation, ambiguity, and mistranslation. Moreover, we have considered different mistakes that result from an inefficient translation too –punctuation, weird expressions, etc.

4.3.1. **Equivalent terms: frequency**

Rated by frequency, the main idea we have seen from the results was that there is a huge difference in the frequency of terms in Spanish and English. If we look at the first word in the Spanish corpus –*medicamento*–, we cannot appreciate that difference because its frequency is 323, while in the English corpus, the first word –*take*– appears 344 times. However, this result should not be so representative because the English term *take* can be found in the Spanish texts with numerous different forms: *tomar* (195), *utilizar* (73), etc, as

we can see below. In the second place, we find *poder* in Spanish (272) and *medicine* (223) in English; still, the difference is not so significant. In this way, if we look at the remaining results, we can find similar frequencies: the three following words are *médico, tomar,* and *dosis* in Spanish (228, 195, and 145, respectively), and *doctor, tablet,* and *side* in English (214, 160, and 157, respectively). Except for the word *tomar*, which we have already commented, the frequency of nouns is similar because, unlike verbs, we have just one equivalent to a word in the other language, e.g. the equivalent of *médico* would be *doctor*; the equivalent of *dosis* would be *dose*, etc. When observing the Spanish results, we can see that some results should not be considered, as the case of *pharma* because it refers to the Spanish pharmaceutical laboratory *Kern Pharma* and, consequently, it has no equivalents in the English corpus, so it is not relevant from the point of view of translation. There are other examples like the inclusion in the corpora of URL data –*http*– or abbreviations –*ej, kg, nº, efg*–, which are all of them considered as nouns when sometimes they are not.

On the other hand, we also considered interesting to analyse the most frequently used words attending to their POS, especially nouns, verbs, and adjectives. By observing the results, it can be stated that both Spanish and English corpora contain mainly nouns.

According to the frequency of each grammatical category, we can observe significant differences between Spanish and English. If we focus on nouns, we find 501 simple NPs in Spanish –referring to the Noun Phrase (NP) only consisting in a noun– and 320 simple NPs in English. Regarding the adjectives, we can observe 145 simple Adjective Phrases (AdjP) in Spanish and 81 in English. Finally, concerning verbs, we find 138 in Spanish and 71 in English. These results support the idea that the Spanish texts are denser than the English ones and, in this sense, the latter are more likely to be translations than the Spanish ones.

Moreover, we have discovered many complex constructions in English, especially NPs, e.g. Adj+Adj+N –*Low immune system*–, Adj+N+N –*High blood pressure*–, N+N or compound nouns –*blood cell, kidney problem*. In addition, we have found more complex compound nouns, especially when referring to highly technical terms pertaining to a scientific specialised domain, e.g. *sodium starch fumarate, proton pump inhibitor.* In Spanish, the NPs are not as complex as in English and the most usual constructions are N+Adj –*dolor abdominal, reacción alérgica*– and N+Prepositional Phrase (PP) –*infarto de miocardio, uso de memantina*. Let us now consider the most frequently used words of each grammatical category and their equivalents in both Spanish and English:

Table 8: Most frequently used words of each POS in Spanish and English and equivalents. Source: *TermoStat*

	SPANISH	EQUIVALENTS	ENGLISH	EQUIVALENTS
VERBS	Poder (273) Tomar (195) Consultar (82)	Can (78), May (156), Might (9) Take (334) Ask (35), Consult (5), Check (14)	Take (344) Use (131) Do (85)	Tomar (195), Ingerir (12), emplear (11), utilizar (47) Utilizar (84), usar (18) No equivalent
NOUNS	Medicamento (323) Dosis (145) Médico (228)	Medicine (223), Drug (11), Medication (2) Dose (130), Dosage (5) Doctor (214)	Medicine (223) Doctor (214) Tablet (160)	Medicamento (323), fármaco (2) Médico (228) Comprimido (89)
ADJECTIVES	Severe (35) Allergic (32) High (26)	Grave (49), severo (2) Alérgico/a(s) (31) Alto/a(s) (21), elevado/a(s) (8)	Posible (52) Grave (49) Frecuente (37)	Possible (46) Severe (35), serious (19) Frequent (3), common (9),

As we can see in Table 8, some of these results coincide in the list of terms because some of them appear in both cases as the most used words as they are broadly representative of the medical language –*medicine* or *médico*–, while others do not. Furthermore, we see huge differences when comparing the terms with their equivalents: we find considerably more Spanish equivalents than English ones. This is due to the fact that Spanish PILs are longer and contain more information than the English ones.

Regarding the issue of density, Gualda proposes some differences between Spanish and English. He states that the English language is more compact than Spanish and a text in English contains fewer words than the same text translated into Spanish –10% fewer words. In this sense, the English language contains more density of information than the Spanish language (n.p.). This means that the English language conveys more information in less space, so it contains a greater density of information. In this way, a Spanish text occupies more space than an English text.

This idea of density is present in our PILs. First, that spatial density can be seen through several examples as the one of the term *medicamento*, which appears 323 times, while *medicine* only 223 and the remaining equivalents which total 236. However, there are other cases in which this equivalence is more equally distributed, as the case of *allergic* (32) and *alérgico/a(s)* (31). Second, it is important to mention some peculiar cases, such as the verb *utilizar*, since we only considered the results of each sense which appears in the table with different frequencies –e.g. for the verb *take*, the frequency of the equivalent *utilizar* in that specific sense is 47, but for the sense of the verb *use*, the frequency of *utilizar* is 84. This happens particularly with the English terms because they are more likely to be polysemic,

that is, contain more than one sense, e.g. the word *use*, which has several meanings. The same occurs with other terms such as *take*, which has several equivalents in Spanish. Also, another case is that the verb *do* has no equivalents in Spanish because it rather works as a functional word.

Thus, all these results make more likely the idea that the texts are not actual translations. The difference in frequency between the words and their equivalents in Spanish and English, as we have seen in Table 8, make us consider the idea that the PILs have not been translated from one language into the other, or, at least, most of them have not.

4.3.2. **Translation procedures**

In this section, we have commented on the most representative translation procedures we can find in the texts. In Table 9, we can see some examples of each procedure:

Table 9: Translation procedures in our Spanish and English PILs with solutions. Source: *AntConc* and my creation.

	SPANISH	**ENGLISH**	**POSSIBLE SOLUTION**
FORMAL/INFORMAL	Analgésico Consulte Población pediátrica Problemas de circulación	Pain killers Ask Children Poor circulation	
TRANSPOSITION	Dolor muscular Aspecto del producto Erupción cutánea con picor Los llamados receptores NMDA que participan en la transmisión… Puede producir cambios	Muscle pains What Valsartan tablets look like Itchy skin NMDA-receptors that are involved in transmitting… May change	
BORROWINGS	Miastenia Vigilancia Diarrea Artrosis Sobre	Myasthenia gravis Surveillance Diarrhoea Osteoarthritis Sachet	
DESCRIPTION	Anticoagulantes Antipirético Pérdida de cabello acelerada La administración de memantina puede producir cambios […]: amantadina	Medicines used to thin the blood Which […] also reduces your temperature when you have a fever Alopecia The use of medicinal products called amantadine (for the treatment of Parkinson's disease) …	

CALQUE	Cirugía de bypass Espacie las dosis Vencer la infección Bajo número de glóbulos blancos	Bypass surgery Space the doses Fight the infection Low number of white blood cells	Cirugía de baipás Reparta las dosis Número reducido de…
LITERAL TRANS.	Valsartán *Kern Pharma* actúa bloqueando el efecto… Le indicará cuánta amoxicilina debe administrar… Hable con su médico Su médico le puede decidir realizar	Valsartan tablets work by blocking the effect… How much Amoxicillin capsules you should give… Talk to your doctor Your doctor may decide to perform	Valsartán bloquea el efecto… Le indicará la cantidad de amoxicilina… Consulte con su médico Es probable que su médico decida realizarle
AMBIGUITY	Adultos […]: 2 a 10 mg La utilización de *Paracetamol* en pacientes […] puede provocar daño en el hígado La ranura sirve únicamente para partir el comprimido si… Otros efectos adversos son: […] muy raros: pancreatitis No requiere condiciones especiales de conservación	The usual adult dose is 2 to 15 mg daily No evidence that *Paracetamol* causes any ill effects The score line […] is not intended for breaking the tablet Frequency unknown […]: pancreatitis These tablets should be stored in a dry place, at or below 25º protected from light…	
MISTRANSLATION	Sistema inmunológico disminuido Debe de interrumpir el tratamiento	Low immune systems You should stop taking	Sistema inmunológico debilitado Debe interrumpir

As shown in Table 9, these are the most relevant procedures from the point of view of a translation analysis in our texts. In this way, we have considered eight translation procedures. The first one refers to the formality or informality of the language. The second one is the transposition, which implies a change of POS from one language to another. The third one is the borrowing, which consists of a foreign word that is adopted in a particular language. The fourth procedure is the description, in which a term is presented in another language by its

description. The fifth procedure refers to calque as a mistranslation of words that are similar in structure but have different meanings. The sixth one is the literal translation, which consists of a word for word translation of certain structures that makes it loses its natural occurring in the target language. The seventh procedure is the ambiguity, which refers to the contradictions that arise when comparing the information contained in the Spanish and English PILs. Finally, the mistranslation consists of certain structures that are not only translated in a wrong way, but also prove to be ungrammatical. For the calque, the literal translation, and the mistranslation, we have provided a column for the solutions to the Spanish wrong words or expressions.

As we have said before, we observe that the Spanish language of PILs is more formal than the English one, but it is more complex because of its formality and the highly technical language that is employed and that should be avoided in expert-to-layman texts like these. Moreover, the English texts are more descriptive and easy to understand for the laypeople, which results in a better acquisition of the content of the English PILs. This description procedure occurs mainly with those diseases or medicines that do not have a simpler equivalent and they tend to be translated by substituting the complex term or by accompanying it.

Another issue is that there is also a lack of information, which means that we do not find the same information in the PILs of both languages. That lack of information leads to omissions, but not from the point of view of translation, but from the point of view of communication since these omissions may lead to complications when the patient takes a medicine. This issue makes the task of comparing the texts difficult –that is identifying similar structures or equivalents– because there are cases in which the information is very different from one PIL to the other. The most recurrent case of this communicative omission is when a side effect is not reported in a Spanish leaflet when it is present in the English one, or when these effects do not appear because the same medicine has been developed by different laboratories in Spain and England, so the excipients may vary.

Regarding the transposition, we observe a lot of different types. In the first one, *muscle pains* results in *dolor muscular*, so the noun *muscle* becomes the adjective *muscular* in Spanish. In the second case, the interrogative sentences are nominalized, which is something widely used in these texts. In the third example, we find a crossed transposition in which the adjective becomes the noun and the noun becomes the adjective. The remaining results are nominalizations too, but the noun becomes a verb in this case.

Next, let's comment the borrowings. As we have seen, the English borrowings of our PILs come from Latin, Greek, and French. In them, we can find some terms such as *gastro-esophageal* or *thrombi*, which are terms coming from Greek. On the other hand, some of the Latin borrowings are naturalized such as *myasthenia*, while some are not, as the case of *diarrhoea*. The French ones are pure, such as *sachet*. In the case of Spanish, all of them come from Latin and we may not consider them as borrowings since the Spanish language is a Romance language, so the possible borrowings are well integrated into the language.

Considering the descriptions, they are mainly made from Spanish into English, which means that the language of English PILs is more likely to describe terms than that of the Spanish PILs. This may result from the formality of each language, that is, as the Spanish language is more formal, we have found more technical words in the Spanish than in the English PILs. Even if we have clear English equivalents for those specific words, the writers of the English PILs have avoided the use of some technical words by providing a clear description of them so that readers fully understand them. This is the case of the first result *anticoagulantes* in Spanish. This word could have been translated as *anticoagulants*, but the writers decided to provide a description of it: *medicines used to thin the blood*. However, this also happens from Spanish into English. One example is the term *alopecia* in English, for which the Spanish leaflet provides the description of *pérdida de cabello acelerada*. In other cases, they decided to provide both the term and its description, as in the case of *amadantina* in Spanish, and *amadantine (for the treatment of Parkinson's disease)* in English.

Concerning calques, we have found some examples for which we propose an alternative –see Table 9. This is the case of the English construction *low number of white cells*, and its Spanish equivalent is *bajo número de glóbulos blancos*, which does not sound natural. Widely related to the calque is the literal translation, of which we can find a lot of examples, such as the sentence *Talk to your doctor*, which in Spanish is expressed as *Hable con su médico*, which sounds strange since, as we said before, the Spanish medical language is more formal.

Next, we can talk about the ambiguity. This type of ambiguity does not refer to the different interpretations of a certain structure or word, but to the different interpretations that were found in supposedly the same information in the Spanish and English PILs. This ambiguity has to do with sentences or structures that convey different information from one language to the other. In this sense, the information that appears in the Spanish PILs contradicts that of the English PILs, and the other way round. If we consider the example of *the score line is not intended for breaking the tablet*, and its equivalent *la ranuera sirve*

únicamente para partir el comprimido si…, we can clearly see that the information is contradictory. What is more, the word *ranuera* is misspelled.

Finally, we can focus on the procedure of mistranslation which is sometimes similar to the literal translation since both imply wrong translations. However, it goes beyond that because it displays not only unnatural results, but also ungrammatical ones such as *debe de interrumpir* which contains a grammatical mistake since the proper construction is *debe interrumpir*.

Together with all these procedures, we have to mention that there are mistakes in punctuation and spelling in both cases, e.g. *estógamo* or *ranuera*. We did not include them in the table because they are not relevant from a translation point of view, but they may be the result of inefficient and careless translations.

5. DISCUSSION

In this section, we will summarise the characteristics of PILs and their main ideas in order to confirm or refute our hypotheses. First, we have obtained information about PILs and their characteristics to make a comparison between the Spanish and English PILs by analysing their language in order to define the genre of PILs. Second, we want to extract the main ideas of the analyses in order to confirm or refute our hypotheses. Our first hypothesis is that the English PILs have been translated from the Spanish ones since the latter were taken from the very same laboratory, which is *Kern Pharma*. Second, we have also considered that the probability of the PIL being a translation has to do with the popularity of the medicine. This means that medicines like *Memantine* are more likely to be translations than others such as *Paracetamol* or *Ibuprofen*.

Regarding the characteristics of PILs, we can comment the more relevant similarities and differences. First, we have seen that the superstructure of PILs is the same in Spanish and English as it is imposed by the European Commission. As the superstructure is identical in both cases, the macrostructure, i.e. the ideas contained in the PILs is also the same because we have the same sections. The main difference in the rhetoric analysis is the sixth section because it includes the laboratories involved in the manufacture of medicines and they are different depending on the medicine and the country, as described in depth below.

Second, we can focus on the linguistic analysis. Regarding grammar, the grammatical categories used in the PILs are very different depending on the language, particularly adjectives. Concerning syntax, there are also differences in the use of verb tenses between the Spanish and English PILs, but there are some of them very representative of the language of PILs in both cases

such as the use of the imperative mood or modal verbs. The complexity of verb tenses is also a characteristic of the language shared by the Spanish and English PILs. The syntactic classification of sentences in our PILs is the same in both languages and there are also sentence types very representative of the language of PILs such as the conditional adverbial subordinate clause or the adjectival subordinate clause. The latter is very frequent as to make descriptions –e.g. of medicines, of complex terms, etc., which is typical not only of PILs but also in the whole scientific popularization. In respect of semantics, it is found a language which is in many cases illegible for the intended audience –laypeople– and full of ambiguity and redundancy in both languages. Unlike the Spanish PILs, the problem of the legibility of PILs is partly solved by the avoidance of synonyms. Synonyms may confuse the reader, particularly those terms which are very technical. Also, we have identified the semantic classification of sentences –modality– which is different in Spanish than in English. However, the imperative sentence is the most typical type of sentence in both Spanish and English PILs, which makes the imperative modality to be characteristic of PILs. The hyperonyms are also shared in our Spanish and English PILs, as we will see below, so the vocabulary included is virtually the same.

Finally, the translation analysis also shows characteristics of the PILs. The main difference between Spanish and English PILs is the formality of the language of the Spanish ones and the informality of the English ones. In both cases, we can find the use of transpositions, calques, literal translation, ambiguity, and mistranslation. Borrowings and descriptions are exclusive to the English PILs since they include many terms coming from Latin, Greek, and French. Descriptions are also present in the Spanish PILs, but to a lesser extent.

Once we have defined the main characteristics of PILs, we need to focus on the main ideas of each analysis in order to resolve the hypotheses. On the one hand, the rhetoric analysis has helped us to realize that our PILs are not all translations. It is not only because these medicines were produced or manufactured by different laboratories –and thus so are the PILs, but also because either their structure or the language used in them are completely different. However, we found exceptions regarding the *Omeprazole* and *Memantine* PILs. Only the *Omeprazole* PILs are sure to be translations because they were produced by the same laboratory, contain the same structure, and include some translation techniques, such as transpositions and calques. *Memantine* PILs are very likely to have been translated too for the same reasons, but it is striking due to the origin of the English PIL: the medicine was manufactured in Malta, which is a country whose main official language is Maltese, but also English. On the other hand, the hypothesis of the popularity of PILs is confirmed since there may be a large number of laboratories that market the most commonly used medicines. In addition, it is supported by the idea that the two pairs of PILs of our project

that result to be translations, which are *Omeprazole* and *Memantine*, refer to medicines that are much less popular than others such as *Ibuprofen* or *Paracetamol*.

Conversely, we have seen that some of the texts are not actually translated because of the nature of the medical language and the given structural patterns. Due to the standards of PILs imposed by the European Commission, we have found similarities in some of the structures of our Spanish and English PILs. Moreover, we have also found similarities in the use of language in our PILs because both countries belong to the Beveridge model and our PILs have been taken from reliable sources. However, even if the health systems are similar because both countries belong to the same model, they do have some differences, so the information included in the PILs may differ as well. These similiarities and differences can be seen through the analysis of the language of our PILs, particularly through the linguistic and translation analyses. These analyses have served us to categorize the PIL as a genre, since this has not yet been proposed.

In the linguistic analysis, we have discussed the grammar, syntax, and semantics of the PILs. Concerning grammar, the adjective is the grammatical category that differs the most between the Spanish and English PILs. English adjectives are less frequent than the Spanish ones because the English premodification is mostly made with the use of verbal constructions –e.g. *existing factors* or nouns –compound nouns. Moreover, Spanish and English adjectives occur with given constructions all along the PILs –e.g. *usual dose*, *es posible que.* The English verbs are likely to be polysemic because their frequency is lower than that of the Spanish verbs, while the number of Spanish verbs is larger and more diverse. One of the consequences of this is that the English PILs contain constant repetitions of verbs while the Spanish ones contain synonyms to avoid those repetitions. In the case of nouns, the Spanish ones are higher in number due to the recurrent nominalizations, which means that words that appear as verbs in the English PILs are found in many cases as nouns in the Spanish PILs.

Regarding the syntax, we can talk about verb tenses and types of sentences. On the one hand, the most-used verb tenses are the periphrastic verb form in Spanish and the modal verb along with the passive structure in English. We notice an authoritative mood through the use of the present simple in imperative mood in both Spanish and English. However, we realise that the imperative modality present in our PILs is often softened by the use of periphrastic verb forms and modal verbs. In general, the use of these verb tenses results in a complex style and language, which is characteristic of the LSP and, in particular, of the medical language in general. This complexity and the use of an authoritative mood may influence negatively on the patient making it difficult and problematic for him/her to read the PIL. The most-used sentence types are the conditional adverbial subordinate clause and the adjective subordinate clause in both languages. The first type

is used to describe hypothetical situations, for example in the consumption of a medicine, while the second one is used for the description of symptoms, illnesses, etc. The fact that the three most-used sentence types in both languages coincide reinforces the idea that PILs have fixed structural patterns.

The semantic analysis gives us relevant information about the language. First, a controlled, subtle, and clear language was expected as we are dealing with popularized texts, but the result is an illegible language full of redundancy and ambiguity. For this reason, we do not find didactic repetitions since they are rather redundant and confuse the reader. With the modal repetition, we can mention some modalities prevalent in our PILs. The PILs of both languages are characterised by the use of an imperative, doubt, and interrogative modality. To conclude this section, the lexical fields show that the technical lexicon of this scientific discourse is simplified and that the use of descriptions for defining complex terms, especially in the English PILs is common.

Finally, the key point of our project is the translation analysis. Even if we have already stated that our PILs are not mostly translations, there are some major characteristics that arise from this analysis regarding the language. First, we notice that the Spanish PILs contain a more formal language than the English PILs which partly explains their complexity. Besides, the English PILs contain a more descriptive language, particularly with complex terms, and is more representative of the macrogenre of scientific medical popularization. The lack of information we have seen in our PILs is also relevant, especially in some sections. Constant omissions of information are found throughout the texts. We also discern a Latin legacy in our PILs, which is very representative of the medical lexicon, as well as non-naturalized French terms. Finally, there are plenty of ambiguous situations in which PILs of the same medicine contain contradictory information. However, it may be caused by the different excipients used in the creation of a medicine that influence the side effects the patient may suffer.

In conclusion, we have stated the reasons why our PILs are not translations and that the more popular a medicine is, the less probability of it to have been translated. In addition, we have established the similarities and differences in both structure and language between the Spanish and English PILs, so that now we are certain that our PILs are a genre of the medical field.

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7. APPENDIX

Appendix 1: Selection of PILs for the Spanish corpus

Source: Centro de Información Online de Medicamentos de la AEMPS (CIMA)

<https://www.aemps.gob.es/cima/publico/home.html>

Ibuprofeno

PROSPECTO: INFORMACIÓN PARA EL USUARIO

***Ibuprofeno Kern Pharma* 600 mg comprimidos recubiertos con película EFG**

Lea todo el prospecto detenidamente antes de empezar a tomar este medicamento, porque contiene información importante para usted.

- Conserve este prospecto ya que puede tener que volver a leerlo.
- Si tiene alguna duda consulte a su médico o farmacéutico.
- Este medicamento se le ha recetado solamente a usted y no debe dárselo a otras personas aunque tengan los mismos síntomas, ya que puede perjudicarles.
- Si experimenta efectos adversos, consulte a su médico o farmacéutico, incluso si se trata de efectos adversos que no aparecen en este prospecto. Ver sección 4.

Contenido del prospecto:

1. Qué es *Ibuprofeno Kern Pharma* 600 mg y para qué se utiliza

Ibuprofeno pertenece al grupo de medicamentos llamados antiinflamatorios no esteroideos (AINEs).

Este medicamento está indicado para el tratamiento de la fiebre, el tratamiento del dolor de intensidad leve o moderado incluida la migraña, el tratamiento de la artritis (inflamación de las articulaciones, incluyendo habitualmente las de manos y pies, dando lugar a hinchazón y dolor), la artritis reumatoide juvenil, artrosis (trastorno de carácter crónico que ocasiona el daño del cartílago), espondilitis anquilosante (inflamación que afecta las articulaciones de la columna vertebral), inflamación no reumática y la dismenorrea primaria (menstruación dolorosa).

2. Qué necesita saber antes de empezar a tomar *Ibuprofeno Kern Pharma* 600 mg

No tome *Ibuprofeno Kern Pharma* 600 mg

- Si es alérgico (hipersensible) al *Ibuprofeno*, a otros medicamentos del grupo de los antiinflamatorios no esteroideos (AINEs), a la aspirina o a cualquiera de los demás componentes de este medicamento. Las reacciones que indican la alergia podrían ser: erupción cutánea con picor, hinchazón de la cara, labios o lengua, secreción nasal, dificultad respiratoria o asma.
- Si padece una enfermedad grave del hígado o los riñones.
- Si ha tenido una úlcera o hemorragia de estómago o de duodeno o ha sufrido una perforación del aparato digestivo.
- Si vomita sangre.
- Si presenta heces negras o una diarrea con sangre.
- Si padece trastornos hemorrágicos o de la coagulación sanguínea, o está tomando anticoagulantes

  (medicamentos utilizados para "fluidificar" la sangre). Si es necesario utilizar a la vez medicamentos anticoagulantes, el médico realizará unas pruebas para la coagulación sanguínea.

- Si padece una insuficiencia cardiaca grave.
- Si se encuentra en el tercer trimestre del embarazo.

Advertencias y precauciones

Consulte a su médico, farmacéutico o enfermero antes de empezar a tomar este medicamento.

Informe a su médico:

- Si tiene edemas (retención de líquidos).
- Si padece o ha padecido algún trastorno del corazón o tiene tensión arterial alta.
- Si padece asma o cualquier otro trastorno respiratorio.
- Si está recibiendo tratamiento con *Ibuprofeno* ya que puede enmascarar la fiebre, que es un signo importante de infección, dificultando su diagnóstico.
- Si padece una enfermedad de los riñones o del hígado, tiene más de 60 años o necesita tomar el medicamento de forma prolongada (más de 1 a 2 semanas), es posible que su médico deba efectuar controles de forma regular. Su médico le indicará la frecuencia de estos controles.
- Si presenta síntomas de deshidratación, p.ej. diarrea grave o vómitos tome abundante líquido y contacte inmediatamente con su médico, ya que el *Ibuprofeno* en este caso concreto podría provocar como consecuencia de la deshidratación una insuficiencia renal.
- Si ha tenido o desarrolla una úlcera, hemorragia o perforación en el estómago o en el duodeno, pudiéndose manifestar por un dolor abdominal intenso o persistente y/o por heces de color negro, o incluso sin síntomas previos de alerta. Este riesgo es mayor cuando se utilizan dosis altas y tratamientos prolongados, en pacientes con antecedentes de úlcera péptica y en los pacientes de edad avanzada. En estos casos su médico considerará la posibilidad de asociar un medicamento protector del estómago.

- Si toma simultáneamente medicamentos que alteran la coagulación de la sangre como, anticoagulantes orales, antiagregantes plaquetarios del tipo del ácido acetilsalicílico. También debe comentarle la utilización de otros medicamentos que podrían aumentar el riesgo de dichas hemorragias como los corticoides y los antidepresivos inhibidores selectivos de la recaptación de serotonina.
- Si padece la enfermedad de Crohn (enfermedad crónica en la que el sistema inmune ataca el intestino provocando inflamación que produce generalmente diarrea con sangre) o una colitis ulcerosa pues los medicamentos del tipo *Ibuprofen*o pueden empeorar estas patologías.
- Si está en tratamiento con diuréticos (medicamentos para orinar) porque su médico debe vigilar el funcionamiento de su riñón.
- Si padece lupus eritematoso sistémico (enfermedad crónica que afecta al sistema inmunitario y que puede afectar distintos órganos vitales, al sistema nervioso, los vasos sanguíneos, la piel y las articulaciones) ya que puede producirse meningitis aséptica (inflamación de las meninges que son las membranas que protegen el cerebro y la medula espinal, no causada por bacterias).
- Si padece porfiria intermitente aguda (enfermedad metabólica que afecta a su sangre y que puede provocar síntomas como coloración rojiza de la orina, sangre en orina o enfermedad en el hígado), para que valore la conveniencia o no del tratamiento con *Ibuprofen*o.
- Si sufre dolores de cabeza tras un tratamiento prolongado no debe tomar dosis más elevadas del medicamento.
- Es posible que se produzcan reacciones alérgicas con este medicamento.
- El médico efectuará un control más estricto si recibe *Ibuprofen*o tras ser sometido a cirugía mayor.
- Es aconsejable no tomar este medicamento si tiene varicela.

Es importante que utilice la dosis más pequeña que alivie/controle el dolor y no debe tomar este medicamento más tiempo del necesario para controlar sus síntomas.

<u>Precauciones cardiovasculares</u>

Los medicamentos antiinflamatorios/analgésicos como *Ibuprofen*o se pueden asociar con un pequeño aumento del riesgo de sufrir un ataque al corazón o un ictus, en especial cuando se utiliza en dosis altas. No supere la dosis recomendada ni la duración del tratamiento.

Debe comentar su tratamiento con su médico o farmacéutico antes de tomar *Ibuprofen*o si:

- tiene problemas de corazón incluida una insuficiencia cardiaca, angina (dolor torácico) o si ha sufrido un ataque al corazón, cirugía de bypass, arteriopatía periférica (problemas de circulación en las piernas o pies debido a un estrechamiento o a un bloqueo de las arterias), o cualquier tipo de ictus (incluido un "mini-ictus" o accidente isquémico transitorio "AIT").

- tiene la presión arterial alta, diabetes, el colesterol alto, tiene antecedentes familiares de enfermedad de corazón o ictus, o si es fumador.

Asimismo este tipo de medicamentos pueden producir retención de líquidos, especialmente en pacientes con insuficiencia cardíaca y/o tensión arterial elevada (hipertensión).

Precauciones durante el embarazo y en mujeres en edad fértil

Debido a que la administración de medicamentos del tipo *Ibuprofen*o se ha asociado a un aumento del riesgo de sufrir anomalías congénitas/abortos no se recomienda la administración del mismo durante el primer y segundo trimestre del embarazo salvo que se considere estrictamente necesario. En estos casos la dosis y duración se limitará al mínimo posible.

En el tercer trimestre la administración de *Ibuprofen*o recubiertos está contraindicada.

Para las pacientes en edad fértil se debe tener en cuenta que los medicamentos del tipo *Ibuprofen*o se han asociado con una disminución de la capacidad para concebir.

Uso de *Ibuprofen*o *Kern Pharma* con otros medicamentos

Informe a su médico o farmacéutico si está utilizando, o ha utilizado recientemente cualquier otro medicamento, incluso los adquiridos sin receta.

*Ibuprofen*o *Kern Pharma* puede afectar o ser afectado por otros medicamentos. Por ejemplo:

- Otros antiinflamatorios no esteroideos como el ácido acetilsalicílico.
- Antiagregantes plaquetarios (impiden la formación de trombos o coágulos en los vasos sanguíneos) como ticlodipina.
- Medicamentos anticoagulantes (p. ej. para tratar problemas de coagulación/evitar la coagulación, p. ej. ácido acetilsalicílico, warfarina, ticlopidina).Litio (medicamento que se utiliza para tratar la depresión). Posiblemente su médico le ajustará la dosis de este medicamento.
- Metotrexato (para tratar el cáncer y enfermedades inflamatorias). Posiblemente su médico le ajustará la dosis de este medicamento.
- Mifepristona (inductor de abortos).
- Digoxina y otros glucósidos cardiotónicos (se emplean en el tratamiento de los trastornos del corazón).
- Hidantoínas como fenitoína (se emplea en el tratamiento de la epilepsia).
- Sulfamidas como el sulfametoxazol y el cotrimoxazol (se emplean en el tratamiento de algunas infecciones bacterianas).
- Corticoides como la cortisona y la prednisolona.
- Diuréticos (medicamentos empleados para aumentar la eliminación de orina).
- Pentoxifilina (para tratar la claudicación intermitente).
- Probenecid (utilizado en pacientes con gota o junto con la penicilina en infecciones).
- Antibióticos del grupo de las quinolonas como el norfloxacino.
- Sulfinpirazona (para la gota).
- Sulfonilureas como la tolbutamida (para la diabetes).
- Tacrolimus o ciclosporina (utilizado en trasplantes de órganos para evitar el rechazo).
- Zidovudina (medicamento contra el virus del SIDA).

- Medicamentos que bajan la presión arterial alta (inhibidores de la ECA como captopril, betabloqueantes como medicamentos con atenolol y antagonistas de los receptores de angiotensina-II como losartán).
- Trombolíticos (medicamentos que disuelven los trombos).
- Antibióticos aminoglucósidos como la neomicina.
- Extractos de hierbas: del árbol Ginkgo biloba.

Otros medicamentos también pueden afectar o ser afectados por el tratamiento con *Ibuprofen*o *Kern Pharma*. Por tanto, debe consultar siempre a su médico o farmacéutico antes de utilizar *Ibuprofen*o *Kern Pharma* con otros medicamentos.

La toma de *Ibuprofen*o puede alterar las siguientes pruebas de laboratorio:

- Tiempo de hemorragia (puede prolongarse durante 1 día después de suspender el tratamiento)
- Concentración de glucosa en sangre (puede disminuir)
- Aclaramiento de creatinina (puede disminuir)
- Hematocrito o hemoglobina (puede disminuir)
- Concentraciones sanguíneas de nitrógeno ureico y concentraciones séricas de creatinina y potasio (puede aumentar)
- Con pruebas de la función hepática: incremento de valores de transaminasas

Informe a su médico si va a someterse a un análisis clínico y está tomando o ha tomado recientemente *Ibuprofen*o.

Uso de *Ibuprofen*o *Kern Pharma* 600 mg con los alimentos y bebidas

Puede tomarlo solo o con los alimentos. En general se recomienda tomarlo antes de las comidas o con leche para reducir así la posibilidad de que se produzcan molestias en el estómago.

Embarazo y lactancia

Consulte a su médico o farmacéutico antes de utilizar cualquier medicamento.

No se debe tomar *Ibuprofen*o durante el embarazo, especialmente durante el tercer trimestre (ver sección precauciones durante el embarazo y en mujeres en edad fértil).

Aunque sólo pasan pequeñas cantidades del medicamento a la leche materna, se recomienda no tomar *Ibuprofen*o por períodos prolongados durante la lactancia.

Por ello, si se queda embarazada o está en periodo de lactancia, consulte a su médico.

Conducción y uso de máquinas

Si experimenta mareo, vértigo, alteraciones de la visión u otros síntomas mientras esté tomando este medicamento, no debe conducir ni utilizar maquinaria peligrosa. Si solamente toma una dosis de *Ibuprofen*o o durante un periodo corto, no es necesario que adopte precauciones especiales.

3. Cómo tomar *Ibuprofen*o *Kern Pharma* 600 mg comprimidos

Siga exactamente las instrucciones de administración de *Ibuprofen*o indicadas por su médico. Consulte a su médico o farmacéutico si tiene dudas.

Su médico le indicará la duración del tratamiento con *Ibuprofen*o. No suspenda el tratamiento antes, ya que entonces no se obtendrían los resultados esperados. Del mismo modo tampoco emplee *Ibuprofen*o más tiempo del indicado por su médico.

Es importante que utilice la dosis más pequeña que alivie/controle el dolor y no debe tomar *Ibuprofen*o más tiempo del necesario para controlar sus síntomas.

Este medicamento se administra por vía oral.Los pacientes con molestias de estómago deben tomar el medicamento con leche y/o durante las comidas.

Adultos:

En adultos y adolescentes desde 14 a 18 años se tomará un comprimido (600 mg) cada 6 a 8 horas, dependiendo de la intensidad del cuadro y de la respuesta al tratamiento.

En algunos procesos pueden requerirse dosis superiores pero, en cualquier caso, se recomienda no sobrepasar la dosis máxima diaria de 2400 mg en adultos y de 1600 mg en adolescentes de 12 a 18 años.

Uso en niños y adolescentes:

No se recomienda el uso de este medicamento en niños y adolescentes menores de 14 años, ya que la dosis de *Ibuprofen*o que contiene no es adecuada para la posología recomendada en estos niños.

Uso en personas de edad avanzada:

Si tiene más de 60 años, es posible que su médico le recete una dosis más baja de lo habitual. Si es así, sólo podrá aumentarse la dosis una vez que su médico haya comprobado que tolera bien el medicamento.

Pacientes con enfermedades de los riñones y/o del hígado:

Si padece una enfermedad de los riñones y/o del hígado, es posible que su médico le recete una dosis más baja de lo habitual. Si es así, tome la dosis exacta que éste le haya prescrito.

Si estima que la acción de este medicamento es demasiado fuerte o débil, comuníqueselo a su médico o farmacéutico.

Si toma más dosis de *Ibuprofen*o *Kern Pharma* 600 mg del que debe

Si ha tomado más *Ibuprofen*o de lo que debe o ha ingerido accidentalmente el contenido del envase, consulte inmediatamente a su médico o farmacéutico o al Servicio de Información Toxicológica, teléfono: 91 562 04 20, indicando el medicamento y la cantidad ingerida. Se recomienda llevar el envase y el prospecto del medicamento al profesional sanitario. Los síntomas leves de una sobredosis son: dolor abdominal, náuseas, vómitos, indiferencia, sueño, dolor de cabeza, movimientos involuntarios rápidos del ojo, zumbido de oídos y falta de coordinación de los músculos.

Es raro que aparezcan síntomas más graves como hemorragia intestinal, bajada de la tensión, bajada de la temperatura corporal, acidosis metabólica, convulsiones, alteración de la función del riñón, coma, distress respiratorio del adulto y parada transitoria de la respiración en niños (después de ingerir grandes cantidades).

Si se ha producido una intoxicación grave, el médico adoptará las medidas necesarias.

En caso de ingestión de cantidades importantes deberá administrarse carbón activado. El vaciado de estómago se planteará si ha ingerido cantidades importantes y durante los 60 minutos siguientes a la ingestión

Si olvidó tomar *Ibuprofen*o *Kern Pharma* 600 mg

No tome una dosis doble para compensar las dosis olvidadas.

Si olvida tomar su dosis correspondiente, tómela tan pronto como se acuerde. Sin embargo, si la hora de la siguiente toma está muy próxima, salte la dosis que olvidó y tome la dosis siguiente en su hora habitual.

4. Posibles efectos adversos

Al igual que todos los medicamentos, este medicamento puede producir efectos adversos, aunque no todas las personas los sufran.

Los efectos adversos de los medicamentos como *Ibuprofen*o son más comunes en personas mayores de 65 años.

La incidencia de efectos adversos es menor en tratamientos cortos y si la dosis diaria está por debajo de la dosis máxima recomendada.

Las frecuencias se establecen según la siguiente clasificación: muy frecuentes (en más de 1 de cada 10 pacientes); frecuentes (entre 1 y 10 de cada 100 pacientes); poco frecuentes (entre 1 y 10 de cada 1.000 pacientes); raros (entre 1 y 10 de cada 10.000 pacientes); muy raros (en menos de 1 de cada 10.000 pacientes); frecuencia desconocida (no se puede estimar a partir de los datos disponibles).

Se han observado los siguientes efectos adversos:

Gastrointestinales:

Los efectos adversos más frecuentes que ocurren con los medicamentos como son los gastrointestinales: úlceras pépticas, hemorragias digestivas, perforaciones (en algunos casos mortales), especialmente en los pacientes de edad avanzada. También se han observado náuseas, vómitos, diarrea, flatulencia, estreñimiento, ardor de estómago, dolor abdominal, sangre en heces, aftas bucales, empeoramiento de colitis ulcerosa y enfermedad de Crohn. Menos frecuentemente se ha observado la aparición de gastritis.

Otros efectos adversos son:

Poco frecuentes: inflamación de la mucosa bucal con formación de úlceras.

Raros: inflamación del esófago, estrechamiento del esófago (estenosis esofágica), exacerbación de enfermedad de los divertículos intestinales, colitis hemorrágica inespecífica (gastroenteritis que cursa con diarrea con sangre).

Muy raros: pancreatitis.

Cardiovasculares:

Los medicamentos como *Ibuprofen*o, pueden asociarse con un moderado aumento de riesgo de sufrir un ataque cardiaco ("infarto de miocardio") o cerebral.

También se han observado edema (retención de líquidos), hipertensión arterial, e insuficiencia cardiaca en asociación con tratamientos con medicamentos del tipo *Ibuprofen*o.

Cutáneos:

Los medicamentos como *Ibuprofen*o pueden asociarse, en muy raras ocasiones a reacciones ampollosas muy graves como el Síndrome de Stevens Johnson (erosiones diseminadas que afectan a la piel y a dos o más mucosas y lesiones de color púrpura, preferiblemente en el tronco) y la necrólisis epidérmica tóxica (erosiones en mucosas y lesiones dolorosas con necrosis y desprendimiento de la epidermis).

Otros efectos adversos son:

Frecuentes: erupción en la piel.

Poco frecuentes: enrojecimiento de la piel, picor o hinchazón de la piel, púrpura (manchas violáceas en la piel).

Muy raros: caída del cabello, eritema multiforme (lesión en la piel), reacciones en la piel por influencia de la luz, inflamación de los vasos sanguíneos de la piel.

Excepcionalmente pueden darse infecciones cutáneas graves y complicaciones en el tejido blando durante la varicela.

Del sistema inmunológico:

Poco frecuentes: edema pasajero en áreas de la piel, mucosas o a veces en vísceras (angioedema), inflamación de la mucosa nasal, broncoespasmo (espasmo de los bronquios que impiden el paso del aire hacia los pulmones).

Raros: reacciones alérgicas graves (shock anafiláctico). En caso de reacción de hipersensibilidad generalizada grave puede aparecer hinchazón de cara, lengua y laringe, broncoespasmo, asma, taquicardia, hipotensión y shock.

Muy raros: dolor en las articulaciones y fiebre (lupus eritematoso).

Del sistema nervioso central:

Frecuentes: fatiga o somnolencia, dolor de cabeza y mareos o sensación de inestabilidad.

Raros: parestesia (sensación de adormecimiento, hormigueo, acorchamiento, etc. más frecuente en manos, pies, brazos o piernas).

Muy raros: meningitis aséptica. En la mayor parte de los casos en los que se ha comunicado meningitis aséptica con *Ibuprofen*o, el paciente sufría alguna forma de enfermedad autoinmunitaria (como lupus eritematoso sistémico u otras enfermedades del colágeno) lo que suponía un factor de riesgo. Los síntomas

de meningitis aséptica observados fueron rigidez en cuello, dolor de cabeza, náuseas, vómitos, fiebre o desorientación.

Psiquiátricos:

Poco frecuentes: insomnio, ansiedad, inquietud.

Raros: desorientación o confusión, nerviosismo, irritabilidad, depresión, reacción psicótica.

Auditivos:

Frecuentes: vértigo. Poco frecuentes: zumbidos o pitidos en los oídos.

Raros: dificultad auditiva.

Oculares:

Poco frecuentes: alteraciones de la visión.

Raros: visión anormal o borrosa.

Sanguíneos:

Raros: disminución de plaquetas, disminución de los glóbulos blancos (puede manifestarse por la aparición de infecciones frecuentes con fiebre, escalofríos o dolor de garganta), disminución de los glóbulos rojos (puede manifestarse por dificultad respiratoria y palidez de la piel), disminución de granulocitos (un tipo de glóbulos blancos que puede predisponer a que se contraigan infecciones), pancitopenia (deficiencia de glóbulos rojos, blancos y plaquetas en la sangre), agranulocitosis (disminución muy grande de granulocitos), anemia aplásica (insuficiencia de la médula ósea para producir diferentes tipos de células) o anemia hemolítica (destrucción prematura de los glóbulos rojos). Los primeros síntomas son: fiebre, dolor de garganta, úlceras superficiales en la boca, síntomas pseudogripales, cansancio extremo, hemorragia nasal y cutánea.

Muy raros: prolongación del tiempo de sangrado.

Renales:

En base a la experiencia con los AINEs en general, no pueden excluirse casos de nefritis intersticial (trastorno del riñón), síndrome nefrótico (trastorno caracterizado por proteínas en la orina e hinchazón del cuerpo) e insuficiencia renal (pérdida súbita de la capacidad de funcionamiento del riñón).

Hepáticos:

Los medicamentos como *Ibuprofen*o pueden asociarse, en raras ocasiones a lesiones hepáticas.

Otros efectos adversos raros son: hepatitis (inflamación del hígado), anomalías de la función hepática e ictericia (coloración amarilla de la piel y ojos).

Frecuencia desconocida: insuficiencia hepática (deterioro severo del hígado).

Generales:

Agravamiento de las inflamaciones durante procesos infecciosos.

Hasta la fecha no se han comunicado reacciones alérgicas graves con *Ibuprofeno*, aunque no pueden descartarse. Las manifestaciones de este tipo de reacciones podrían ser fiebre, erupción en la piel, dolor abdominal, dolor de cabeza intenso y persistente, náuseas, vómitos, hinchazón de la cara, lengua y garganta, dificultad respiratoria, asma, palpitaciones, hipotensión (presión sanguínea más baja de lo usual) o shock.

Si aparece alguno de los efectos adversos citados a continuación, interrumpa el tratamiento y acuda de inmediato a su médico:

Reacciones alérgicas tales como erupciones en la piel, hinchazón de la cara, pitos en el pecho o dificultad respiratoria.

Vómitos de sangre, o de aspecto similar a los posos de café.

Sangre en las heces o diarrea con sangre.

Dolor intenso de estómago.

Ampollas o descamación importante en la piel.

Dolor de cabeza intenso o persistente.

Coloración amarilla de la piel (ictericia).

Signos de hipersensibilidad (alergia) grave (ver más arriba en este mismo apartado).

Hinchazón de las extremidades o acumulación de líquido en los brazos o piernas.

Comunicación de efectos adversos

Si experimenta cualquier tipo de efecto adverso, consulte a su médico, farmacéutico o enfermero, incluso si se trata de posibles efectos adversos que no aparecen en este prospecto. También puede comunicarlos directamente a través del Sistema Español de Farmacovigilancia de Medicamentos de uso humano: https://www.notificaram.es. Mediante la comunicación de efectos adversos usted puede contribuir a proporcionar más información sobre la seguridad de este medicamento.

5. Conservación de *Ibuprofeno Kern Pharma* 600 mg comprimidos

Mantener este medicamento fuera de la vista y del alcance de los niños.

No requiere condiciones especiales de conservación.

No utilice este medicamento después de la fecha de caducidad que aparece en el envase después de "CAD".

La fecha de caducidad es el último día del mes que se indica.

Los medicamentos no se deben tirar por los desagües ni a la basura. Deposite los envases y los medicamentos que no necesita en el Punto SIGRE de su farmacia habitual. En caso de duda, pregunte a su farmacéutico cómo deshacerse de los envases y de los medicamentos que no necesita. De esta forma ayudará a proteger el medio ambiente.

7. Contenido del envase e información adicional

COMPOSICIÓN DE *IBUPROFENO KERN PHARMA* 600 MG COMPRIMIDOS

- El principio activo es *Ibuprofeno*. Cada comprimido contiene 600 mg de *Ibuprofeno*.
- Los demás componentes son: almidón de maíz, almidón pregelatinizado de maíz, celulosa microcristalina, dióxido de sílice coloidal y estearato de magnesio en el núcleo del comprimido e hipromelosa, celulosa microcristalina, polioxil 40 estearato, dióxido de titanio (E-171), polietilenglicol y propilenglicol en el recubrimiento.

Aspecto del producto y contenido del envase

Ibuprofeno Kern Pharma 600 mg son comprimidos alargados de color blanco. Se presentan en blíster en envases con 40 comprimidos y envase clínico de 500 comprimidos.

Titular de la autorización de comercialización y responsable de la fabricación

Kern Pharma, S.L.

Venus, 72 - Pol. Ind. Colón II

08228 Terrassa - Barcelona

España

Este prospecto ha sido revisado en Mayo 2016

La información detallada y actualizada de este medicamento está disponible en la página web de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) http://www.aemps.gob.es/.

OMEPRAZOL

Prospecto: Información para el usuario

OMEPRAZOL *KERN PHARMA* 20 MG CÁPSULAS DURAS GASTRORRESISTENTES EFG

Lea todo el prospecto detenidamente antes de empezar a tomar este medicamento, porque contiene información importante para usted.

- Conserve este prospecto, ya que puede tener que volver a leerlo.
- Si tiene alguna duda, consulte a su médico o farmacéutico.
- Este medicamento se le ha recetado solamente a usted y no debe dárselo a otras personas, aunque tengan los mismos síntomas que usted, ya que puede perjudicarles.
- Si experimenta efectos adversos, consulte a médico o farmacéutico incluso si se trata de efectos adversos que no aparecen en este prospecto. Ver sección 4.

Contenido del prospecto:

13. Contenido del envase e información adicional

1. Qué es Omeprazol *Kern Pharma* y para qué se utiliza

Omeprazol *Kern Pharma* contiene el principio activo omeprazol. Pertenece a un grupo de medicamentos denominados "inhibidores de la bomba de protones". Estos medicamentos actúan reduciendo la cantidad de ácido producida por el estómago.

Omeprazol *Kern Pharma* se utiliza para tratar las siguientes enfermedades:

En adultos:

- "Enfermedad por reflujo gastroesofágico" (ERGE). En este trastorno, el ácido del estómago pasa al esófago (el tubo que une la garganta con el estómago), provocando dolor, inflamación y ardor.
- Úlceras en la parte superior del intestino (úlcera duodenal) o en el estómago (úlcera gástrica).
- Úlceras infectadas por una bacteria llamada "*Helicobacter pylori"*. Si padece esta enfermedad, es posible que su médico le recete además antibióticos para tratar la infección y permitir que cicatrice la úlcera.
- Úlceras causadas por unos medicamentos denominados AINEs (antiinflamatorios no esteroideos). Omeprazol *Kern Pharma* puede usarse además para impedir la formación de úlceras si está tomando AINEs.
- Exceso de ácido en el estómago provocado por un tumor en el páncreas (síndrome de Zollinger-Ellison).

En niños:

Niños de más de 1 año de edad y ≥ 10 kg

- "Enfermedad por reflujo gastroesofágico" (ERGE). En este trastorno, el ácido del estómago pasa al esófago (el tubo que une la garganta con el estómago), provocando dolor, inflamación y ardor.

  En los niños, los síntomas de la enfermedad pueden incluir el retorno del contenido del estómago a la boca (regurgitación), vómitos y un aumento de peso insuficiente

Niños de más de 4 años de edad y adolescentes

- Úlceras infectadas por una bacteria llamada "*Helicobacter pylori"*. Si su hijo padece esta enfermedad, es posible que su médico le recete además antibióticos para tratar la infección y permitir que cicatrice la úlcera.

2. Qué necesita saber antes de empezar a tomar Omeprazol *Kern Pharma*

No tome Omeprazol *Kern Pharma*

- si es alérgico (hipersensible) al omeprazol o a cualquiera de los demás componentes de Omerpazol *Kern Pharma*.
- si es alérgico a medicamentos que contengan inhibidores de la bomba de protones (ej. pantoprazol, lansoprazol, rabeprazol, esomeprazol).
- si está tomando un medicamento que contenga nelfinavir (usado para la infección por VIH).

Advertencias y precauciones

Omeprazol *Kern Pharma* puede ocultar los síntomas de otras enfermedades. Por tanto, si experimenta cualquiera de las siguientes dolencias antes de empezar a tomar Omeprazol *Kern Pharma* o durante el tratamiento, consulte inmediatamente con su médico:

- Adelgaza mucho sin motivo aparente y tiene problemas para tragar.
- Tiene dolor de estómago o indigestión.
- Empieza a vomitar la comida o a vomitar sangre.
- Sus deposiciones son de color negro (heces teñidas de sangre).
- Si presenta diarrea grave o persistente, ya que se ha asociado el omeprazol a un ligero aumento de diarreas infecciosas.
- Tiene problemas de hígado graves.

- Si alguna vez ha tenido una reacción en la piel después del tratamiento con un medicamento similar a Omeprazol *Kern Pharma* para reducir la acidez de estógamo.
- Si está previsto que le realicen un análisis especifico de sangre (Cromogranina A).

Si sufre una erupción cutánea, especialmente en zonas de la piel expuestas al sol, consulte a su médico lo antes posible, ya que puede ser necesario interrumpir el tratamiento con Omeprazol *Kern Pharma*. Recuerde mencionar cualquier otro síntoma que pueda notar, como dolor en las articulaciones.

Si toma Omeprazol *Kern Pharma* durante un periodo largo (más de 1 año) probablemente su médico le realizará revisiones periódicas. Debe informar de cualquier síntoma y circunstancia nueva o inusual siempre que visite a su médico.

Uso de otros medicamentos

Informe a su médico o farmacéutico si está utilizando o ha utilizado recientemente otros medicamentos, incluso los adquiridos sin receta. Omeprazol *Kern Pharma* puede afectar al mecanismo de acción de algunos medicamentos y algunos medicamentos pueden afectar a Omeprazol *Kern Pharma*.

No tome Omeprazol *Kern Pharma* si está tomando un medicamento que contenga **nelfinavir** (usado para tratar la infección por VIH).

Informe a su médico o farmacéutico si está tomando alguno de los siguientes medicamentos:

- Ketoconazol, itraconazol o voriconazol (usados para tratar las infecciones por hongos)
- Digoxina (usada para el tratamiento de problemas de corazón)
- Diazepam (usado para tratar la ansiedad, relajar los músculos o en la epilepsia)

- Fenitoína (usada en la epilepsia). Si está tomando fenitoína, su médico tendrá que mantenerle controlado cuando empiece o termine el tratamiento con Omeprazol *Kern Pharma*
- Medicamentos empleados para impedir la formación de coágulos de sangre, como warfarina u otros antagonistas de la vitamina K. Su médico tendrá que mantenerle controlado cuando empiece o termine el tratamiento con Omeprazol *Kern Pharma*
- Rifampicina (se usa para tratar la tuberculosis)
- Atazanavir (usado para tratar la infección por VIH)
- Tacrolimús (en casos de trasplante de órganos)
- Hierba de San Juan (*Hypericum perforatum*) (usada para tratar la depresión leve)

- Cilostazol (usado para tratar la claudicación intermitente)
- Saquinavir (usado para tratar la infección por VIH)
- Clopidogrel (usado para prevenir los coágulos de sangre (trombos))

Si su médico, además de Omeprazol *Kern Pharma*, le ha recetado los antibióticos amoxicilina y claritromicina para tratar las úlceras causadas por la infección por *Helicobacter pylori*, es muy importante que le informe de los demás medicamentos que esté tomando.

Toma de Omeprazol *Kern Pharma* con los alimentos y bebidas

Puede tomar sus cápsulas con alimentos o con el estómago vacío.

Embarazo y lactancia

Antes de tomar Omeprazol *Kern Pharma*, informe a su médico si está embarazada o intentando quedarse embarazada. Su médico decidirá si puede tomar Omeprazol *Kern Pharma* durante ese tiempo.

Su médico decidirá si puede tomar Omeprazol *Kern Pharma* si está en periodo de lactancia.

Conducción y uso de máquinas

No es probable que Omeprazol *Kern Pharma* afecte a su capacidad para conducir o utilizar herramientas o máquinas. Pueden aparecer efectos adversos tales como mareo y alteraciones visuales (ver sección 4). Si ocurrieran, no debería conducir o utilizar máquinas.

Información importante sobre algunos de los componentes de Omeprazol *Kern Pharma*

Este medicamento contiene sacarosa. Si su médico le ha indicado que padece una intolerancia a ciertos azúcares, consulte con él antes de tomar este medicamento.

3. Cómo tomar Omeprazol *Kern Pharma*

Siga exactamente las instrucciones de administración de Omeprazol *Kern Pharma* indicadas por su médico.

Consulte a su médico o farmacéutico si tiene dudas.

Su médico le indicará cuántas cápsulas debe tomar y durante cuánto tiempo. Esto dependerá de su afección y de su edad.

Las dosis habituales se indican a continuación.

Adultos:

Tratamiento de los síntomas de la ERGE, como **ardor y regurgitación ácida:**

- Si su médico comprueba que tiene daños leves en el esófago, la dosis normal es de 20 mg una vez al día durante 4-8 semanas. Es posible que su médico le recete una dosis de 40 mg durante otras 8 semanas si el esófago todavía no ha cicatrizado.
- La dosis normal una vez cicatrizado el esófago es de 10 mg una vez al día.

- Si no tiene daños en el esófago, la dosis normal es de 10 mg una vez al día.

Tratamiento de las **úlceras de la parte superior del intestino** (úlcera duodenal):

- La dosis normal es de 20 mg una vez al día, durante 2 semanas. Es posible que su médico le receta esa misma dosis durante otras 2 semanas si la úlcera todavía no ha cicatrizado.
- Si la úlcera no cicatriza del todo, la dosis podrá aumentarse a 40 mg una vez al día durante 4 semanas.

Tratamiento de las **úlceras del estómago** (úlcera gástrica):

- La dosis normal es de 20 mg una vez al día durante 4 semanas. Es posible que su médico le recete esa misma dosis durante otras 4 semanas si la úlcera todavía no ha cicatrizado.
- Si la úlcera no cicatriza del todo, la dosis podrá aumentarse a 40 mg una vez al día durante 8 semanas.

Prevención de la reaparición de las **úlceras de estómago y duodeno**:

- La dosis normal es de 10 mg o 20 mg una vez al día. Puede que su médico aumente la dosis a 40 mg una vez al día.

Tratamiento de las úlceras de estómago y duodeno causadas por los AINEs (antiinflamatorios no esteroideos):

- La dosis normal es de 20 mg una vez al día durante 4-8 semanas.

Prevención de las úlceras de estómago y duodeno durante la administración de **AINEs:**

- La dosis normal es de 20 mg una vez al día.

Tratamiento de las **úlceras causadas** por la infección **por *Helicobacter pylori* y** prevención de su reaparición:

- La dosis normal es de 20 mg de Omeprazol *Kern Pharma* dos veces al día durante una semana.
- Su médico le indicará además que tome dos antibióticos de los siguientes: amoxicilina, claritromicina y metronidazol.

Tratamiento del exceso de ácido en el estómago provocado por un **tumor en el páncreas (síndrome de**

Zollinger-Ellison):

- La dosis habitual es de 60 mg al día.
- Su médico ajustará la dosis dependiendo de sus necesidades y decidirá además durante cuánto tiempo tiene que tomar el medicamento.

Niños:

Tratamiento de los síntomas de la ERGE, como **ardor y regurgitación ácida:**

- Los niños mayores de un año de edad que pesen más de 10 kg pueden tomar omeprazol. La dosis de los niños se basa en el peso corporal y el médico decidirá la dosis correcta.

Tratamiento de las **úlceras causadas** por la infección **por *Helicobacter pylori*** y prevención de su reaparición:

- Los niños mayores de 4 años pueden tomar omeprazol. La dosis de los niños se basa en el peso corporal y el médico decidirá la dosis correcta.

– El médico recetará además a su hijo dos antibióticos, amoxicilina y claritromicina.

Cómo tomar este medicamento

– Se recomienda tomar las cápsulas por la mañana.

– Puede tomar sus cápsulas con alimentos o con el estómago vacío.

– Trague las cápsulas enteras con medio vaso de agua. No mastique ni triture las cápsulas, ya que contienen gránulos recubiertos que impiden que el medicamento se descomponga por la acción del ácido del estómago. Es importante no dañar los gránulos.

Qué debe hacer si usted o su hijo tienen problemas para tragar las cápsulas

– Si usted o su hijo tienen problemas para tragar las cápsulas:

  - Abra las cápsulas y trague el contenido directamente con medio vaso de agua o vierta el contenido en un vaso de agua sin gas, un zumo de frutas ácido (p. ej., manzana, naranja o piña) o compota de manzana.
  - Agite siempre la mezcla justo antes de beberla (la mezcla no será transparente). A continuación, bébase la mezcla inmediatamente o en el plazo de 30 minutos.
  - Para asegurarse de que se ha tomado todo el medicamento, llene el vaso de agua hasta la mitad, enjuáguelo bien y bébase el agua. Las partes sólidas contienen el medicamento; no las mastique ni las triture.

Si toma más Omeprazol *Kern Pharma* del que debiera

Si ha tomado más Omeprazol *Kern Pharma* del recetado por su médico, consulte inmediatamente a su médico o farmacéutico. También puede llamar al Servicio de Información Toxicológica, teléfono 91 562 04 20 indicando el medicamento y la cantidad ingerida.

Si olvidó tomar Omeprazol *Kern Pharma*

Si se olvidó de tomar una dosis, tómela en cuanto se acuerde. No obstante, si queda poco tiempo para la toma siguiente, sáltese la dosis olvidada. No tome una dosis doble para compensar las dosis olvidadas.

4. Posibles efectos adversos

Al igual que todos los medicamentos, Omeprazol *Kern Pharma* puede producir efectos adversos, aunque no todas las personas los sufran.

Si aprecia alguno de los siguientes efectos adversos raros pero graves, deje de tomar Omeprazol *Kern Pharma* y consulte al médico inmediatamente:

- Silbidos repentinos al respirar (sibilancias repentinas), hinchazón de los labios, la lengua y la garganta o del cuerpo, erupción en la piel, desmayo o dificultades al tragar (reacción alérgica grave).
- Enrojecimiento de la piel con formación de ampollas o descamación. También podrían aparecer ampollas intensas y sangrado en los labios, los ojos, la boca, la nariz y los genitales. Podría tratarse de "síndrome de Stevens-Johnson" o "necrólisis epidérmica tóxica".
- Coloración amarilla de la piel, orina oscura y cansancio, que pueden ser síntomas de problemas del hígado.

Los efectos adversos pueden ocurrir con determinadas frecuencias, que se definen tal y como se indica a continuación:

Muy frecuentes:	afectan a más de 1 paciente de cada 10
Frecuentes:	afectan de 1 a 10 pacientes de cada 100
Poco frecuentes:	afectan de 1 a 10 pacientes de cada 1.000
Raras:	afectan de 1 a 10 pacientes de cada 10.000
Muy raras:	afectan a menos de 1 paciente de cada 10.000
No conocidas:	No se puede determinar la frecuencia a partir de los datos disponibles

Otros efectos adversos son:

Efectos adversos frecuentes

- Dolor de cabeza.
- Efectos en el estómago o el intestino: diarrea, dolor de estómago, estreñimiento y gases (flatulencia).
- Náuseas o vómitos.
- Pólipos benignos en el estómago

Efectos adversos poco frecuentes

- Hinchazón de los pies y los tobillos.

- Trastornos del sueño (insomnio).

- Mareo, sensación de hormigueo, somnolencia.
- Sensación de que todo da vueltas (vértigo).
- Alteraciones de los análisis de sangre que sirven para comprobar el funcionamiento del hígado.
- Erupción en la piel, habones y picores.
- Sensación de malestar general y falta de energía.

Efectos adversos raros

- Problemas en la sangre, como disminución de los glóbulos blancos o las plaquetas. Esto puede causar debilidad o hematomas y aumentar la probabilidad de contraer infecciones.
- Reacciones alérgicas, a veces muy intensas, que incluyen hinchazón de los labios, la lengua y la garganta, fiebre y sibilancias.
- Concentración baja de sodio en la sangre. Puede provocar debilidad, vómitos y calambres.
- Agitación, confusión o depresión.
- Alteraciones del gusto.
- Problemas visuales, como visión borrosa.
- Sensación repentina de respiración dificultosa (broncoespasmo).
- Sequedad de boca.
- Inflamación del interior de la boca.
- Infección denominada “candidiasis” que puede afectar al intestino y que está provocada por un hongo.
- Problemas de hígado, como ictericia, que pueden causar color amarillo de la piel, orina oscura y cansancio.
- Caída del cabello (alopecia).
- Erupción en la piel con la exposición a la luz solar.
- Dolor articular (artralgias) o dolor muscular (mialgias).
- Problemas graves de riñón (nefritis intersticial).
- Aumento de la sudoración.

Efectos adversos muy raros

- Alteraciones del recuento sanguíneo, como agranulocitosis (falta de glóbulos blancos).
- Agresividad.
- Ver, sentir u oír cosas que no existen (alucinaciones).
- Problemas graves de hígado que provocan insuficiencia hepática e inflamación del cerebro.
- Aparición repentina de una erupción intensa, formación de ampollas o descamación de la piel. Puede acompañarse de fiebre alta y dolores articulares (eritema multiforme, síndrome de Stevens-Johnson, necrólisis epidérmica tóxica).
- Debilidad muscular.
- Aumento del tamaño de las mamas en los varones.

En casos muy raros Omeprazol *Kern Pharma* puede afectar a los glóbulos blancos de la sangre y provocar una inmunodeficiencia. Si padece una infección con síntomas como fiebre con un estado general **muy** deteriorado o fiebre con síntomas de infección local, como dolor de cuello, garganta o boca o dificultades para orinar, deberá consultar a su médico lo antes posible para realizar un análisis de sangre y poder descartar una carencia de glóbulos blancos (agranulocitosis). Es importante que en ese momento proporcione información acerca del medicamento que esté tomando.

Frecuencia no conocida

Si usted está tomando omeprazol durante más de tres meses es posible que los niveles de magnesio en sangre puedan descender. Los niveles bajos de magnesio pueden causar fatiga, contracciones musculares involuntarias, desorientación, convulsiones, mareos, aumento del ritmo cardiaco. Si usted tiene algunos de estos síntomas, acuda al médico inmediatamente. Niveles bajos de magnesio también pueden producir una disminución de los niveles de potasio y calcio en sangre. Su médico le puede decidir realizar análisis de sangre periódicos para controlar los niveles de magnesio.

Si está tomando inhibidores de la bomba de protones como omeprazol, especialmente durante un periodo de más de un año puede aumentar ligeramente el riesgo de fractura de cadera, muñeca y columna vertebral. Informe a su médico si tiene osteoporosis o si está tomando corticosteroides (pueden incrementar el riesgo de osteoporosis).

Puede presentar erupción cutánea, posiblemente con dolor en las articulaciones.

Comunicación de efectos adversos

Si experimenta cualquier tipo de efecto adverso, consulte con su médico o farmacéutico, incluso si se trata de posibles efectos adversos que no aparecen en este prospecto. También puede comunicarlos directamente a través del Sistema Español de Farmacovigilancia de Medicamentos de uso humano: www.notificaRAM.es. Mediante la comunicación de efectos adversos puede contribuir a proporcionar más información sobre la seguridad de este medicamento.

5. Conservación de Omeprazol *Kern Pharma*

Mantener este medicamento fuera de la vista y del alcance de los niños.

No utilice Omeprazol *Kern Pharma* después de la fecha de caducidad que aparece en el envase después de CAD. La fecha de caducidad es el último día del mes que se indica.

Frasco:

No requiere condiciones especiales de conservación.

Blister:

No conservar a temperatura superior a 30ºC.

Conservar este blíster en el embalaje original para protegerlo de la humedad

Los medicamentos no se deben tirar por los desagües ni a la basura. Deposite los envases y los

medicamentos que no necesita en el Punto SIGRE de la farmacia. En caso de duda pregunte a su farmacéutico cómo deshacerse de los envases y de los medicamentos que no necesita. De esta forma ayudará a proteger el medio ambiente.

6. Contenido del envase e información adicional

Composición de Omeprazol *Kern Pharma*

- El principio activo es omeprazol. Omeprazol *Kern Pharma* cápsulas contiene 20 mg de omeprazol.
- Los demás componentes (excipientes) son esferas de azúcar (sacarosa y almidón de maíz), hipromelosa (E-464), fosfato disódico dihidrato, talco (E-533b), dióxido de titanio (E171), dispersión al 30% de copolímero del ácido metracrílico acrilato de etilo (1:1) y trietilcitrato (E-1050), cápsula de gelatina (conteniendo dióxido de titanio (E-171), agua y gelatina), tinta de impresión (conteniendo laca, alcohol etílico, alcohol isopropílico, propilenglicol, alcohol n-butílico, hidróxido de amonio, hidróxido de potasio, agua purificada y óxido de hierro negro (E172)).

Aspecto del producto y contenido del envase

Las cápsulas de Omeprazol *Kern Pharma*, 20 mg están formadas por un cuerpo y una tapa de color blanco, y contienen gránulos con recubrimiento entérico.

Tamaños de los envases: Frasco de HDPE blanco con tapón y anillo de seguridad, equipado con sílica gel, un agente desecante: 28 cápsulas. Blisters de 14, 28 ó 56 cápsulas.

Puede que solamente estén comercializados algunos tamaños de envases.

Titular de la autorización de comercialización

Kern Pharma, S.L.

Venus, 72 - Pol. Ind. Colón II

08228 Terrassa (Barcelona)

España

Responsable de la fabricación

Laboratorios Dr. Esteve S.A.

C/ Sant Martí, s/n. Polígono Ind. La Roca

08107 Martorelles (Barcelona)

Este prospecto ha sido aprobado en Enero 2013

Fecha de la última revisión de este prospecto: Septiembre 2016

La información detallada y actualizada de este medicamento está disponible en la página Web de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) http://www.aemps.gob.es/

PARACETAMOL

Prospecto: Información para el usuario

***Paracetamol Kern Pharma* 1 g comprimidos EFG**

Lea todo el prospecto detenidamente antes de empezar a tomar este medicamento, porque contiene información importante para usted.

- Conserve este prospecto, ya que puede tener que volver a leerlo.
- Si tiene alguna duda, consulte a su médico o farmacéutico.
- Este medicamento se le ha recetado solamente a usted, y no debe dárselo a otras personas aunque tengan los mismos síntomas que usted, ya que puede perjudicarles.
- Si experimenta efectos adversos, consulte a su médico o farmacéutico, incluso si se trata de efectos adversos que no aparecen en este prospecto.

Contenido del prospecto:

1. Qué es *Paracetamol Kern Pharma* y para qué se utiliza

Paracetamol Kern Pharma pertenece al grupo de medicamentos llamados analgésicos y antipiréticos.

Está indicado para el alivio o tratamiento del dolor ocasional leve o moderado, como dolor de cabeza, dental, muscular (contracturas) o de espalda (lumbago) y en estados febriles.

Debe consultar al médico si los síntomas empeoran o persisten después de 5 días o la fiebre más de 3 días.

2. Qué necesita saber antes de empezar a tomar *Paracetamol Kern Pharma*

No tome *Paracetamol Kern Pharma*

- Si es alérgico al *Paracetamol* o a cualquiera de los demás componentes de *Paracetamol Kern Pharma*.
- Si padece alguna enfermedad en el hígado.

Advertencias y precauciones

- No tomar más dosis de la recomendada.
- Si padece enfermedad del riñón, corazón o del pulmón, o tiene anemia (disminución de la tasa de hemoglobina en la sangre, a causa o no de una disminución de glóbulos rojos), debe consultar con su médico antes de tomar este medicamento.
- En alcohólicos crónicos se deberá tener la precaución de no tomar más de 2 g/día de *Paracetamol*.
- Si el dolor se mantiene durante más de 5 días, la fiebre más de 3 días o bien el dolor o la fiebre empeoran o aparecen otros síntomas, hay que interrumpir el tratamiento y consultar al médico.
- En niños y adolescentes menores de 15 años consulte a su médico o farmacéutico ya que existen otras presentaciones con dosis que se adaptan a este grupo de pacientes.

Uso de *Paracetamol Kern Pharma* con otros medicamentos

Informe a su médico o farmacéutico si está utilizando o ha utilizado recientemente cualquier otro medicamento, incluso los adquiridos sin receta médica.

El *Paracetamol* puede tener interacciones con los siguientes medicamentos:

- Antibióticos (cloranfenicol)
- Anticoagulantes (utilizados para el tratamiento de enfermedades tromboembólicas)
- Antiepilépticos (utilizados para el tratamiento de las crisis epilépticas)
- Anticonceptivos
- Diuréticos (utilizados para aumentar la eliminación de orina)
- Isoniazida (utilizado para el tratamiento de la tuberculosis)
- Lamotrigina (utilizado para el tratamiento de la epilepsia)
- Probenecid (utilizado para el tratamiento de la gota)
- Propranolol (utilizado para el tratamiento de la hipertensión, arritmias cardíacas)
- Rifampicina (utilizado para el tratamiento de la tuberculosis)
- Anticolinérgicos (utilizados para el alivio de espasmos o contracciones de estómago, intestino y vejiga)
- Zidovudina (utilizado para el tratamiento de las infecciones por VIH)
- Colestiramina (utilizado *para disminuir los niveles de colesterol en sangre)*

No utilizar con otros analgésicos (medicamentos que disminuyen el dolor) sin consultar al médico.

Como norma general para cualquier medicamento es recomendable informar sistemáticamente al médico o farmacéutico si está en tratamiento con otros medicamentos. En caso de tratamiento con anticoagulantes orales se puede administrar ocasionalmente como analgésico de elección.

Interferencias con pruebas analíticas

Si le van a realizar alguna prueba diagnóstica (incluidos análisis de sangre, orina, pruebas cutáneas que utilizan alergenos, etc...) comunique al médico que está tomando este medicamento, ya que puede alterar los resultados.

Uso de *Paracetamol Kern Pharma* con alimentos y bebida

La utilización de *Paracetamol* en pacientes que consumen habitualmente alcohol (tres o más bebidas alcohólicas al día – cerveza, vino, licor…al día) puede provocar daño en el hígado.

Embarazo y lactancia

Embarazo

Consulte a su médico o farmacéutico antes de utilizar cualquier medicamento.

Si está usted embarazada o cree que pudiera estarlo, consulte a su médico antes de tomar este medicamento. El consumo de medicamentos durante el embarazo puede ser peligroso para el embrión o el feto, y debe ser vigilado por su médico.

Lactancia

Consulte a su médico o farmacéutico antes de utilizar cualquier medicamento.

Pueden aparecer pequeñas cantidades de *Paracetamol* en la leche materna, por lo tanto, se recomienda que consulte a su médico o farmacéutico antes de utilizar este medicamento.

Conducción y uso de máquinas

No se ha descrito ningún efecto que modifique la capacidad de conducción y de manejo de maquinaria.

3. Cómo tomar *Paracetamol Kern Pharma*

Siga exactamente las instrucciones de administración del medicamento contenidas en este prospecto o las indicadas por su médico, farmacéutico o enfermero. En caso de duda pregunte a su médico, farmacéutico o enfermero.

La dosis recomendada es:

Adultos y niños mayores de 15 años: 1 comprimido (1 g de *Paracetamol*) 3–4 veces al día. Las tomas deben espaciarse al menos 4 horas. No se tomarán más de 4 comprimidos (4 g) en 24 horas.

Pacientes con enfermedad en el hígado o riñón: deben consultar a su médico.

Pacientes de edad avanzada: deben consultar a su médico.

Cuando se requiera la administración de dosis inferiores a 1 g de *Paracetamol* por toma se deberán emplear otras presentaciones de *Paracetamol* que se adapten a la dosificación requerida.

La ranura sirve únicamente para partir el comprimido si le resulta difícil tragarlo entero. *Paracetamol Kern Pharma* debe tomarse por vía oral. Según sus preferencias, los comprimidos se pueden ingerir directamente o partidos por la mitad con agua u otro líquido.

Si se estima que la acción de este medicamento es demasiado fuerte o débil, comuníqueselo a su médico o farmacéutico.

Si toma más *Paracetamol Kern Pharma* del que debiera

Si usted ha tomado más *Paracetamol* del que debiera, consulte inmediatamente a su médico o farmacéutico, o llame al Servicio de Información Toxicológica, teléfono: 91 562 04 20, indicando el medicamento y la cantidad ingerida.

Si se ha tomado una sobredosis, debe acudir inmediatamente a un centro médico aunque no haya síntomas, ya que a menudo no se manifiestan hasta pasados tres días desde la toma de la sobredosis, aún en casos de intoxicación grave.

Los síntomas de sobredosis pueden ser: mareos, vómitos, pérdida de apetito, coloración amarillenta de la piel y los ojos (ictericia) y dolor abdominal.

El tratamiento de la sobredosis es más eficaz si se inicia dentro de las 4 horas siguientes a la toma del medicamento.

Los pacientes en tratamiento con barbitúricos o que padezcan alcoholismo crónico pueden ser más susceptibles a una sobredosis de *Paracetamol*.

Si olvidó tomar *Paracetamol Kern Pharma*

No tome una dosis doble para compensar las dosis olvidadas, simplemente tome la dosis olvidada cuando se acuerde, tomando las siguientes dosis con la separación entre tomas indicada en cada caso (al menos 4 horas).

Si tiene cualquier otra duda sobre el uso de este producto, pregunte a su médico o farmacéutico.

4. Posibles efectos adversos

Al igual que todos los medicamentos, *Paracetamol Kern Pharma* puede producir efectos adversos, aunque no todas las personas los sufran.

Paracetamol Kern Pharma puede producir los siguientes efectos adversos:

- Raros (pueden afectar **hasta** 1 de cada 1.000 personas): malestar y bajada de tensión.
- Muy raros (pueden afectar **hasta** 1 de cada 10.000 pacientes): reacciones alérgicas (como reacciones cutáneas), bajada de glucosa, alteraciones sanguíneas, y alteraciones del hígado y del riñón.

Se han notificado muy raramente casos de reacciones graves en la piel.

Si considera que alguno de los efectos adversos que sufre es grave o si aprecia cualquier efecto adverso no mencionado en este prospecto, informe a su médico o farmacéutico.

5. Conservación de *Paracetamol Kern Pharma*

Mantener fuera de la vista y del alcance de los niños.

Este medicamento no requiere condiciones especiales de conservación.

No utilice este medicamento después de la fecha de caducidad que aparece en el envase después de "CAD".

La fecha de caducidad es el último día del mes que se indica.

Los medicamentos no se deben tirar por los desagües ni a la basura. Deposite los envases y los medicamentos que no necesita en el Punto SIGRE de la farmacia. En caso de duda pregunte a su farmacéutico cómo deshacerse de los envases y de medicamentos que no necesita. De esta froma ayudará a proteger el medio ambiente.

6. Contenido del envase e información adicional

Composición de *Paracetamol Kern Pharma*

- El principio activo es *Paracetamol*. Cada comprimido tiene 1 g de *Paracetamol*.
- Los demás componentes son: almidón pregelatinizado de maíz, ácido esteárico y povidona.

Aspecto del producto y contenido del envase

Paracetamol Kern Pharma 1 g se presenta en comprimidos para administración oral. Los comprimidos son blancos, oblongos y ranurados en una de las caras. Las cajas son de 20 ó 40 comprimidos acondicionados en blister de PVC/aluminio.

Titular de la autorización de comercialización y responsable de la fabricación

Kern Pharma, S.L.

Venus, 72 - Pol. Ind. Colón II

08228 Terrassa - Barcelona

España

Fecha de la última revisión de este prospecto: Diciembre 2015.

La información detallada y actualizada de este medicamento está disponible en la página web de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) http://www.aemps.gob.es/

AMOXICILINA

Prospecto: Información para el usuario

Amoxicilina *Kern Pharma* 500 mg cápsulas duras EFG

Lea todo el prospecto detenidamente antes de empezar a tomar este medicamento, porque contiene información importante para usted.

- Conserve este prospecto, ya que puede tener que volver a leerlo.
- Si tiene alguna duda, consulte a su médico o farmacéutico.
- Este medicamento se le ha recetado solamente a usted (o a su hijo), y no debe dárselo a otras personas aunque tengan los mismos síntomas que usted, ya que puede perjudicarles.
- Si experimenta efectos adversos, consulte a su médico o farmacéutico, incluso si se trata de efectos adversos que no aparecen en este prospecto. Ver sección 4.

Contenido del prospecto:

1. Qué es Amoxicilina *Kern Pharma* y para qué se utiliza

Qué es Amoxicilina *Kern Pharma*

Amoxicilina *Kern Pharma* es un antibiótico. El principio activo es amoxicilina. Este pertenece a un grupo

de medicamentos denominados “penicilinas”.

Los antibióticos se utilizan para tratar infecciones bacterianas y no sirven para tratar infecciones víricas como la gripe o el catarro.

Es importante que siga las instrucciones relativas a la dosis, el intervalo de administración y la duración del tratamiento indicadas por su médico.

No guarde ni reutilice este medicamento. Si una vez finalizado el tratamiento le sobra antibiótico, devuélvalo a la farmacia para su correcta eliminación. No debe tirar los medicamentos por el desagüe ni a la basura.

Para qué se utiliza Amoxicilina *Kern Pharma*

Amoxicilina *Kern Pharma* se utiliza para tratar infecciones causadas por bacterias en distintas partes del cuerpo. Amoxicilina *Kern Pharma* también se puede usar en combinación con otros medicamentos para tratar úlceras de estómago.

- **Qué necesita saber antes de empezar a tomar Amoxicilina**

Kern Pharma* No tome Amoxicilina *Kern Pharma

– si es alérgico a la amoxicilina, penicilinas o a cualquiera de los demás componentes de este medicamento (incluidos en la sección 6)

– si alguna vez ha tenido una reacción alérgica a cualquier otro antibiótico. Esto podría incluir erupción en la piel o hinchazón de la cara o la garganta

No tome amoxicilina si alguno de los puntos anteriores le afecta. Si no está seguro, consulte con su médico o farmacéutico antes de tomar este medicamento.

Advertencias y precauciones

Consulte a su médico o farmacéutico antes de tomar amoxicilina si:

– tiene mononucleosis infecciosa (fiebre, dolor de garganta, glándulas hinchadas y cansancio extremo)
– tiene problemas de riñón
– no orina regularmente.

Si no está seguro de si alguna de las situaciones anteriores le afectan, informe a su médico o farmacéutico antes de tomar amoxicilina.

Análisis de sangre y orina

Si se le están realizando:

– análisis de orina (glucosa en orina) o análisis de sangre para la función hepática

– análisis de estriol (utilizado durante el embarazo para comprobar si el bebé se desarrolla de forma normal).

Informe a su médico o farmacéutico de que está tomando amoxicilina. Esto es porque amoxicilina puede alterar los resultados de estos tipos de análisis.

Uso de Amoxicilina *Kern Pharma* con otros medicamentos

Informe a su médico o farmacéutico si está utilizando, ha utilizado recientemente o podría tener que utilizar cualquier otro medicamento.

– Si está tomando alopurinol (usado para la gota) con amoxicilina, puede ser más probable que sufra una reacción alérgica en la piel.

– Si está tomando probenecid (usado para la gota), su médico puede que le ajuste la dosis de amoxicilina.

– Si está tomando anticoagulantes (como la warfarina) con amoxicilina pueden ser necesarios más análisis de sangre.

– Si está tomando otros antibióticos (como tetraciclina) amoxicilina puede ser menos eficaz.

– Si está tomando metotrexato (usado para el tratamiento del cáncer y psoriasis severa) amoxicilina puede producir un aumento en los efectos adversos.

Embarazo y lactancia

Si está embarazada o en periodo de lactancia, cree que podría estar embarazada o tiene intención de quedarse embarazada, consulte a su médico o farmacéutico antes de utilizar este medicamento.

Conducción y uso de máquinas

Amoxicilina puede tener efectos adversos y los síntomas (como reacciones alérgicas, mareos y convulsiones) pueden hacer que no deba conducir.

No conduzca o maneje maquinaria a no ser que se encuentre bien.

Información importante sobre alguno de los componentes de Amoxicilina *Kern Pharma*

Este medicamento puede producir reacciones alérgicas porque contiene carmoisina (azorrubina, E-122).

Puede provocar asma, especialmente en pacientes alérgicos al ácido acetilsalicílico.

3. Cómo tomar Amoxicilina *Kern Pharma*

Siga exactamente las instrucciones de administración de este medicamento indicadas por su médico o farmacéutico. En caso de duda, consulte de nuevo a su médico o farmacéutico.

- Trague las cápsulas con agua, sin abrirlas.
- Espacie las dosis uniformemente durante el día, al menos separadas 4 horas.

La dosis habitual es:

Niños de menos de 40 kg de peso

Todas las dosis se basan en el peso corporal del niño en kilogramos.

- Su médico le indicará cuánta amoxicilina debe administrar a su bebé o niño.
- La dosis habitual es de 40 mg a 90 mg por cada kilogramo de peso corporal al día, administrado en dos o tres dosis divididas.
- La dosis máxima recomendada es de 100 mg por cada kilogramo de peso corporal al día.

Adultos, pacientes de edad avanzada y niños de 40 kg de peso o más

La dosis habitual de amoxicilina es de 250 mg a 500 mg tres veces al día o de 750 mg a 1 g cada 12 horas, dependiendo de la gravedad y del tipo de infección.

- **Infecciones graves:** de 750 mg a 1 g tres veces al día.
- **Infección del tracto urinario:** 3 g dos veces al día, durante un día.

– **Enfermedad de Lyme (una infección producida por unos parásitos llamados garrapatas):** eritema
migrans aislado (etapa temprana – erupción circular rosa o roja): 4 g al día; manifestaciones sistémicas

(etapa tardía – con síntomas más graves o cuando la enfermedad se disemina por su cuerpo): hasta 6 g al día.

– **Úlceras de estómago:** una dosis de 750 mg o una dosis de 1 g, dos veces al día, durante 7 días con otros antibióticos y medicamentos para tratar las úlceras de estómago.

– **Para prevenir infección del corazón durante la cirugía:** la dosis variará dependiendo del tipo de cirugía. Se pueden administrar otros medicamentos al mismo tiempo. Su médico, farmacéutico o enfermero le podrán dar más detalles.
– La dosis máxima recomendada es de 6 g al día.

Problemas renales

Si tiene problemas renales, la dosis puede ser inferior a la dosis habitual.

Si toma más Amoxicilina *Kern Pharma* del que debe

Si ha tomado más amoxicilina de la que debe, los signos pueden ser malestar de estómago (náuseas, vómitos o diarrea) o cristales en la orina, que puede observarse como orina turbia o problemas para orinar. Hable con su médico lo antes posible. Lleve el medicamento para enseñárselo. También puede llamar al Servicio de Información Toxicológica, teléfono 91 562 04 20, indicando el medicamento y la cantidad ingerida.

Si olvidó tomar Amoxicilina *Kern Pharma*

– Si olvida tomar una dosis, tómela tan pronto como se acuerde.
– No tome la siguiente dosis demasiado pronto, espere al menos 4 horas antes de tomar la siguiente dosis.
– No tome una dosis doble para compensar las dosis olvidadas.

Cuánto tiempo debe tomar Amoxicilina *Kern Pharma*

– Continúe tomando amoxicilina durante el tiempo que su médico le haya dicho, aunque se encuentre mejor. Necesita tomar todas las dosis para vencer la infección. Si algunas bacterias sobreviven pueden hacer que la infección reaparezca.
– Una vez que termine el tratamiento, si se sigue encontrando mal debe volver a ir a ver a su médico.

Puede aparecer candidiasis (una infección por hongos de las partes húmedas del cuerpo que puede causar dolor, picor y secreción blanca) si se toma amoxicilina durante un tiempo prolongado. Si esto le ocurre, consulte a su médico.

Si toma amoxicilina durante un tiempo prolongado, su médico puede realizarle análisis adicionales para comprobar que sus riñones, hígado y sangre funcionan de forma normal.

Si tiene cualquier otra duda sobre el uso de este medicamento, pregunte a su médico o farmacéutico.

4. Posibles efectos adversos

Al igual que todos los medicamentos, este medicamento puede producir efectos adversos, aunque no todas las personas los sufran.

Deje de tomar amoxicilina y vaya a ver a un médico inmediatamente si sufre cualquiera de los siguientes efectos adversos graves – puede necesitar tratamiento médico urgente:

Los siguientes efectos adversos son muy raros (pueden afectar hasta 1 de cada 10.000 personas)

– reacciones alérgicas, los signos pueden incluir: picor de la piel o erupción, hinchazón de la cara, labios, lengua, cuerpo o dificultades para respirar. Estos pueden ser graves y, en algunas ocasiones, se han producido muertes.

– erupción en la piel o puntos redondos rojos planos como la punta de un alfiler bajo la superficie de la piel o moratones en la piel. Esto es debido a la inflamación de las paredes de los vasos sanguíneos debido a una reacción alérgica. Puede estar asociada a dolor de las articulaciones (artritis) y a problemas en los riñones.

– puede aparecer una reacción alérgica retrasada al cabo de 7 a 12 días tras tomar Amoxicilina *Kern Pharma*, algunos signos incluyen: erupciones, fiebre, dolor de las articulaciones y agrandamiento de los nódulos linfáticos especialmente bajo los brazos.

– una reacción de la piel llamada ‘eritema multiforme’ en la que puede desarrollar: ronchas moradas o rojizas con picor en la piel, especialmente en las palmas de las manos o en las

plantas de los pies, áreas hinchadas abultadas en la piel, tejidos blandos en la superficie de la boca, ojos y genitales. Puede tener fiebre y estar muy cansado.

- otras reacciones de la piel graves pueden incluir: cambio en el color de la piel, bultos bajo la piel, ampollas, granos con pus, descamación, enrojecimiento, dolor, picor. Estas pueden estar asociadas a fiebre, dolor de cabeza y dolor corporal.

- síntomas de tipo gripal con erupción cutánea, fiebre, inflamación de glándulas y resultados anormales en los análisis de sangre (como aumento de los leucocitos (eosinofilia) y elevación de las enzimas hepáticas) (reacción medicamentosa con eosinofilia y síntomas sistémicos (DRESS)).

- fiebre, escalofríos, dolor de garganta u otros signos de infección, o aparición de moratones con facilidad. Estos pueden ser signos de un problema con sus células de la sangre.

- reacción de *Jarisch-Herxheimer* que ocurre durante el tratamiento con Amoxicilina *Kern Pharma* para la enfermedad de Lyme y causa fiebre, escalofríos, dolor de cabeza, dolor muscular y erupción en la piel.

- inflamación del intestino grueso (colon) con diarrea (algunas veces con sangre), dolor y fiebre.

- pueden aparecer efectos adversos graves en el hígado. Estos están asociados principalmente a pacientes con tratamientos prolongados, a hombres y a la edad avanzada. Debe avisar a su médico inmediatamente si tiene:

  - diarrea grave con sangrado

  - ampollas, enrojecimiento o moratones en la piel
  - orina oscura o heces pálidas

  - la piel y el blanco de los ojos de color amarillento (ictericia). Ver también anemia más abajo que puede dar lugar a ictericia.

Estos pueden ocurrir durante el tratamiento o hasta varias semanas después.

Si cualquiera de los anteriores síntomas aparece deje de tomar el medicamento y vaya a ver a su médico inmediatamente.

Algunas veces puede sufrir reacciones cutáneas menos graves como:

- una erupción moderada con picor (ronchas redondas, de color rosado - rojo), áreas hinchadas con aspecto de ampollas en antebrazos, piernas, palmas, manos o pies. Esto es poco frecuente (puede afectar hasta 1 de cada 100 personas).

Si tiene cualquiera de ellos hable con su médico dado que tendrá que interrumpir su tratamiento con Amoxicilina *Kern Pharma*.

Otros posibles efectos adversos son:

Frecuentes (pueden afectar hasta 1 de cada 10 personas)

- erupción cutánea.
- náuseas.
- diarrea.

Poco frecuentes (pueden afectar hasta 1 de cada 100 personas)

- vómitos.

Muy raros (pueden afectar hasta 1 de cada 10.000 personas)

- candidiasis (infección por hongos en la vagina, boca o pliegues de la piel), puede obtener tratamiento de su médico o farmacéutico para la candidiasis.
- problemas de riñón.
- ataques epilépticos (convulsiones), observados en pacientes tratados con dosis altas o con problemas de riñón.
- mareos.
- hiperactividad.
- cristales en la orina, que pueden aparecer como orina turbia o dificultad o molestias al orinar. Asegúrese de beber mucho líquido para reducir la posibilidad de estos síntomas.
- la lengua puede cambiar de color a amarillo, marrón o negro y puede tener aspecto piloso
- una rotura excesiva de glóbulos rojos que provoca un tipo de anemia. Los signos incluyen: cansancio, dolor de cabeza, dificultad para respirar, mareos, palidez y coloración amarillenta de la piel y del blanco de los ojos.
- bajo número de glóbulos blancos.
- bajo número de células implicadas en la coagulación de la sangre.
- la sangre puede tardar más de lo normal en coagular. Puede apreciar esto si le sangra la nariz o se corta.

Comunicación de efectos adversos

Si experimenta cualquier tipo de efecto adverso, consulte a su médico, farmacéutico o enfermero, incluso si se trata de posibles efectos adversos que no aparecen en este prospecto. También puede comunicarlos

directamente a través del Sistema Español de Farmacovigilancia de Medicamentos de Uso Humano: https://www.notificaram.es. Mediante la comunicación de efectos adversos usted puede contribuir a proporcionar más información sobre la seguridad de este medicamento.

5. Conservación de Amoxicilina *Kern Pharma*

Mantener este medicamento fuera de la vista y del alcance de los niños.

No conservar a temperatura superior a 30ºC. Conservar en el embalaje original.

No utilice este medicamento después de la fecha de caducidad que aparece en el envase después de "CAD".

La fecha de caducidad es el último día del mes que se indica.

Los medicamentos no se deben tirar por los desagües ni a la basura. Deposite los envases y los medicamentos que no necesita en el Punto SIGRE de la farmacia. En caso de duda pregunte a su farmacéutico cómo deshacerse de los envases y de los medicamentos que no necesita. De esta forma ayudará a proteger el medio ambiente.

6. Contenido del envase e información adicional

Composición de Amoxicilina *Kern Pharma*

- El principio activo es amoxicilina. Cada cápsula contiene 500 mg de amoxicilina.
- Los demás componentes (excipientes) son: estearato de magnesio y celulosa microcristalina. Cada

  cápsula de gelatina contiene: gelatina, dióxido de titanio (E-171), lauril sulfato sódico y como colorantes óxido de hierro amarillo (E-172), azul patente V (E-131) y carmoisina (azorrubina, E-122).

Aspecto del producto y contenido del envase

Amoxicilina *Kern Pharma* 500 mg cápsulas son cápsulas de gelatina dura de cabeza color granate con "A" impreso y cuerpo amarillo con "86" impreso. Se acondicionan en un blister PVC/Aclar/Aluminio en un estuche. Está disponible en envases de 20 y 30 cápsulas.

Titular de la autorización de comercialización y responsable de la fabricación *Kern Pharma*, S.L.

Venus, 72 - Pol. Ind. Colón II

08228 Terrassa - Barcelona

España

Fecha de la última revisión de este prospecto: Octubre 2017.

La información detallada y actualizada de este medicamento está disponible en la página Web de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) http://www.aemps.gob.es/

Consejo general con respecto al uso de antibióticos

Los antibióticos se usan para el tratamiento de las infecciones bacterianas. No son eficaces contra las infecciones víricas.

A veces una infección causada por bacterias no responde al tratamiento antibiótico. Una de las razones más comunes por las que esto ocurre es porque las bacterias que causan la infección son resistentes al antibiótico que se está tomando. Esto significa que las bacterias pueden sobrevivir o crecer a pesar del antibiótico.

Las bacterias pueden hacerse resistentes a los antibióticos por muchas razones. Utilizar los antibióticos adecuadamente puede reducir las posibilidades de que las bacterias se hagan resistentes a ellos.

Cuando su médico le receta un antibiótico es únicamente para tratar su enfermedad actual. Prestar atención a los siguientes consejos le ayudará a prevenir la aparición de bacterias resistentes que pueden hacer que el antibiótico no actúe:

- Es muy importante que tome el antibiótico en la dosis adecuada, a las horas indicadas y durante el correcto número de días. Lea las instrucciones del prospecto y, si no entiende algo, pregunte a su médico o farmacéutico.

- No debe tomar un antibiótico a no ser que se le haya recetado especialmente a usted y debe usarlo solo para la infección para la que se lo han recetado.
- No debe tomar antibióticos que le hayan recetado a otras personas incluso si tuvieron una infección similar a la suya.
- No debe dar antibióticos que le hayan recetado a usted a otras personas.
- Si aún le queda antibiótico tras completar el tratamiento, entregue todos los medicamentos no utilizados a su farmacia para asegurarse de que se cumplen los requisitos de eliminación.

PROSPECTO: INFORMACIÓN PARA EL USUARIO
Acetilcisteína *Kern Pharma* 600 mg comprimidos efervescentes EFG Acetilcisteína

Lea todo el prospecto detenidamente antes de empezar a tomar este medicamento, porque contiene información importante para usted.

- Conserve este prospecto, ya que puede tener que volver a leerlo.
- Si tiene alguna duda, consulte a su médico o farmacéutico.
- Este medicamento se le ha recetado solamente a usted y no debe dárselo a otras personas, aunque tengan los mismos síntomas que usted, ya que puede perjudicarles
- Si experimenta efectos adversos, consulte a su médico o farmacéutico, incluso si se trata de efectos adversos que no aparecen en este prospecto.

Contenido del prospecto:

1. Qué es Acetilcisteína *Kern Pharma* y para qué se utiliza

La acetilcisteína pertenece al grupo de medicamentos denominados mucolíticos.

Acetilcisteína *Kern Pharma* se utiliza para fluidificar las secreciones bronquiales excesivas y/o espesas. Está indicado en el tratamiento de apoyo de los procesos respiratorios que cursan con hipersecreción mucosa excesiva o espesa tales como:

- bronquitis (inflamación de los bronquios) aguda y crónica,
- enfermedad pulmonar obstructiva crónica (EPOC),
- enfisema (inflamación de los alvéolos de los pulmones, que disminuyen la función respiratoria),
- atelectasia (disminución del volumen pulmonar) debida a obstrucción mucosa,
- complicaciones de la fibrosis quística y otras patologías relacionadas.

2. Qué necesita saber antes de empezar a tomar Acetilcisteína

Kern Pharma* No tome Acetilcisteína *Kern Pharma

- Si es alérgico (hipersensible) a la acetilcisteína o a cualquiera de los demás componentes de Acetilcisteína *Kern Pharma*.
- Si padece úlcera de estómago o duodeno.
- Si padece asma u otra insuficiencia respiratoria grave, ya que puede aumentar la

obstrucción de las vías respiratorias.
- Este medicamento no debe administrase a niños menores de 2 años.

Advertencias y precauciones
- Si padece problemas respiratorios

Uso de Acetilcisteína *Kern Pharma* con otros medicamentos

Informe a su médico o farmacéutico si está utilizando o ha utilizado recientemente cualquier otro medicamento, incluso los adquiridos sin receta médica.

No se han detectado interacciones e incompatibilidades con otros medicamentos, aunque se recomienda no tomar este medicamento con:
- antitusivos (medicamentos utilizados para calmar la tos)
- medicamentos que disminuyen las secreciones bronquiales (ej. Atropina).

Embarazo y lactancia

Embarazo

Consulte a su médico o farmacéutico antes de utilizar cualquier medicamento.
Su médico valorará la necesidad de emplear este medicamento. Solo debe utilizarse en el embarazo cuando, a criterio de su médico, los beneficios compensen los posibles riesgos.

Lactancia
Consulte a su médico o farmacéutico antes de utilizar cualquier medicamento.
Su médico valorará la necesidad de emplear este medicamento. Solo debe utilizarse durante la lactancia cuando, a criterio de su médico, los beneficios compensen los posibles riesgos.

Conducción y uso de máquinas
No se ha descrito que acetilcisteína afecte a la capacidad para conducir o utilizar máquinas.

Acetilcisteína *Kern Pharma* contiene lactosa y sodio.
Si su médico le ha indicado que padece una intolerancia a ciertos azúcares, consulte con él antes de tomar este medicamento.

Los pacientes con dietas pobres en sodio deben tener en cuenta que este medicamento contiene 138,83 mg (6,038 mmol) de sodio por dosis (600 mg).

La eventual presencia de un leve olor sulfúreo no indica la alteración del preparado, sino que es propia del principio activo.

3. Cómo tomar Acetilcisteína *Kern Pharma*

Siga exactamente las instrucciones de administración de Acetilcisteína *Kern Pharma* indicadas por su médico. Consulte a su médico o farmacéutico si tiene dudas.
Recuerde tomar su medicamento.

Su médico le indicará la duración del tratamiento con Acetilcisteína *Kern Pharma*. No suspenda el tratamiento antes ya que si lo hace no alcanzará el efecto deseado.

Si estima que la acción de Acetilcisteína *Kern Pharma* es demasiado fuerte o débil,

comuníqueselo a su médico o farmacéutico.

Los comprimidos de Acetilcisteína *Kern Pharma* 600 mg son para administración por vía oral introduciendo el comprimido en un vaso con un poco de agua. Se obtiene así una solución de sabor agradable que se puede beber directamente del vaso.

Adultos y niños mayores de 7 años: La dosis diaria recomendada es de 600 mg de acetilcisteína al día, por vía oral, y en una toma diaria de 600 mg.

Complicaciones pulmonares de la fibrosis quística:

La dosis media recomendada para la acetilcisteína en estos casos es la siguiente:

- Adultos y niños mayores de 7 años: de 200 a 400 mg de acetilcisteína cada 8 horas.
- Niños de 2 a 7 años: 200 mg de acetilcisteína cada 8 horas.

Existen otras presentaciones de este medicamento en el mercado que se ajustan a estas dosis.

Si toma más Acetilcisteína *Kern Pharma* del que debiera

Si ha tomado más Acetilcisteína *Kern Pharma* de lo que debe, consulte a su médico o farmacéutico.

En caso de sobredosis o de ingesta accidental de Acetilcisteína *Kern Pharma*, acuda a un Centro Médico o llame al Servicio de Información Toxicológica, teléfono 915 620 420, indicando el producto y la cantidad ingerida.

Se recomienda llevar el envase y el prospecto del medicamento al profesional sanitario.

La acetilcisteína ha sido suministrada en el hombre a dosis de hasta 500 mg/Kg/día sin provocar efectos secundarios por lo que es posible excluir la posibilidad de intoxicación por sobredosificación de este principio activo.

Si olvidó tomar Acetilcisteína *Kern Pharma*

No tome una dosis doble para compensar las dosis olvidadas. Tome la dosis olvidada lo antes posible. Sin embargo, si queda poco tiempo para la siguiente toma espere hasta ese momento para continuar con el tratamiento.

Si tiene cualquier otra duda sobre el uso de este producto, pregunte a su médico o farmacéutico.

Si interrumpe el tratamiento con Acetilcisteína *Kern Pharma*

No suspenda el tratamiento antes, ya que entonces no logrará el efecto previsto.

Si tiene cualquier otra duda sobre el uso de este producto, pregunte a su médico o farmacéutico.

4. Posibles efectos adversos

Al igual que todos los medicamentos, Acetilcisteína *Kern Pharma* puede producir efectos adversos, aunque no todas las personas los sufran.

Ocasionalmente se han descrito efectos adversos, de carácter leve y transitorio, siendo los más frecuentes los trastornos en el estómago y el intestino: náuseas, vómitos y diarreas.

Raramente se presentan reacciones alérgicas, acompañadas de enrojecimiento de la piel y dificultad para respirar.

Si aparecen estos síntomas, se recomienda interrumpir el tratamiento y acudir al médico.
Si considera que alguno de los efectos adversos que sufre es grave, o si aprecia cualquier efecto adverso no mencionado en este prospecto, informe a su médico o farmacéutico.

5. Conservación de Acetilcisteína *Kern Pharma*

Mantener este medicamento fuera de la vista y del alcance de los niños.

No tome Acetilcisteína *Kern Pharma* después de la fecha de caducidad indicada en el envase después de CAD. La fecha de caducidad es el último día del mes que se indica.

Conservar en su envase original.

Los medicamentos no se deben tirar por los desagües ni a la basura. Deposite los envases y los medicamentos que no necesita en el Punto SIGRE de la farmacia. En caso de duda pregunte a su farmacéutico como deshacerse de los envases y de los medicamentos que no necesita. De esta forma ayudará a proteger el medio ambiente.

6. Contenido del envase en información adicional

Composición de Acetilcisteína *Kern Pharma*

- El principio activo es acetilcisteína. Cada comprimido contiene 600 mg de acetilcisteína.
- Los demás componentes (excipientes) son: ácido cítrico anhidro (E-330), ácidoascórbico (E-300), hidrógenocarbonato de sodio (E-500), carbonato de sodio anhidro (E-500), lactosa anhidra, manitol (E-421), aroma de limón, ciclamato de sodio, sacarina sódica (E-954), citrato de sodio dihidrato (E-331).

Aspecto del producto y contenido del envase

Acetilcisteína *Kern Pharma* 600 mg se presenta en forma de comprimidos efervescentes redondos, blancos, con una superficie lisa y sin defectos, y con una ranura en una cara. Se presentan en un tubo conteniendo 20 comprimidos efervescentes.

Titular de la autorización de comercialización y responsable de la fabricación

KERN PHARMA, S.L.
Polígon
o Ind.
Colón II
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72
08228 Terrassa (Barcelona)

Este prospecto ha sido aprobado en Noviembre 2006.

La información detallada y actualizada de este medicamento está disponible en la página Web de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) http://www.aemps.gob.es/

PROSPECTO: INFORMACIÓN PARA EL USUARIO

Diazepan Prodes 5 mg comprimidos

Diazepam

Lea todo el prospecto detenidamente antes de empezar a tomar el medicamento.

- Conserve este prospecto, ya que puede tener que volver a leerlo.
- Si tiene alguna duda, consulte a su médico o farmacéutico.
- Este medicamento se le ha recetado a usted y no debe dárselo a otras personas, aunque tengan los mismos síntomas, ya que puede perjudicarles.
- Si considera que alguno de los efectos adversos que sufre es grave o si aprecia cualquier efecto adverso no mencionado en este prospecto, informe a su médico o farmacéutico.

Contenido del prospecto:

- Qué es Diazepan Prodes 5 mg comprimidos y para qué se utiliza

El diazepam, principio activo de la especialidad, es un derivado benzodiazepínico que presenta actividad tranquilizante, sedante, miorrelajante (relajante muscular), anticonvulsivante (para las convulsiones) y antipsicótica.

Los médicos recetan este medicamento a personas que padecen ansiedad, agitación y tensión psíquica debidas a estados psiconeuróticos y trastornos situacionales transitorios. También lo recetan a pacientes con privación alcohólica, ya que puede ser útil para el alivio sintomático de la agitación aguda, el temblor y las alucinaciones.

Además, se emplea junto con otros medicamentos para el alivio del dolor músculo-esquelético debido a espasmos (contracturas) o patología local (inflamación de músculos o articulaciones, traumatismos, etc.). También puede utilizarse para tratar la espasticidad (rigidez) en afecciones

tales como parálisis cerebral y paraplejia, así como en la atetosis (movimientos involuntarios) y en el síndrome de rigidez generalizada.

También, puede utilizarse el diazepam junto con otros medicamentos en el tratamiento de los trastornos convulsivos ya que como tratamiento único no ha demostrado ser útil. En estos casos, el médico debe evaluar periódicamente la utilidad del medicamento para cada paciente.

2. Antes de tomar Diazepan Prodes 5 mg comprimidos

Este medicamento es para la administración oral.

No tome Diazepan Prodes

- Si es alérgico (hipersensible) al diazepam o a cualquiera de los demás componentes de Diazepan Prodes.
- Si tiene dependencia de otras sustancias, incluido el alcohol, a menos que su médico se lo indique.

- Si tiene glaucoma de ángulo cerrado (aumento de la tensión en el ojo) y padece hipercapnia crónica grave (aumento del dióxido de carbono o CO_2 en sangre).

Tenga especial cuidado con Diazepan Prodes

- Si padece miastenia (debilidad y fatiga de los músculos), ya que se puede sufrir una mayor fatiga muscular, si padece insuficiencia respiratoria moderada, así como si padece insuficiencia del riñón o del hígado. Su médico deberá ajustarle la dosis.

- Si padece depresión deberá tener en cuenta que el diazepam sólo actúa sobre el componente ansioso, por lo que no constituye por sí mismo un tratamiento de la depresión y puede eventualmente desenmascarar algunos signos de la misma.

Uso de otros medicamentos

Informe a su médico o farmacéutico si está utilizando o ha utilizado recientemente otros medicamentos, incluso los adquiridos sin receta.

No deberá tomar Diazepan Prodes junto con medicamentos de acción sobre el sistema nervioso central, tales como neurolépticos (medicamentos utilizados en psiquiatría), tranquilizantes, antidepresivos, hipnóticos (facilitadores del sueño), anticonvulsivantes (para las convulsiones), analgésicos (para el dolor) y anestésicos, ya que aumentan la acción sedante del diazepam.

Tampoco deberá tomar Diazepan Prodes junto con cisaprida (medicamento utilizado para trastornos gastrointestinales) ya que ésta produce un aumento transitorio del efecto sedante del diazepam, al igual que la cimetidina (medicamento para la acidez gástrica), lo que aumenta el riesgo de somnolencia.

Si toma Diazepan Prodes conjuntamente con fenitoína (medicamento para la epilepsia) su médico deberá controlar las concentraciones en sangre de esta última, ya que pueden sufrir variaciones imprevisibles provocando signos de toxicidad o disminución de su actividad o ningún cambio.

Toma de Diazepan Prodes con alimentos y bebidas

Deberá evitar la ingestión de bebidas alcohólicas durante el tratamiento con Diazepan Prodes 5 mg comprimidos, ya que el alcohol potencia la acción sedante.

Embarazo y lactancia

Consulte a su médico o farmacéutico antes de utilizar cualquier medicamento.

Si está o sospecha estar embarazada, o bien desea estarlo, deberá informar a su médico antes de comenzar el tratamiento, y él decidirá la conveniencia de que tome o no Diazepan Prodes.

El diazepam se elimina por la leche materna por lo que no se recomienda su utilización durante el período de lactancia; si su médico considera que usted lo tiene que tomar, deberá sustituir la lactancia natural.

Conducción y uso de máquinas

Durante el tratamiento con Diazepan Prodes, no deberá realizar actividades peligrosas que requieran un estado de completa alerta mental, tales como manejo de maquinaria peligrosa o conducción de vehículos.

Información importante sobre algunos de los componentes de Diazepan Prodes

Este medicamento contiene lactosa. Si su médico le ha indicado que padece una intolerancia a ciertos azúcares, consulte con él antes de tomar este medicamento.

3. Cómo tomar Diazepan Prodes 5 mg comprimidos

Siga exactamente las instrucciones de administración de Diazepan Prodes indicadas por su médico.

Consulte a su médico o farmacéutico si tiene dudas.

Recuerde tomar su medicamento.

La dosis de Diazepan Prodes 5 mg comprimidos debe ser la que su médico le indique en función de sus necesidades individuales.

Deberá tomar este medicamento a las horas que le diga su médico, normalmente por la tarde o noche.

Adultos

Síntomas de ansiedad: 2 a 10 mg, 2 a 4 veces al día, dependiendo de la gravedad de los síntomas.

Alivio sintomático en la privación alcohólica aguda: 10 mg, 3 ó 4 veces durante las primeras 24 horas, reduciendo a 5 mg, 3 ó 4 veces al día, según necesidad.

Junto con otros medicamentos para el alivio del espasmo o contractura músculo-esquelética: 2 a 10 mg, 3 ó 4 veces al día.

Junto con otros medicamentos en terapia anticonvulsivante (para las convulsiones): 2 a 10 mg, 2 ó 4 veces al día.

Dosificaciones especiales

En niños: 2 a 2,5 mg, 1 ó 2 veces al día, incrementándose gradualmente según necesidades y tolerancia; como norma general 0,1-0,3 mg/kg al día. Debido a la variedad de respuesta de los niños a los medicamentos que actúan sobre el Sistema Nervioso Central, debe iniciarse el tratamiento con la dosis más baja e incrementarse según se requiera. No utilizar en niños menores de 6 meses de edad.

En ancianos o pacientes con alguna enfermedad del riñón o del hígado: 2 a 2,5 mg , 1 ó 2 veces al día, aumentando luego gradualmente según necesidad y tolerancia.

En pacientes con enfermedad del riñón o del hígado se observará una especial atención al individualizar la dosis.

Si estima que la acción de Diazepan Prodes 5 mg comprimidos es demasiado fuerte o débil, comuníqueselo a su médico o farmacéutico.

Su médico le indicará la duración del tratamiento con Diazepan Prodes 5 mg comprimidos. No suspenda el tratamiento antes de que su médico se lo indique y en las condiciones que él le prescriba. La duración del tratamiento debe ser lo más corta posible. De forma general la duración total del tratamiento no debe superar las 8-12 semanas incluyendo la retirada gradual del mismo.

Tras seis semanas de tratamiento no cabe esperar mayores mejorías por lo que tratamientos más continuados han de considerarse exclusivamente como terapia de mantenimiento. Durante una terapia de mantenimiento prolongada, se deben dejar intervalos regulares sin medicación, para fijar la necesidad de una continuación de la terapia. Sin embargo, el tratamiento no se interrumpirá bruscamente, sino que la dosis se irá disminuyendo gradualmente.

Si toma más Diazepan Prodes del que debiera

Puede sufrir somnolencia y sueño, aunque le podrán despertar fácilmente. En caso de sobredosis o ingestión accidental, consulte al Servicio de Información Toxicológica, teléfono 91 562 04 20, o bien avise al médico inmediatamente o acuda al servicio de urgencias del hospital más próximo. Lleve este prospecto con usted. En la mayoría de los casos bastará una vigilancia atenta de las funciones vitales o el uso del antagonista de las benzodiazepinas ANEXATE® (principio activo: Flumazenilo) como terapia.

Si el paciente ha ingerido una cantidad muy elevada puede producirse coma, falta de reflejos, depresión cardio-respiratoria y apnea (trastorno con breves interrupciones involuntarias de la respiración), requiriendo medidas apropiadas (ventilación, apoyo cardiovascular) y también flumazenilo, como terapia específica.

Si olvidó tomar Diazepan Prodes

No tome una dosis doble para compensar las dosis olvidadas. En caso de olvidar tomar una dosis aguarde a la siguiente cuando toque.

Si interrumpe el tratamiento con Diazepan Prodes

El uso de benzodiazepinas puede inducir a una dependencia. Esto ocurre, principalmente, si usa el medicamento de forma ininterrumpida durante largo tiempo. Para prevenir al máximo este riesgo debe consultar al médico regularmente para que éste decida si usted debe continuar el tratamiento. No deberá aumentar, en absoluto, las dosis prescritas por el médico, ni prolongará el tratamiento más tiempo del recomendado.

Al dejar de tomar Diazepan Prodes 5 mg comprimidos puede aparecer inquietud, ansiedad, insomnio, falta de concentración, dolor de cabeza y sudores. No es recomendable, en general, interrumpir bruscamente la medicación, sino reducir gradualmente la dosis, de acuerdo siempre con las instrucciones del médico.

Si tiene cualquier otra duda sobre el uso de este producto, pregunte a su médico o farmacéutico.

4. Posibles efectos adversos

Al igual que todos los medicamentos, Diazepan Prodes puede producir efectos adversos, aunque no todas las personas los sufran.

Los más comunes son fatiga, somnolencia y debilidad muscular; normalmente son dependientes de la dosis. Otros efectos menos frecuentes son amnesia anterógrada (falta de memoria reciente), confusión, estreñimiento, depresión, diplopia (visión doble), dificultad de articular las palabras, dolor de cabeza, hipotensión (tensión arterial baja), incontinencia, trastornos de la líbido (falta de apetito sexual), náuseas, sequedad de boca o secreción salivar exagerada, erupciones cutáneas, temblor, retención urinaria, vértigo y visión borrosa; muy raramente, alteración de los análisis en sangre del hígado (como elevación de las transaminasas y de la fosfatasa alcalina), así como algunos casos de ictericia (coloración amarillenta de piel y mucosas). Se han observado reacciones paradójicas, tales como excitación aguda, ansiedad, trastornos del sueño y alucinaciones. Si ocurrieran estos efectos se debería interrumpir el tratamiento.

Si considera que alguno de los efectos adversos que sufre es grave o si aprecia cualquier efecto adverso no mencionado en este prospecto, informe a su médico o farmacéutico.

5. Conservación de Diazepan Prodes 5 mg comprimidos

No se precisan condiciones especiales de conservación.

Mantener fuera del alcance y de la vista de los niños.

No utilice Diazepan Prodes 5 mg comprimidos después de la fecha de caducidad que aparece en el envase después de CAD. La fecha de caducidad es el último día del mes que se indica.

Los medicamentos no se deben tirar por los desagües ni a la basura. Pregunte a su farmacéutico cómo deshacerse de los envases y de los medicamentos que no necesita. De esta forma ayudará a proteger el medio ambiente.

6. Información adicional

Composición de Diazepan Prodes 5 mg comprimidos

- El principio activo es diazepam.
- Los demás componentes son lactosa, almidón de maíz, croscarmelosa de sodio, povidona (E-1201), sílice coloidal, estearato de magnesio (E-470b) y talco.

Aspecto del producto y contenido del envase

Diazepan Prodes 5 mg comprimidos son comprimidos de color blanco. Se acondiciona en blister y se presenta en envases de 30 comprimidos.

Titular de la autorización de comercialización y responsable de la fabricación

KERN PHARMA, S.L

Polígono Ind. Colón II

Venus, 72

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Este prospecto ha sido aprobado en Noviembre 2010.

ACICLOVIR

Prospecto: Información para el paciente

Aciclovir *Kern Pharma* 200 mg comprimidos dispersables EFG

Lea todo el prospecto detenidamente antes de empezar a tomar este medicamento, porque contiene información importante para usted.

- Conserve este prospecto, ya que puede tener que volver a leerlo.
- Si tiene alguna duda, consulte a su médico o farmacéutico.
- Este medicamento se le ha recetado solamente a usted y no debe dárselo a otras personas, aunque tengan los mismos síntomas, ya que puede perjudicarles.
- Si experimenta efectos adversos, consulte a su médico o farmacéutico, incluso si se trata de efectos adversos que no aparecen en este prospecto. Ver sección 4.

Contenido del prospecto:

1. Qué es Aciclovir *Kern Pharma* y para que se utiliza

Aciclovir es un medicamento antiviral que se emplea en el tratamiento de infecciones producidas por virus.

Este medicamento está indicado en el tratamiento de: infecciones de la piel y mucosas producidas por el virus herpes simple en pacientes inmunodeprimidos (sistema inmunológico disminuido) y su prevención, herpes genital (siendo eficaz en el primer período de herpes genital), herpes zóster en pacientes inmunocompetentes (con funcionamiento adecuado del sistema inmunológico) y varicela.

También está indicado en aquellos pacientes de riesgo (diabéticos, malnutridos, etc.) y/o con herpes zóster grave, siendo el beneficio menor en el resto de pacientes.

2. Qué necesita saber antes de tomar Aciclovir *Kern Pharma*

No tome Aciclovir *Kern Pharma*

Si es alérgico (hipersensible) al aciclovir o a cualquiera de los demás componentes de este medicamento incluidos en la sección 6.

Advertencias y precauciones

Consulte a su médico o farmacéutico antes de empezar a tomar este medicamento.

- Si padece alguna enfermedad de riñón o tiene usted edad avanzada, es posible que su médico utilice una dosis más baja. Asimismo, debe beber suficiente cantidad de líquido durante el tratamiento para mantener una hidratación adecuada.
- En personas de edad avanzada se recomienda un aporte de líquido adecuado mientras estén sometidas a altas dosis de aciclovir por vía oral.
- Se deberá tener cuidado para evitar la transmisión potencial del virus, especialmente cuando están presentes las lesiones activas. **Para evitar transmisión de la infección a la pareja**, se deben evitar las relaciones sexuales de pacientes de herpes genital con lesiones visibles.

Niños y adolescentes

Este medicamento se recomienda en el tratamiento y prevención de infecciones producidas por virus herpes simple en niños inmunodeficientes. Ver el apartado **3.Cómo tomar Aciclovir *Kern Pharma*.**

No se dispone de una posología estudiada para el tratamiento de supresión de recurrencias por virus herpes simple en niños inmunodeprimidos.

Para el tratamiento de la varicela en niños menores de 2 años, ver el apartado **3.Cómo tomar Aciclovir *Kern Pharma*.**

Para el tratamiento de la varicela en niños mayores de 6 años, existen otras presentaciones más adecuadas

Toma de Aciclovir *Kern Pharma* con otros medicamentos

Informe a su médico o farmacéutico si está utilizando o ha utilizando recientemente o podría tener que utilizar cualquier otro medicamento, incluso los adquiridos sin receta.

La administración simultánea con probenecid (medicamento utilizado para el tratamiento de la gota), cimetidina (medicamento para el tratamiento de la acidez de estómago) o mofetilo (para prevenir un rechazo de órgano trasplantado) aumenta la vida media de aciclovir y el área bajo la curva de sus concentraciones plasmáticas, lo que deberá ser tenido en cuenta por su médico aunque no sea necesario ajuste de dosis.

No se han descrito otras interacciones medicamentosas, aunque los medicamentos que alteran la fisiología renal podrían influir en la farmacocinética de aciclovir.

Toma de Aciclovir *Kern Pharma* con alimentos y bebidas

Los comprimidos de aciclovir pueden dispersarse en un mínimo de 50 ml de agua, o tragarse enteros con un poco de agua.

Embarazo y lactancia

Embarazo

Consulte a su médico o farmacéutico antes de tomar un medicamento.

La experiencia en humanos es limitada, por ello el aciclovir sólo se utilizará en aquellos casos en los que previamente la valoración beneficio -riesgo de su aplicación aconseje su utilización.

Lactancia

Consulte a su médico o farmacéutico antes de tomar un medicamento.

Estudios realizados en humanos muestran que después de la administración de este medicamento, puede aparecer aciclovir en la leche materna, por lo que se aconseja sustituir la lactancia natural.

Conducción y uso de máquinas

Debido a las características de este medicamento no es probable. Sin embargo, se ha observado que en algunos casos se presentan signos de cansancio, dolor de cabeza y reacciones neurológicas leves. Estas reacciones se deben tener en cuenta a la hora de conducir y manejar máquinas.

3. Cómo tomar Aciclovir *Kern Pharma*

La primera dosis debe ser administrada tan pronto como sea posible una vez desarrollada la infección.

En el caso de infecciones recurrentes, será conveniente comenzar el tratamiento al primer síntoma o signo, o cuando aparezcan las lesiones.

Siga estas instrucciones a menos que su médico le haya dado otras indicaciones distintas.
Recuerde tomar su medicamento.

Los comprimidos de aciclovir, pueden dispersarse en un mínimo de 50 ml de agua, o tragarse enteros con un poco de agua. La ranura sirve únicamente para partir el comprimido si le resulta difícil tragárselo entero.

Su médico le indicará la duración de su tratamiento con este medicamento. No suspenda el tratamiento antes.

Adultos:

Pacientes con función renal normal:

- Para el tratamiento de infecciones producidas por virus herpes simple: 1 comprimido 5 veces al día a intervalos de aproximadamente 4 horas, omitiendo la dosis nocturna, durante 5 días.

  En pacientes gravemente inmunodeprimidos y en aquellos con dificultades en la absorción intestinal, la dosis puede ser doblada a 400 mg (2 comprimidos) 5 veces al día.

- Para la supresión de recurrencias producidas por virus herpes simple en pacientes inmunocompetentes (funcionamiento adecuado del sistema inmunológico): 1 comprimido 4 veces al día a intervalos de aproximadamente 6 horas o bien 2 comprimidos 2 veces al día, cada 12 horas. El tratamiento será interrumpido periódicamente a intervalos de 6 a 12 meses para observar posibles cambios en el proceso de la enfermedad.

- Para la prevención de infecciones producidas por virus herpes simple en pacientes inmunocomprometidos: 1 comprimido 4 veces al día a intervalos de 6 horas. En pacientes gravemente inmunocomprometidos y en aquellos con dificultades en la absorción intestinal, la dosis puede ser doblada a 400 mg (2 comprimidos) 4 veces al día.

- Para el tratamiento de infecciones por herpes zóster: 4 comprimidos de 200 mg 5 veces al día a intervalos de 4 horas, omitiendo la dosis nocturna, durante 7 días.

Pacientes con función renal alterada:

- En el tratamiento de infecciones por virus herpes simple, en pacientes con un aclaramiento de creatinina igual o inferior a 10 ml/minuto, 1 comprimido cada 12 horas.

- En el tratamiento de infecciones por herpes zóster, se recomiendan 4 comprimidos de 200 mg 2 veces al día para pacientes con un aclaramiento de creatinina inferior a 10 ml/minuto

y 4 comprimidos de 200 mg 3 ó 4 veces al día a intervalos de 6-8 horas para pacientes con un aclaramiento de creatinina de 10-25 ml/minuto.

Pacientes en edad avanzada

- En pacientes de edad avanzada se recomienda un aporte de líquido adecuado mientras estén sometidas a dosis altas de aciclovir por vía oral.
- En aquellos pacientes de edad avanzada con una función renal alterada se administrará una dosis reducida.

Población pediátrica

- Para el tratamiento de infecciones por virus herpes simple y prevención en niños inmunodeprimidos*:*

  Niños mayores de 2 años: serán tratados con dosis de adultos.
  Niños menores de 2 años: serán tratados con la mitad de la dosis de adultos.

3

- Para el tratamiento de infecciones por varicela:

  Niños entre 2 y 6 años: 2 comprimidos de 200 mg 4 veces al día durante 5 días.

  Niños menores de 2 años: 1 comprimido de 200 mg 4 veces al día durante 5 días.

La posología puede calcularse con más exactitud como 20 mg por kg de peso corporal (sin sobrepasar 800 mg 4 veces al día).

Si toma más Aciclovir *Kern Pharma* del que debe

Dado que aciclovir, es sólo parcialmente absorbido por vía digestiva, es poco probable la aparición de efectos tóxicos graves después de la ingestión de 5 g de aciclovir en una sola toma.

En caso de sobredosis o ingesta accidental, consulte inmediatamente a su médico o farmacéutico o llame al Servicio de Información Toxicológica, teléfono 91 562 04 20, indicando el medicamento y la cantidad ingerida.

Información para el profesional sanitario en caso de sobredosis

Aciclovir es dializable. La hemodiálisis aumenta sensiblemente la eliminación del aciclovir de la sangre y puede, por tanto, ser considerada una opción de tratamiento en caso de sobredosis sintomática.

Si olvidó tomar Aciclovir *Kern Pharma*

No tome una dosis doble para compensar las dosis olvidadas, simplemente continúe con el tratamiento habitual tan pronto como sea posible.

Si interrumpe el tratamiento con Aciclovir *Kern Pharma*

No debe interrumpir el tratamiento antes de lo aconsejado por su médico, ya que su curación podría no ser completa y podría volver a manifestarse su enfermedad.

4. Posibles efectos adversos

Al igual que todos los medicamentos, este medicamento puede producir efectos adversos, aunque no todas las personas los sufran.

Frecuentes (pueden afectar hasta 1 de cada 10 personas): dolor de cabeza, mareos, náuseas, vómitos, diarrea, dolor abdominal, picores, erupciones cutáneas (incluyendo fotosensibilidad), fatiga, fiebre.

Poco frecuentes (pueden afectar hasta 1 de cada 100 personas): urticaria, pérdida de cabello acelerada y difusa.

Raros (pueden afectar hasta 1 de cada 1.000 personas): dificultad en la respiración, aumento reversible de bilirrubina y las enzimas hepáticas relacionadas, inflamación de la piel, aumento de la urea y creatinina en sangre, reacción alérgica grave en todo el cuerpo.

Muy raros (pueden afectar hasta 1 de cada 10.000 personas): disminución de los índices hematológicos, hepatitis, ictericia (coloración amarillenta de la piel), fallo renal agudo, dolor renal. Este medicamento puede producir otros efectos adversos muy raros como agitación, confusión, temblores, dificultad de movimientos, dificultad al hablar, confusión o imaginación de cosas (alucinaciones), convulsiones, somnolencia, encefalopatía (alteración en el cerebro), coma. Estos efectos son generalmente reversibles y normalmente afectan a pacientes con alteraciones renales o con otros factores predisponentes (ver apartado **Advertencias y precauciones**).

Comunicación de efectos adversos

Si experimenta cualquier tipo de efecto adverso, consulte a su médico o farmacéutico, incluso si se trata de posibles efectos adversos que no aparecen en este prospecto. También puede comunicarlos directamente a través del Sistema Español de Farmacovigilancia de Medicamentos de uso humano: https://www.notificaram.es. Mediante la comunicación de efectos adversos usted puede contribuir a proporcionar más información sobre la seguridad de este medicamento.

5. Conservación de Aciclovir *Kern Pharma*

Mantener este medicamento fuera de la vista y del alcance de los niños.

No utilice este medicamento después de la fecha de caducidad que aparece en el envase después de CAD. La fecha de caducidad es el último día del mes que se indica.

No conservar a temperatura superior a 25ºC.

Los medicamentos no se deben tirar por los desagües ni a la basura. Deposite los envases y los

medicamentos que no necesita en el Punto SIGRE de la farmacia. En caso de duda pregunte a su farmacéutico cómo deshacerse de los envases y de los medicamentos que no necesita. De esta forma ayudará a proteger el medio ambiente.

Contenido del envase e información adicional

Composición de Aciclovir *Kern Pharma*

- El principio activo es aciclovir. Cada comprimido contiene 200 mg de aciclovir.
- Los demás componentes son: celulosa microcristalina, povidona K-30, silicato de aluminio y magnesio, estearato de magnesio, carboximetilalmidón sódico (tipo A) (procedente de almidón de patata), indigotina (carmín de índigo) (E-132), polietilenglicol 400 y 8000, hidroxipropilmetilcelulosa.

Aspecto del producto y contenido del envase

Comprimidos dispersables, redondos, recubiertos, de color azul, ranurados en ambas caras. La ranura sirve para fraccionar y facilitar la deglución pero no para dividir en dosis iguales.

Cada envase contiene 25 ó 100 comprimidos, acondicionados en blister de PVC/PVDC/Al.

Puede que solamente estén comercializados algunos tamaños de envases.

Titular de la autorización de comercialización y responsable de la fabricación *Kern Pharma*, S.L.

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Fecha de la última revisión de este prospecto: Abril 2015

La información detallada y actualizada de este medicamento está disponible en la página Web de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) http://www.aemps.gob.es/.

6

PROSPECTO: INFORMACIÓN PARA EL USUARIO

Glucosamina *Kern Pharma* 1.500 mg polvo para solución oral EFG

Sulfato de Glucosamina

Lea todo el prospecto detenidamente antes de empezar a tomar el medicamento.

- Conserve este prospecto, ya que puede tener que volver a leerlo.
- Si tiene alguna duda, consulte a su médico o farmacéutico.
- Este medicamento se le ha recetado a usted y no debe usted dárselo a otras personas, aunque tengan los mismos síntomas, ya que puede perjudicarles.
- Si considera que alguno de los efectos adversos que sufre es grave o si aprecia cualquier efecto adverso no mencionado en este prospecto, informe a su médico o farmacéutico.

Contenido del prospecto:

- Qué es Glucosamina *Kern Pharma* y para qué se utiliza

Glucosamina *Kern Pharma* pertenece al grupo de medicamentos denominados otros compuestos antiinflamatorios y antirreumáticos no esteroideos.

Glucosamina *Kern Pharma* está indicada para aliviar los síntomas producidos por la artrosis de rodilla leve a moderada.

2. Antes de tomar Glucosamina *Kern Pharma*

No tome Glucosamina *Kern Pharma*:

- si es alérgico (hipersensible) a glucosamina o a cualquiera de los demás componentes de Glucosamina *Kern Pharma*,
- si es alérgico (hipersensible) a los mariscos, debido a que glucosamina se obtiene de los mariscos.

Tenga especial cuidado con Glucosamina *Kern Pharma*:

- si tiene alterada la tolerancia al azúcar (glucosa). Pueden ser necesarios controles más frecuentes de los niveles del azúcar en sangre, cuando se empieza el tratamiento con glucosamina,
- si tiene algún factor de riesgo para sufrir enfermedades del corazón o de las arterias, ya que en algunos casos se ha observado aumentos del colesterol en pacientes tratados con glucosamina,
- si tiene asma. Cuando empiece el tratamiento con glucosamina, debe tener en cuenta que los síntomas pueden empeorar,
- si tiene cualquier alteración del riñón o del hígado, debido a que no se han llevado a cabo investigaciones en estas condiciones y, por lo tanto, no pueden darse recomendaciones sobre dosificación.

Debe consultar a su médico para descartar la presencia de otras enfermedades articulares para las que debería considerarse otro tratamiento.

No tome Glucosamina *Kern Pharma* si es menor de 18 años.

Uso de otros medicamentos

Informe a su médico o farmacéutico si está utilizando o ha utilizado recientemente otros medicamentos, incluso los adquiridos sin receta.

Tenga cuidado si toma Glucosamina *Kern Pharma* simultáneamente con otros medicamentos, especialmente con warfarina y tetraciclina. Acuda a su médico para obtener consejo adecuado.

Toma de Glucosamina *Kern Pharma* con los alimentos y bebidas

Disolver el contenido del sobre de Glucosamina *Kern Pharma* en un vaso de agua y tómelo una vez al día, preferiblemente en las comidas.

Embarazo y lactancia

Consulte a su médico o farmacéutico antes de utilizar cualquier medicamento.

Glucosamina *Kern Pharma* no debe utilizarse durante el embarazo.

No se recomienda el uso de glucosamina durante la lactancia

Conducción y uso de máquinas

No se han realizado estudios sobre cómo afecta Glucosamina *Kern Pharma* sobre la capacidad de conducir y utilizar máquinas. Sin embargo, si usted experimenta máreo o somnolencia al tomar Glucosamina *Kern Pharma*, no debería conducir ni manejar máquinas (ver apartado 4 "Posibles efectos adversos").

Información importante sobre algunos de los componentes de Glucosamina *Kern Pharma*:

Los pacientes con dietas pobres en sodio deben tener en cuenta que este medicamento contiene 151 mg (6,57 mmol) de sodio por sobre.

Este medicamento contiene sorbitol. Si su médico le ha indicado que padece una intolerancia a ciertos azúcares, consulte con él antes de tomar/usar este medicamento.

Este medicamento puede ser perjudicial para personas con fenilcetonuria porque contiene aspartamo que es una fuente de fenilalanina.

3. Cómo tomar Glucosamina *Kern Pharma*

Siga exactamente las instrucciones de administración de Glucosamina *Kern Pharma* indicadas por su médico. Consulte a su médico o farmacéutico si tiene dudas. Su médico le ajustará la dosis de acuerdo a su estado.

Modo de administración y posología

La dosis normal de inicio es de un sobre (disuelto en un vaso de agua) una vez al día, preferiblemente en las comidas.

Para uso oral.

Duración del tratamiento

Glucosamina no está indicada para el tratamiento de síntomas agudos dolorosos. El alivio de los síntomas (especialmente el alivio del dolor) puede que no se manifieste hasta después de varias semanas de tratamiento, y en algunos casos incluso más. Si no experimenta alivio de los síntomas después de 2-3 meses, debe reconsiderarse la continuación del tratamiento con glucosamina.

Si toma más Glucosamina *Kern Pharma* del que debiera

Si toma más Glucosamina *Kern Pharma* del que debiera, o si otra persona o niño toma este medicamento, coménteselo a su médico o farmacéutico.

Signos y síntomas de sobredosis con glucosamina incluyen dolor de cabeza, mareos, confusión, dolor articular, nauseas, vómitos, diarrea o estreñimiento. No continue tomando Glucosamina *Kern Pharma* a la menor presencia de los síntomas mencionados anteriormente.

En caso de sobredosis o ingesta accidental, consulte inmediatamente a su médico o farmacéutico o llame al Servicio de Información Toxicológica. Teléfono: (91) 562 04 20, indicando el medicamento y la cantida tomada.

Si olvidó tomar Glucosamina *Kern Pharma*

No tome una dosis doble para compensar las dosis olvidadas.

Si tiene cualquier otra duda sobre el uso de este producto, pregunte a su médico o farmacéutico.

4. Posibles efectos adversos

Al igual que todos los medicamentos, Glucosamina *Kern Pharma* puede producir efectos adversos, aunque no todas las personas los sufran.

Debe de interrumpir el tratamiento de glucosamina y acudir inmediatamente a su médico si experimenta síntomas de angioedema, tales como:

- Hinchazón de cara, lengua o garganta.
- Dificultad para tragar.
- Urticaria y dificultad para respirar.

Los efectos adversos más frecuentemente observados son:

Frecuentes (que afecta de 1 a 10 de cada 100 personas)

- Dolor de cabeza.
- Cansancio.
- Nauseas.
- Dolor abdominal.
- Indigestión.
- Diarrea.
- Estreñimiento.

Poco frecuentes (que afecta de 1 a 10 de cada 1.000 personas)

- Erupción.
- Picor.
- Enrojecimiento.

Frecuencia no conocida (no puede estimarse a partir de los datos disponibles)

- Mareo.
- Empeoramiento de los síntomas del asma.
- Hinchazón en tobillos, piernas y pie.
- Urticaria.
- Aumento de los niveles de colesterol y empeoramiento de los niveles de azúcar (glucosa) en sangre con diabetes mellitus.

Si considera que alguno de los efectos adversos que sufre es grave o si aprecia cualquier efecto adverso no mencionado en este prospecto, informe a su médico o farmacéutico.

5. Conservación de Glucosamina *Kern Pharma*

Conservar por debajo de 25ºC.

Mantener fuera del alcance y de la vista de los niños.

No utilice Glucosamina *Kern Pharma* después de la fecha de caducidad que aparece en el sobre y envase despues de la abreviatura Cad. La fecha de caducidad es el último día del mes que se indica.

Los medicamentos no se deben tirar por los desagües ni a la basura. Pregunte a su farmacéutico cómo deshacerse de los envases y de los medicamentos que no necesita. De esta forma ayudará a proteger el medio ambiente.

6. Información adicional

Composición de Glucosamina *Kern Pharma*:

- El principio activo es glucosamina. Cada sobre de Glucosamina *Kern Pharma* contiene 1.500 mg de sulfato de glucosamina como sulfato de glucosamina cloruro sódico equivalente a 1.178 mg de glucosamina.
- Los demás componentes son: aspartamo (E951), sorbitol (E420), sodio, ácido cítrico y macrogol 4000.

Aspecto del producto y contenido del envase

El polvo es blanco cristalino e inodoro y se envasa en sobres monodosis.

Cada envase contiene 20 ó 30 sobres.

Puede que solamente estén comercializados algunos tamaños de envases

Titular de la autorización de comercialización y responsable de la fabricación

Titular y Responsable de la fabricación:

KERN PHARMA, S.L.

Venus, 72. Poligono Industrial Colon II.

08228 Tarrasa, Barcelona

Este prospecto ha sido aprobado en MAYO de 2009.

Prospecto: información para el paciente

Memantina *Kern Pharma* 10 mg comprimidos EFG

Hidrocloruro de memantina

Lea todo el prospecto detenidamente antes de empezar a tomar este medicamento porque contiene información importante para usted.

- Conserve este prospecto, ya que puede tener que volver a leerlo.
- Si tiene alguna duda, consulte a su médico o farmacéutico.
- Este medicamento se le ha recetado a usted, y no debe dárselo a otras personas aunque tengan los mismos síntomas que usted, ya que puede perjudicarles.
- Si experimenta efectos adversos, consulte a su médico o farmacéutico, incluso si se trata de efectos adversos que no aparecen en este prospecto. Ver sección 4.

Contenido del prospecto:

- Qué es Memantina *Kern Pharma* y para qué se utiliza

Cómo actúa Memantina *Kern Pharma*

Memantina *Kern Pharma* pertenece a un grupo de medicamentos denominados medicamentos anti-demencia.

La pérdida de memoria en la enfermedad de Alzheimer se debe a una alteración en las señales del cerebro. El cerebro contiene los llamados receptores N-metil-D-aspartato (NMDA) que participan en la transmisión de señales nerviosas importantes en el aprendizaje y la memoria. Memantina pertenece al grupo de medicamentos llamados antagonistas de los receptores NMDA. Memantina actúa sobre estos receptores mejorando la transmisión de las señales nerviosas y la memoria.

Para qué se utiliza Memantina *Kern Pharma*

Memantina *Kern Pharma* se utiliza en el tratamiento de pacientes con enfermedad de Alzheimer de moderada a grave.

2. Que necesita saber antes de empezar a tomar Memantina *Kern Pharma*

No tome Memantina *Kern Pharma*

- si es alérgico al principio activo hidrocloruro de memantina o a cualquiera de los demás componentes de este medicamento (incluidos en la sección 6).

Advertencias y precauciones

Consulte a su médico o farmacéutico antes de empezar a tomar Memantina *Kern Pharma*:

- si tiene antecedentes de crisis epilépticas,
- si ha sufrido recientemente un infarto de miocardio (ataque al corazón), si sufre enfermedad cardíaca congestiva o si tiene hipertensión (la presión arterial elevada) no controlada.

En las situaciones anteriores, el tratamiento debe ser supervisado cuidadosamente y el médico debe reevaluar el beneficio clínico de memantina regularmente.

Si padece insuficiencia renal (problemas en los riñones) su médico debe controlar atentamente la función renal y si es necesario, adaptar las dosis de memantina.

Se debe evitar el uso de memantina junto con otros medicamentos como amantadina (para el tratamiento del Parkinson), ketamina (fármaco generalmente usado para producir anestesia), dextrometorfano (fármaco para el tratamiento de la tos) y otros antagonistas del NMDA.

No se recomienda el uso de memantina en niños y adolescentes menores de 18 años.

Toma de Memantina *Kern Pharma* con otros medicamentos

Informe a su médico o farmacéutico si está utilizando, ha utilizado recientemente o podría tener que utilizar cualquier otro medicamento.

En concreto, la administración de memantina puede producir cambios en los efectos de los siguientes medicamentos, por lo que puede que su médico necesite ajustar la dosis:

- amantadina, ketamina, dextrometorfano.

- dantroleno, baclofeno.
- cimetidina, ranitidina, procainamida, quinidina, quinina, nicotina.
- hidroclorotiazida (o cualquier combinación con hidroclorotiazida).
- anticolinérgicos (sustancias generalmente utilizadas para tratar alteraciones del movimiento o espasmos intestinales).
- anticonvulsivantes (sustancias utilizadas para prevenir y eliminar las convulsiones).
- barbitúricos (sustancias generalmente utilizadas para inducir el sueño).
- agonistas dopaminérgicos (sustancias como L-dopa, bromocriptina).
- neurolépticos (sustancias utilizadas en el tratamiento de enfermedades mentales).
- anticoagulantes orales.

Si ingresa en un hospital, informe a su médico que está tomando Memantina *Kern Pharma*.

Toma de Memantina *Kern Pharma* con alimentos, bebidas y alcohol

Debe informar a su médico si ha cambiado recientemente o tiene la intención de cambiar su dieta de manera sustancial (por ejemplo de dieta normal a dieta vegetariana estricta) o si padece acidosis tubular renal (ATR, exceso de sustancias productoras de ácido en la sangre debido a una disfunción renal (problema de riñón)) o infecciones graves del tracto urinario (conducto de la orina), ya que su médico puede tener que ajustar la dosis del medicamento.

Embarazo, lactancia y fertilidad

Si está embarazada o en periodo de lactancia, cree que podría estar embarazada o tiene intención de quedarse embarazada, consulte a su médico o farmacéutico antes de utilizar este medicamento.

No se recomienda el uso de memantina en mujeres embarazadas.

Las mujeres que toman memantina deben suspender la lactancia natural.

Conducción y uso de máquinas

Su médico le informará de si su enfermedad le permite conducir y usar máquinas con seguridad. Asimismo, Memantina puede alterar su capacidad de reacción, por lo que la conducción o el manejo de máquinas pueden resultar inapropiados.

Memantina *Kern Pharma* contiene lactosa

Si su médico le ha indicado que padece una intolerancia a ciertos azúcares, consulte con él antes de tomar este medicamento.

3. Cómo Memantina *Kern Pharma*

Siga exactamente las instrucciones de administración de este medicamento indicadas por su médico. En caso de duda, consulte de nuevo a su médico o farmacéutico.

Posología

La dosis recomendada de memantina en pacientes adultos y pacientes de edad avanzada es de 20 mg administrados una vez al día. Para reducir el riesgo de efectos adversos, esta dosis se alcanza gradualmente siguiendo el siguiente esquema diario:

Semana 1	medio comprimido de 10 mg
Semana 2	un comprimido de 10 mg
Semana 3	un comprimido y medio de 10 mg
Semana 4 y siguientes	dos comprimidos de 10 mg una vez al día

La dosis normal de inicio es de medio comprimido una vez al día (5 mg) la primera semana. Se aumenta a un comprimido al día (10 mg) la segunda semana y a 1 comprimido y medio una vez al día en la tercera semana. De la cuarta semana en adelante, la dosis normal es de 20 mg administrados una vez al día (20 mg).

Posología para pacientes con insuficiencia renal

Si padece problemas de riñón, su médico decidirá la dosis apropiada para su condición. En este caso, su médico debe controlar periódicamente su función renal.

Administración

Memantina debe administrarse por vía oral una vez al día. Para sacar el máximo provecho de su medicación, debe tomarla todos los días y a la misma hora. Los comprimidos se deben tragar con un poco de agua. Los comprimidos se pueden tomar con o sin alimentos.

Duración del tratamiento

Continúe tomando memantina mientras sea beneficioso para usted. El médico debe evaluar los efectos de su tratamiento periódicamente.

Si toma más Memantina *Kern Pharma* del que debe

En caso de sobredosis o ingestión accidental, consulte inmediatamente a su médico o farmacéutico o llame al servicio de Información Toxicológica, teléfono: 91 562 04 20, indicando el medicamento y la cantidad ingerida.

- En general, tomar una cantidad excesiva de memantina no debe provocarle ningún daño. Puede experimentar un aumento de los síntomas descritos en la sección 4 "Posibles efectos adversos".
- Si toma una sobredosis de memantina, póngase en contacto con su médico o pida consejo médico, ya que podría necesitar atención médica.

Si olvidó tomar Memantina *Kern Pharma*

- Si se da cuenta de que ha olvidado tomar su dosis de memantina, espere y tome la siguiente dosis a la hora habitual.
- No tome una dosis doble para compensar las dosis olvidadas.

Si tiene cualquier otra duda sobre el uso de este medicamento, pregunte a su médico o farmacéutico.

4. Posibles efectos adversos

Al igual que todos los medicamentos, Memantina *Kern Pharma* puede producir efectos adversos, aunque no todas las personas los sufran.

En general los efectos adversos se clasifican de leves a moderados.

Frecuentes (pueden afectar a entre 1 y 10 de cada 100 pacientes):

- Dolor de cabeza, sueño, estreñimiento, pruebas de función hepática elevadas, vértigo, alteración del equilibrio, respiración difícil, tensión alta e hipersensibilidad al medicamento.

Poco frecuentes (pueden afectar a entre 1 y 10 de cada 1.000 pacientes):

- Cansancio, infecciones por hongos, confusión, alucinaciones, vómitos, alteración de la marcha, insuficiencia cardíaca y formación de coágulos en el sistema venoso (trombosis/tromboembolismo venoso).

Muy raros (pueden afectar a menos de 1 de cada 10.000 pacientes):

- Convulsiones.

Frecuencia no conocida (la frecuencia no puede estimarse a partir de los datos disponibles):

- Inflamación del páncreas, inflamación del hígado (hepatitis) y reacciones psicóticas.

La enfermedad de Alzheimer se ha relacionado con depresión, ideación suicida y suicidio. Se ha informado de la aparición de éstos acontecimientos en pacientes tratados con memantina.

Comunicación de efectos adversos

Si experimenta cualquier tipo de efecto adverso, consulte a su médico o farmacéutico, incluso si se trata de posibles efectos adversos que no aparecen en este prospecto. También puede comunicarlos directamente a través del Sistema Español de Farmacovigilancia de Medicamentos de Uso Humano website: www.notificaRAM.es. Mediante la comunicación de efectos adversos usted puede contribuir a proporcionar más información sobre la seguridad de este medicamento.

Si considera que alguno de los efectos adversos que sufre es grave o si aprecia cualquier efecto adverso no mencionado en este prospecto, informe a su médico o farmacéutico.

5. Conservación de Memantina *Kern Pharma*

Mantener este medicamento fuera de la vista y del alcance de los niños.

No utilice este medicamento después de la fecha de caducidad que aparece en el envase después de "CAD".

La fecha de caducidad es el último día del mes que se indica.

No requiere condiciones especiales de conservación.

Los medicamentos no se deben tirar por los desagües ni a la basura. Deposite los envases y los

medicamentos que no necesita en el Punto SIGRE de la farmacia. En caso de duda pregunte a su farmacéutico cómo deshacerse de los envases y de los medicamentos que no necesita. De esta forma ayudará a proteger el medio ambiente.

6. Contenido del envase e información adicional

Composición de Memantina *Kern Pharma* 10 mg comprimidos

- El principio activo es hidrocloruro de memantina. Cada comprimido contiene 10 mg de hidrocloruro de memantina que equivalen a 8,31 mg de memantina.
- Los demás componentes son almidón de maíz pregelatinizado, celulosa microcristalina, lactosa monohidrato, almidón glicolato sódico (tipo A) (almidón de patata), sílice coloidal anhidra y estearato de magnesio.

Aspecto del producto y contenido del envase

Memantina *Kern Pharma* se presenta en forma de comprimidos redondos, blancos con una ranura en ambas caras. El comprimido se puede dividir en mitades iguales.

Memantina *Kern Pharma* 10 mg comprimidos se presenta en envases de 112 comprimidos y en envase clínico de 490 comprimidos.

Puede que solamente estén comercializados algunos tamaños de envases.

Otras presentaciones

Memantina *Kern Pharma* 20 mg comprimidos EFG

Titular de la autorización de comercialización y responsable de la fabricación

Kern Pharma, S.L.

Pol. Ind. Colón II, C/ Venus 72

08228 Terrassa (Barcelona)

España

Fecha de la última revisión de este prospecto: Abril de 2013.

La información detallada y actualizada de este medicamento está disponible en la página Web de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
*http:/*www.aemps.gob.es/

VALSARTÁN

Prospecto: Información para el usuario

Valsartán *Kern Pharma* 320 mg comprimidos recubiertos con película EFG

Lea todo el prospecto detenidamente antes de empezar a tomar este medicamento, porque contiene información importante para usted.

- Conserve este prospecto, ya que puede tener que volver a leerlo.
- Si tiene alguna duda, consulte a su médico o farmacéutico.
- Este medicamento se le ha recetado solamente a usted, y no debe dárselo a otras personas aunque tengan los mismos síntomas que usted, ya que puede perjudicarles.
- Si experimenta efectos adversos, consulte a su médico o farmacéutico, incluso si se trata de efectos adversos que no aparecen en este prospecto. Ver sección 4.

Contenido del prospecto:

1. Qué es Valsartán *Kern Pharma* y para qué se utiliza

Valsartán *Kern Pharma* pertenece a una clase de medicamentos conocidos como antagonistas de los receptores de la angiotensina II, que ayudan a controlar la presión arterial alta. La angiotensina II es una sustancia del cuerpo que hace que los vasos sanguíneos se estrechen, causando un aumento de la presión arterial. Valsartán *Kern Pharma* actúa bloqueando el efecto de la angiotensina II. Como consecuencia, los vasos sanguíneos se relajan y la presión arterial disminuye.

Valsartán *Kern Pharma* 320 mg comprimidos recubiertos con película **se puede utilizar**

- **para tratar la presión arterial alta en adultos y en niños y adolescentes de 6 a 18 años de edad.** La presión arterial alta aumenta la carga del corazón y de las arterias. Si no se trata, puede dañar los vasos sanguíneos del cerebro, corazón y riñones, y puede provocar un infarto cerebral, insuficiencia cardiaca o insuficiencia renal. La presión arterial alta aumenta el riesgo de ataques cardíacos. La disminución de la presión arterial a valores normales reduce el riesgo de desarrollar estos trastornos.

2. Qué necesita saber antes de empezar a tomar Valsartán *Kern Pharma* No tome Valsartán:

- si es **alérgico** (hipersensible) al valsartán o a cualquiera de los demás componentes de Valsartán, enumerados al final de este prospecto,
- si sufre una **enfermedad grave del hígado,**
- si está **embarazada de más de 3 meses** (es mejor evitar también Valsartán *Kern Pharma* durante los primeros meses del embarazo – ver sección Embarazo).

si tiene diabetes o insuficiencia renal y le están tratando con un medicamento para reducir la presión arterial que contiene aliskirén.

Si alguna de estas situaciones le afecta, no tome Valsartán *Kern Pharma*.

Advertencias y precauciones

Consulte a su médico o farmacéutico antes de empezar a tomar Valsartán *Kern Pharma*.

- si sufre una enfermedad del hígado,
- si sufre una enfermedad grave del riñón o si está siendo sometido a diálisis,
- si sufre un estrechamiento de la arteria del riñón,
- si ha sido sometido recientemente a un trasplante de riñón (recibió un riñón nuevo),
- si está siendo tratado de un ataque cardíaco o de insuficiencia cardiaca, su médico puede comprobar su función renal,
- si sufre una enfermedad cardiaca grave diferente de la insuficiencia cardiaca o del ataque cardíaco,
- si está utilizando medicamentos que aumentan la cantidad de potasio en sangre. Entre ellos figuran los suplementos de potasio o sustitutos de la sal que contienen potasio, los medicamentos ahorradores de potasio y la heparina. Puede ser necesario controlar regularmente la cantidad de potasio en la sangre,
- si es menor de 18 años de edad y toma Valsartán *Kern Pharma* junto con otros medicamentos que inhiben en sistema renina angiotensina aldosterona (medicamentos que bajan la presión arterial), su médico puede controlar periódicamente su función renal y la cantidad de potasio de su sangre,
- si sufre aldosteronismo, una enfermedad en la que las glándulas suprarrenales producen demasiada hormona aldosterona. En este caso, no se recomienda tomar Valsartán,
- si ha perdido mucho líquido (deshidratación) a causa de una diarrea, vómitos o dosis elevadas de diuréticos (medicamentos para aumentar la eliminación de orina),

si está tomando alguno de los siguientes medicamentos utilizados para tratar la hipertensión (presión arterial alta):

un inhibidor de la enzima convertidora de angiotensina (IECA) (por ejemplo enalapril, lisinopril, ramipril), en particular si sufre problemas relacionados con la diabetes aliskirén

Puede que su médico le controle la función renal, la presión arterial y los niveles de electrolitos (por ejemplo, potasio) en la sangre a intervalos regulares.

Ver también la información bajo el encabezado “No tome Valsartán *Kern Pharma*”.

- informe a su médico si está embarazada (o si sospecha que pudiera estarlo). No se recomienda utilizar Valsartán *Kern Pharma* al inicio del embarazo, y en ningún caso deben administrarse si está embarazada de más de tres meses, ya que puede causar daños graves a su bebé cuando se administra a partir de ese momento (ver sección embarazo).

Si alguna de estas situaciones le afecta, informe a su médico antes de tomar Valsartán *Kern Pharma*.

Uso de Valsartán *Kern Pharma* con otros medicamentos

Comunique a su médico o farmacéutico que está utilizando, ha utilizado recientemente o podría tener que utilizar cualquier otro medicamento.

El efecto del tratamiento con Valsartán *Kern Pharma* puede verse alterado si se toma junto con ciertos medicamentos. Puede que su médico tenga que cambiar su dosis y/o tomar otras precauciones o, en algunos casos, interrumpir el tratamiento de alguno de los medicamentos. Esto es aplicable tanto a los medicamentos adquiridos con receta como sin receta, especialmente:

- **otros medicamentos que disminuyan la presión arterial, especialmente diuréticos (medicamentos para aumentar la eliminación de orina), IECAs (tales como enalapril, lisinopril, etc.) o aliskirén (ver también la información bajo los encabezados "No tome Valsartán *Kern Pharma*" y "Advertencias y precauciones")**
- **medicamentos que aumentan la cantidad de potasio** en sangre. Entre ellos figuran los suplementos de potasio o sustitutos de la sal que contienen potasio, los medicamentos ahorradores de potasio y la heparina,
- **ciertos medicamentos para tratar el dolor** llamados antiinflamatorios no esteroideos **(AINEs),**
- **litio,** un medicamento utilizado para tratar ciertos tipos de enfermedades psiquiátricas.

Toma de Valsartán *Kern Pharma* con los alimentos, bebida y alcohol

Puede tomar Valsartán con o sin alimentos.

Embarazo y lactancia

Si está embarazada o en periodo de lactancia, o cree que podría estar embarazada o tiene intención de quedarse embarazada, consulte a su médico o farmacéutico antes de utilizar este medicamento.

- **Embarazo**
  Debe informar a su médico si está embarazada (o si sospecha que pudiera estarlo). Su médico generalmente le recomendará que deje de tomar Valsartán *Kern Pharma* antes de quedarse embarazada o tan pronto como sepa que está embarazada y le recomendará que tome otro medicamento en lugar de Valsartán *Kern Pharma*. No se recomienda utilizar Valsartán *Kern Pharma* al inicio del embarazo, y en ningún caso debe administrarse a partir del tercer mes de embarazo ya que puede causar daños graves a su bebé cuando se administra a partir de ese momento.

- **Lactancia**
  Informe a su médico si está en periodo de lactancia o va a comenzar con el mismo. No se recomienda el uso de Valsartán *Kern Pharma* durante la lactancia materna, y su médico elegirá otro tratamiento para usted si desea dar de mamar, especialmente si su bebé es recién nacido o prematuro.

Conducción y uso de máquinas

Antes de conducir un vehículo, usar herramientas o manejar máquinas, o llevar a cabo otras actividades que requieran concentración, asegúrese de conocer como le afecta Valsartán *Kern Pharma*. Al igual que muchos otros medicamentos utilizados para tratar la presión arterial alta, Valsartán *Kern Pharma* puede causar, en raras ocasiones, mareos y afectar la capacidad de concentración.

3. Cómo tomar Valsartán *Kern Pharma*

Para obtener los mejores resultados y reducir el riesgo de efectos adversos, tome siempre Valsartán *Kern Pharma* exactamente como le indique su médico. Consulte a su médico o farmacéutico si tiene dudas. Las personas con presión arterial alta no notan a menudo ningún signo de la enfermedad; muchas se sienten de forma normal. Esto hace que sea muy importante acudir a sus citas con el médico, incluso si se siente bien.

Pacientes adultos con presión arterial alta: la dosis habitual es de 80 mg al día. En algunos casos su médico puede recetarle dosis más elevadas (p.ej. 160 mg o 320 mg). También puede combinar valsartán con otro medicamento (p.ej. un diurético).

Niños y adolescentes (6 a 18 años de edad) con presión arterial alta

En pacientes que pesan menos de 35 kg la dosis habitual es 40 mg de valsartán una vez al día. En pacientes que pesan 35 kg o más la dosis habitual de inicio es 80 mg de valsartán una vez al día. En algunos casos su médico puede recetarle dosis más elevadas (la dosis puede aumentarse a 160 mg y hasta un máximo de 320 mg).

Puede tomar Valsartán *Kern Pharma* con o sin alimentos. Trague Valsartán *Kern Pharma* con un vaso de agua.
Tome Valsartán *Kern Pharma* aproximadamente a la misma hora cada día.

Si toma más Valsartán *Kern Pharma* del que debe

Si nota un fuerte mareo y/o desmayo, contacte con su médico inmediatamente y túmbese. Si accidentalmente ha tomado demasiados comprimidos, contacte con su médico, farmacéutico u hospital. También puede llamar al Servicio de Información Toxicológica, teléfono 91 562 04 20 indicando el medicamento y la cantidad tomada.

Si olvidó tomar Valsartán *Kern Pharma*

Si olvida tomar una dosis, tómela tan pronto como lo recuerde. No obstante, si es casi la hora de la dosis siguiente, sáltese la dosis olvidada.

No tome una dosis doble para compensar las dosis olvidadas.

Si interrumpe el tratamiento con Valsartán *Kern Pharma*

Si deja su tratamiento con Valsartán *Kern Pharma* su enfermedad puede empeorar. No deje de tomar el medicamento a menos que se lo indique su médico.

Si tiene cualquier otra duda sobre el uso de este medicamento, pregunte a su médico o farmacéutico.

4. Posibles efectos adversos

Al igual que todos los medicamentos, este medicamento puede producir efectos adversos, aunque no todas las personas los sufran.

Estos efectos adversos pueden producirse con ciertas frecuencias, que se definen a continuación:
- muy frecuentes: pueden afectar a más de 1 de cada 10 personas,
- frecuentes: pueden afectar hasta 1 de cada 10 personas,
- poco frecuentes: pueden afectar hasta 1 de cada 100 personas,
- raros: pueden afectar hasta 1 de cada 1.000 personas,
- muy raros: pueden afectar hasta 1 de cada 10.000 personas,
- frecuencia no conocida: la frecuencia no puede estimarse a partir de los datos

disponibles.

Algunos síntomas necesitan atención médica inmediata:

Puede experimentar síntomas de angioedema (una reacción alérgica específica), tales como

- hinchazón en la cara, labios, lengua o garganta,
- dificultad para respirar o tragar,
- urticaria, picor.

Si experimenta alguno de estos síntomas, consulte a un médico

inmediatamente. Los efectos adversos incluyen:

Frecuentes

- mareo,
- presión arterial baja con o sin síntomas como mareo y desmayo al ponerse de pie,
- reducción de la función renal (signos de deterioro renal).

Poco frecuentes

- angioedema (ver sección "Algunos síntomas necesitan atención médica inmediata")
- pérdida súbita del conocimiento (síncope),
- sensación de rotación (vértigo),
- marcada reducción de la función renal (signos de insuficiencia renal aguda),
- espasmos musculares, ritmo cardiaco anormal (signos de hiperpotasemia),
- falta de aliento, dificultad para respirar estando acostado, hinchazón de los pies o piernas (signos de insuficiencia cardiaca),
- dolor de cabeza,
- tos,
- dolor abdominal,
- náuseas,
- diarrea,
- cansancio,
- debilidad.

Frecuencia no conocida

- pueden tener lugar reacciones alérgicas con erupción cutánea, picor y urticaria; síntomas de fiebre, hinchazón y dolor de las articulaciones, dolor muscular, hinchazón de los ganglios linfáticos y/o síntomas similares a los de la gripe (signos de enfermedad del suero),
- manchas rojas purpúreas, fiebre, picor (signos de inflamación de los vasos sanguíneos, también llamada vasculitis),
- hemorragia o moretones más frecuentes de lo habitual (signos de trombocitopenia),
- dolor muscular (mialgia),
- fiebre, dolor de garganta o úlceras en la boca por infecciones (síntomas de bajo nivel de glóbulos blancos, también llamado neutropenia),
- reducción del nivel de hemoglobina y reducción del porcentaje de glóbulos rojos en la sangre (que, en casos graves, puede ocasionar una anemia),
- aumento del nivel de potasio en sangre (que, en casos graves, puede provocar espasmos musculares y un ritmo cardíaco anormal),
- elevación de los valores de la función hepática (que puede indicar lesión hepática), incluyendo un aumento del nivel de bilirrubina en sangre (que, en casos graves, puede provocar que la piel y los ojos se pongan amarillos),

- aumento del nivel del nitrógeno ureico en sangre y aumento del nivel de creatinina sérica (que pueden indicar anomalías de la función renal).

La frecuencia de algunos efectos adversos puede variar en función del su estado. Por ejemplo, ciertos efectos adversos como el mareo y la reducción de la función renal se observaron con menos frecuencia en pacientes adultos tratados con presión arterial alta que en pacientes adultos tratados por insuficiencia cardiaca o después de un ataque cardíaco reciente.

Los efectos adversos en niños y adolescentes son similares a los observados en adultos.

Comunicación de efectos adversos

Si experimenta cualquier tipo de efecto adverso, consulte a su médico, farmacéutico o enfermero, incluso si se trata de posibles efectos adversos que no aparecen en este prospecto. También puede comunicarlos directamente a través del Sistema Español de Farmacovigilancia de Medicamentos de Uso Humano: http://www.notificaram.es. Mediante la comunicación de efectos adversos usted puede contribuir a proporcionar más información sobre la seguridad de este medicamento.

5. Conservación de Valsartán *Kern Pharma*

Mantener este medicamento fuera de la vista y del alcance de los niños.

No conservar a temperatura superior a 30 ºC. Mantener en el envase original.

No utilice este medicamento después de la fecha de caducidad que aparece en el envase después de "CAD". La fecha de caducidad es el último día del mes que se indica.

No utilice este medicamento si observa que el envase está dañado o muestra signos de deterioro.

Los medicamentos no se deben tirar por los desagües ni a la basura. Deposite los envases y los medicamentos que no necesita en el Punto SIGRE de la farmacia. En caso de duda pregunte a su farmacéutico cómo deshacerse de los envases y de los medicamentos que no necesita. De esta forma ayudará a proteger el medio ambiente.

6. Contenido del envase e información adicional

Composición de Valsartán *Kern Pharma*

- El principio activo es valsartán. Cada comprimido contiene 320 mg de valsartán.
- Los demás componentes (excipientes) son: celulosa microcristalina, celulosa en polvo, crospovidona, y estearato de magnesio. Los componentes del recubrimiento del comprimido son: hipromelosa, dióxido de titanio (E-171), macrogol /PEG 8000, óxido de hierro rojo (E-172), óxido de hierro amarillo (E-172) y óxido de hierro negro (E-172).

Aspecto del producto y contenido del envase

Los comprimidos recubiertos con película de Valsartán 320 mg son de color marrón, oblongo y ranurado en una cara. La ranura es sólo para poder fraccionar y facilitar la deglución, pero no para dividir el comprimido en dos mitades iguales.

Se presenta en envases de 28 comprimidos.

Titular de la autorización de comercialización

Kern Pharma, S.L.
Venus, 72 - Pol. Ind.
Colón II 08228 Terrassa
- Barcelona España

Responsable de la fabricación

Atlantic Pharma – Produções Farmacêuticas, S.A.
Rua da Tapada Grande nº 2, Abrunheira. 2710 – 089 Sintra (Portugal)

ó

Laboratorios Lesvi, S.L.
Avda. Barcelona, 69
08970 Sant Joan Despí
(Barcelona)

Fecha de la última revisión de este prospecto: Enero 2017.

La información detallada y actualizada de este medicamento está disponible en la página Web de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
http://www.aemps.gob.es/

Appendix 2: Selection of PILs for the English corpus

Source: Medicines and Healthcare Products Regulatory Agency (MHR): Regulating Medicines and Medical Devices.

<http://www.mhra.gov.uk/spc-pil/index.htm>

IBUPROFEN

PACKAGE LEAFLET: INFORMATION FOR THE USER

***Ibuprofen* 600 mg Film-coated Tablets**

(*Ibuprofen*)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What *Ibuprofen* Tablets are and what they are used for

Ibuprofen belongs to a group of medicines called Non Steroidal Anti-Inflammatory Drugs (known as NSAIDs), which relieve pain and reduce inflammation in joints and soft tissues such as muscles and ligaments.

Ibuprofen tablets are used to:

relieve mild to moderate pain e.g. post-operative pain, toothache, period pain and soft tissue injury (muscles and ligaments)

relieve stiffness and pain in the back and other muscles

reduce inflammation in different types of arthritis.

- **What you need to know before you take *Ibuprofen***

Do NOT take *Ibuprofen* if you:

- are allergic to *Ibuprofen* or any of the other ingredients of this medicine (listed in section 6).
- have or had an allergic reaction to aspirin or any other NSAID (you have ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
- have an increased tendency of bleeding
- are suffering from or have a history of repeated stomach ulcers or other gastric complaint
- are suffering from heart failure, which can cause shortness of breath or ankle swelling
- suffer from kidney or liver problems
- are in last 3 months of your pregnancy
- have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue).

Do not take if you have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking *Ibuprofen*. If you:

- are elderly
- are suffering from or have a history of bronchial asthma
- have a history of stomach or bowel problems
- have problems with your kidneys, heart or liver
- have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue).
- have a history of gastrointestinal disease
- are severely dehydrated

- have problems conceiving or are in the first 6 months of pregnancy
- are taking any non-steroidal anti-inflammatory medicine, including aspirin as this may result into increased tendency of ulceration or bleeding
- have ulcerated colitis or Crohn's disease

If you suffer from any of the following at any time during your treatment STOP TAKING the medicine and seek immediate medical help:

- Pass blood in your faeces (stools/ motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds

STOP TAKING the medicine and tell your doctor if your experience:

- Indigestion or heartburn
- Abdominal pain (pains in your stomach) or other abdominal stomach symptoms

Anti-inflammatory/pain-killer medicines like *Ibuprofen* may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking *Ibuprofen* if you:

- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs of feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Other medicines and *Ibuprofen*

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines of the following:

- any other pain-relieving medication, including aspirin
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid,

  warfarin, ticlopidine)
- diuretics ('water tablets')

- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as

  atenolol medicines, angiotensin-II receptor antagonists such as losartan)

- medicines for heart problems e.g. digoxin, digitoxin
- lithium, a drug used in the treatment of depression
- methotrexate, a treatment for leukaemia
- medicines known as immunosuppressants such as ciclosporin and tacrolimus (used to dampen down your immune response)
- mifepristone in the last 8 - 12 days, used to end a pregnancy
- corticosteroids (medicines to treat a variety of conditions such as allergies and hormone imbalances), e.g. aldosterone, hydrocortisone or prednisolone
- quinolone antibiotics, e.g. ciprofloxacin, norfloxacin or levofloxacin

- zidovudine (an anti-viral drug)
- medicines known as selective serotonin reuptake inhibitors (SSRIs), used for the treatment of depression
- any other *Ibuprofen* preparations, such as those you can buy without a prescription
- cholestyramine (a drug used to lower cholesterol)
- medicines known as sulphonylureas such as glibenclamide and glipizide (used to treat diabetes)
- voriconazole or fluconazole (types of anti-fungal drugs)
- Gingko biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with *Ibuprofen*)
- aminoglycosides (a type of antibiotic).

Some other medicines may also affect or be affected by the treatment of *Ibuprofen* You should therefore always seek the advice of your doctor or pharmacist before you take *Ibuprofen* with other medicines.

Pregnancy, breast-feeding and fertility

The use of *Ibuprofen* whilst pregnant or breast feeding should be avoided.

Ibuprofen should not be used in the last 3 months of pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

Driving and using machines

Ibuprofen may make you feel dizzy or drowsy. If the tablets affect you in this way do not drive or operate machinery

3. How to take *Ibuprofen*

Always take *Ibuprofen* exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you suffer from heart, liver or kidney problems your doctor may lower your dose and carry out regular tests.

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

***Ibuprofen* with food and drink**

The tablets should be swallowed preferably with a drink of water. Take with or after food.

The recommended dose is:

- **Adults**

  Initially 1200 mg per day in divided doses. Larger doses up to 1800 mg per day may be taken if necessary. The maintenance dose will be determined on an individual basis (between 600 - 1200 mg a day).

  Do not take more than 2400 mg in a 24-hour period.

- **Use in children and adolescents**

  Ibuprofen 600 mg tablets are not recommended for use in children.

- **Elderly people**

  To reduce the possibility of side effects if you are elderly, you should take the smallest dose for the shortest possible time. Your doctor may monitor you for bleeding in the stomach.

If you take more *Ibuprofen* than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause stomach pain, feeling sick, being sick, diarrhoea, ringing in the ears, headache, bleeding in the stomach or intestines.

Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take *Ibuprofen*

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one.

Do not take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

If you stop taking *Ibuprofen*

Do not stop taking your medicine without talking to your doctor first even if you feel better.

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

4. Possible side effects

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

If any of the following happen, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)
- Stevens-Johnson syndrome (severe blisters and bleeding in the mucous membranes of the lips, eyes, mouth, nasal passage, and genitals) or severe headache, high temperature, stiffness of the neck, a skin reaction causing blistering and flaking of the skin, intolerance to light
- you pass blood in your faeces (stools/motions)
- you pass black tarry stools

- you vomit any blood or dark particles that look like coffee grounds.
- blood disorders such as low numbers of red or white blood cells, reduction in blood platelets (which may increase the risk of bleeding and bruising), neutropenia (which may cause fever or chills, sore throat, ulcers in your mouth or throat)
- heart problems causing symptoms such as shortness of breath when exercising or lying flat, wheezing and a cough, weight gain.

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

The following side effects have been reported at the approximate frequencies shown:

Rare: may affect up to 1 in 1,000 people

Stop taking the medicine and tell your doctor if you experience:

- abdominal pain (pains in your stomach) or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or being sick
- unexplained wheezing, shortness of breath, skin rash, itching or bruising
- yellowing of the eyes and/or skin
- severe sore throat with high fever
- blurred or disturbed vision, or seeing/hearing strange things
- fluid retention (e.g. swollen ankles).

Very rare: may affect up to 1 in 10,000 people

Very rarely *Ibuprofen* Tablets may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain) especially in patients with an auto-immune disease e.g. Systemic Lupus Erythematosus (SLE) or mixed connective tissue disease; symptoms may include stiff neck, headache, nausea, vomiting, fever, disorientation.

Other side effects (Frequency unknown)

Other side effects that have been reported while taking *Ibuprofen*:

- peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach
- pancreatitis (inflammation of the pancreas)
- diarrhoea

- constipation
- flatulence (wind)
- inflammation or ulceration of the mouth e.g. mouth ulcers and cold sores (ulcerative stomatitis)
- high blood pressure
- kidney problems such as inflammation of the kidneys, kidney damage or kidney failure
- liver problems such as abnormal liver function test results, inflammation of the liver (hepatitis)
- breathlessness and wheezing in patients suffering from or with a previous history of asthma or allergic disease e.g. allergy to house dust mites, cats or dogs
- runny nose
- problems with the senses such as vision problems, inflammation of the optic nerve, pins-and-needles or numbness, ringing in the ears or impaired hearing
- headaches, hallucinations, depression, confusion, dizziness and vertigo (a feeling of dizziness or "spinning", drowsiness and a general feeling of being unwell, lethargy
- difficulty in sleeping, anxiety

Ibuprofen has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis

Medicines such as *Ibuprofen* may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You can minimise the risk of side effects by taking the least amount of tablets for the shortest amount of time necessary to control your symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store *Ibuprofen*

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

These tablets should be stored in a dry place, at or below 25° C, protected from light in the package or container supplied. Do not transfer them to another container.

Do not use *Ibuprofen* after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

- **Contents of the pack and other** information

What *Ibuprofen* tablets contain:

- The active ingredient is *Ibuprofen*.
- The other ingredients are pregelatinised maize starch, maize starch, colloidal silicon dioxide, sodium starch glycolate, and stearic acid. The tablet coating contains hydroxypropyl methylcellulose E464), talc, erythrosine (E127) and titanium dioxide (E171).

What *Ibuprofen* tablets look like and contents of the pack:

- The *Ibuprofen* 600 mg tablets are pink, capsule-shaped film coated tablets. They are coded 600 over 0531 and plain on the reverse.

- The tablets are available in pack sizes of 7, 10, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168, 250, 500, and 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

This leaflet was last revised: August 2015

PL 00289/0280

POM

THIS IS A REPRESENTATION OF AN ELECTRONIC RECORD THAT WAS SIGNED ELECTRONICALLY AND THIS

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Teva Pharmaceuticals Europe B.V

1.3.1 pil-uk-pl-00289-0280-*Ibuprofen*-600mg-film-coated-tablets

APPROVALS

Signed by	Meaning of Signature	Server Date
Darryl Hill	Regulatory Affairs Approval	09-Sep-2015 09:57:42 AM

OMEPRAZOLE

PATIENT INFORMATION LEAFLET

<DISTRIQUIMICA>

OMEPRAZOLE 10MG, 20MG & 40MG GASTRO-RESISTANT HARD CAPSULES

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

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

In this leaflet:

1. WHAT *OMEPRAZOLE* IS AND WHAT IT IS USED FOR

These capsules contain the active substance *Omeprazole*. *Omeprazole* belongs to a group of medicines called proton pump inhibitors. They work by reducing the amount of acid that your stomach produces.

Omeprazole is used to treat the following conditions:

In adults:

- Gastro-esophageal reflux disease (GERD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.

- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Ulcers which are infected with bacteria called *Helicobacter pylori*. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). *Omeprazole* can also be used to stop ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

In children:

Children over 1 year of age and ≥ 10 kg

- Gastro-esophageal reflux disease' (GERD). GERD is described above. In children, the symptoms of the condition can include the return of stomach contents into the mouth (regurgitation), being sick (vomiting) and poor weight gain.

Children and adolescents over 4 years of age

Ulcers which are infected with bacteria called '*Helicobacter pylori'*. If your child has this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

2. BEFORE YOU TAKE *OMEPRAZOLE*

Do not take *Omeprazole*

- If you are allergic(hypersensitive) to *Omeprazole* or any of the other ingredients in these capsules
- if you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, es*Omeprazole*).
- if you are taking a medicine containing nelfinavir (used for HIV infection).

If you are not sure, talk to your doctor or pharmacist before taking these capsules. **Take special care with *Omeprazole***

Omeprazole may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking these capsules or while you are taking them, talk to your doctor straight away:

- You lose a lot of weight for no reason and have problems swallowing.

- You get stomach pain or indigestion.
- You begin to vomit food or blood.
- You pass black stools (blood-stained faeces).
- You experience severe or persistent diarrhoea, as *Omeprazole* has been associated with a small increase in infectious diarrhoea.
- You have severe liver problems.

If you take *Omeprazole* on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because *Omeprazole* can affect the way some medicines work and some medicines can have an effect on *Omeprazole*.

Do not take *Omeprazole* if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus)
- Digoxin (used to treat heart problems)
- Diazepam (used to treat anxiety, relax muscles or in epilepsy)
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking *Omeprazole*
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking *Omeprazole*
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- Tacrolimus (in cases of organ transplantation)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Saquinavir (used to treat HIV infection)

- Clopidogrel (used to prevent blood clots (thrombi))

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as *Omeprazole* to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

Taking *Omeprazole* with food and drink

You can take your capsules with food or on an empty stomach.

Pregnancy and breast-feeding

Before taking these capsules tell your doctor if you are pregnant or trying to get pregnant. Your doctor will decide whether you can take *Omeprazole* during this time.

Your doctor will decide whether you can take *Omeprazole* if you are breastfeeding.

Driving and using machines

Omeprazole is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see Section 4). If affected, you should not drive or operate machinery.

Important information about some of the ingredients of these capsules

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

3. HOW TO TAKE *OMEPRAZOLE*

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

Your doctor will tell you how many capsules to take and how long to take them for. This will depend on your condition and how old you are. The usual doses are given below.

Adults:

To treat symptoms of GERD such as **heartburn and acid regurgitation**:

- If your doctor has found that your gullet has been slightly damaged, the usual dose is 20mg once a day for 4-8 weeks. Your doctor may tell you to take a dose of 40mg for a further 8 weeks if your gullet has not yet healed.
- The usual dose once the gullet has healed is 10mg once a day.
- If your gullet has not been damaged, the usual dose is 10mg once a day.

To treat **ulcers in the upper part of the intestine** (duodenal ulcer):

- The usual dose is 20mg once a day for 2 weeks. Your doctor may tell you to take the same dose for a further 2 weeks if your ulcer has not yet healed.
- If the ulcer has not fully healed, the dose can be increased to 40 mg once a day for 4 weeks.

To treat **ulcers in the stomach** (gastric ulcer):

- The usual dose is 20mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your ulcer has not yet healed.
- If the ulcer has not fully healed, the dose can be increased to 40 mg once a day for 8 weeks.

To **prevent the duodenal and stomach ulcers** from coming back:

- The usual dose is 10mg or 20mg once a day. Your doctor may increase the dose to 40mg once a day.

To treat duodenal and stomach **ulcers caused by NSAIDs** (Non-Steroidal Anti-Inflammatory Drugs):

- The usual dose is 20mg once a day for 4–8 weeks.

To **prevent duodenal and stomach ulcers** if you are taking **NSAIDs:**

- The usual dose is 20mg once a day.

To treat **ulcers caused by *Helicobacter pylori*** infection and to stop them coming back:

- The usual dose is 20 mg twice a day for one week.
- Your doctor will also tell you to take two antibiotics from either amoxicillin, clarithromycin or metronidazole.

To treat too much acid in the stomach caused by a growth in the pancreas **(Zollinger-Ellison syndrome)**:

- The usual dose is 60mg daily.
- Your doctor will adjust the dose depending on your needs and will also decide for how long you need to take the medicine.

Children:

To treat symptoms of GERD such as **heartburn and acid regurgitation**:

- Children over 1 year of age and with a body weight of more than 10 kg may take *Omeprazole*. The dose for children is based on the child's weight and the doctor will decide the correct dose.

To treat **ulcers caused by *Helicobacter pylori*** infection and to stop them coming back:

- Children aged over 4 years may take *Omeprazole*. The dose for children is based on the child's weight and the doctor will decide the correct dose.
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

Taking this medicine

- It is recommended that you take your capsules in the morning.
- You can take your capsules with food or on an empty stomach.
- Swallow your capsules whole with half a glass of water. Do not chew or crush the capsules. This is because the capsules contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

What to do if you or your child have trouble swallowing the capsules

- If you or your child have trouble swallowing the capsules:

  Open the capsules and swallow the contents directly with half a glass of water or put the contents into a glass of still (non-fizzy) water, any acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce.
  Always stir the mixture just before drinking it (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes.

  - To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine - do not chew or crush them.

If you take more *Omeprazole* than you should

If you take more *Omeprazole* than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take your *Omeprazole*

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

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

If you notice any of the following rare but serious side effects, stop taking these capsules and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be Stevens-Johnson syndrome or toxic epidermal necrolysis.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

Side effects may occur with certain frequencies, which are defined as follows:

Very common:	Affects more than 1 user in 10
Common:	Affects 1 to 10 users in 100
Uncommon:	Affects 1 to 10 users in 1,000
Rare:	Affects 1 to 10 users in 10,000
Very rare:	Affects less than 1 user in 10,000
Not known:	Frequency cannot be estimated from the available data

Other side effects include:

Common side effects

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

Uncommon side effects

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as “pins and needles”, feeling sleepy.
- Spinning feeling (vertigo).
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.

Rare side effects

- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth.
- An inflammation of the inside of the mouth.
- An infection called thrush which can affect the gut and is caused by a fungus.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (interstitial nephritis).

- Increased sweating.

Very rare side effects

- Changes in blood count including agranulocytosis (lack of white blood cells).
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Muscle weakness.
- Enlarged breasts in men.

Frequency not known

If you are on *Omeprazole* for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Taking a proton pump inhibitor like *Omeprazole*, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Omeprazole may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medicine at this time.

Do not be concerned by this list of possible side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE *OMEPRAZOLE*

- Keep out of the reach and sight of children.
- Do not use these capsules after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Keep the bottle tightly closed in order to protect from moisture. Do not use after 28 days after first opening.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

Composition of *Omeprazole* capsules

- The active substance is *Omeprazole*. Each capsule contains 10mg, 20mg or 40mg of *Omeprazole*.
- The other ingredients are: hypromellose, talc, titanium dioxide, metacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30% (also sodium laurilsulfate and polysorbate 80), triethylcitrate, ethylcellulose, oleic acid, colloidal anhydrous silica, sugar spheres (sucrose and maize starch), gelatin and black ink (shellac and black iron oxide).

What the product looks like and contents of the pack

The capsules are opaque, white coloured and printed with OM 10, OM 20 and OM 40 for the 10mg capsules, 20mg capsules and 40mg capsules, respectively.

All strengths come in bottle packs of 14 and 28 capsules. The 40mg strength also comes in a bottle pack of 7 capsules. Not all packs may be marketed.

Marketing Authorisation Holder

DISTRIQUIMICA, S.A., Av. Mare de Déu de Montserrat, 221 – Bajos, 08041 Barcelona, Spain

Manufacturer

Laboratorios Dr. Esteve, S.A. Sant Martí, s/n, Polígono Industrial La Roca, 08170, Martorelles, Barcelona, Spain.

This package leaflet was last updated in October 2014.

For information in large print or braille contact the Marketing Authorisation Holder above, telephone 0034.93.446.00.00 or e-mail mcastella@esteve.es.

PARACETAMOL

PACKAGE LEAFLET: INFORMATION FOR THE USER

Paracetamol 1000mg film coated tablets

Paracetamol

Read all of this leaflet carefully before you starts taking this medicine because it contains important information for you.

- Keep this leaflet, you may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes ant possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

44. WHAT *PARACETAMOL* FILM COATED TABLETS ARE AND WHAT THEY ARE USED FOR

Paracetamol 1000 mg film coated tablets are used for the management of mild to moderate pain and fever. The active ingredient is *Paracetamol* which is a painkiller and also reduces your temperature when you have a fever.

-

- WHAT YOU NEED TO KNOW BEFORE YOU TAKE *PARACETAMOL* FILM COATED TABLETS

Do not take *Paracetamol* 1000mg film coated tablets If you

- are allergic (hypersensitive) to *Paracetamol* or any of the other ingredients of this medicine (listed in Section 6: Further information).
- are under 16 years old
- have a body weight of less than 50 Kg.

Do not take *Paracetamol* 1000 mg Tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking *Paracetamol* 1000 mg Tablets.

Take special care when using *Paracetamol* 1000 mg film coated tablets

Talk to your doctor or pharmacist before taking *Paracetamol* 1000 mg

Tablets if:

- you have moderate to severe kidney or liver problems, including acute hepatitis or liver problems
- caused by excessive alcohol consumption
- you have a condition called Gilbert's syndrome which can cause yellowing of the skin or whites of the eyes (mild jaundice)

- you are taking other medicinal products which affect your liver
- you have a hereditary enzyme disorder called glucose-6-phosphate dehydrogenase deficiency
- you have a blood disorder called haemolytic anaemia which causes a reduced number of red blood cells, pale yellow skin and weakness or breathlessness
- you are suffering from dehydration or nutritional problems (chronic malnutrition)
- you have an addiction to alcohol
- you are already **taking any other products that contain *Paracetamol***. If this applies to you then do not take *Paracetamol* 1000 mg film coated tablets without first speaking to your doctor or pharmacist.

Taking other medicines with *Paracetamol* film coated tablets Refer your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without a prescription. Some other medicines may affect or be influenced by *Paracetamol* film coated tablets. In particular it is important to tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines used to thin the blood such as warfarin as *Paracetamol* may increase their effect

- medicines used to stop you feeling sick (nausea) or vomiting (e.g. metoclopramide or domperidone).
- products containing codeine (used to help suppress coughs and relieve pain)
- medicines used to treat high cholesterol (e.g. cholestyramine)
- The antibiotic Chloramphenicol (used to treat infections) but not by local application of eye drops.
- Probenecid (a medicine used to treat high levels of uric acid in the blood stream i.e. gout)
- medicine used to treat fever or mild pain (e.g. salicylamide).

to treat stomach acid), isoniazid (used to treat tuberculosis), zidovudine (used to treat HIV),

- antiepileptic medicines used to treat convulsions (such as phenobarbital, carbamazepine, phenytoin, primidone and glutethimide), St John's Wort (a herbal remedy) and rifampicin (used to treat infections). Always check the leaflet that comes with your other medicine

Do not take *Paracetamol* 1000 mg film coated Tablets if you are taking any other medicines containing *Paracetamol*.

This includes some other painkillers, cough and cold remedies. This also includes a wide range of other medicines available on prescription and over the counter.

Taking *Paracetamol* 1000 mg film coated Tablets with food and drink

You should not drink alcohol whilst taking these tablets. Taking *Paracetamol* 1000 mg film coated Tablets with alcohol can increase your chances of getting side effects.

Paracetamol 1000 mg Tablets can be taken with or without food.

Pregnancy and breast-feeding

Although there is no evidence that *Paracetamol* causes any ill effects, talk to your doctor or pharmacist before taking these tablets if:

you are pregnant, think you may be pregnant or are planning to get pregnant
you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Paracetamol 1000 mg film coated Tablets have not been shown to affect your ability to drive or operate machinery.

3. HOW TO TAKE *PARACETAMOL* FILM COATED TABLETS

Adults and children aged 16 years and over:

Take 1 tablets as per prescribed

- Do not take more frequently than every 4 hours.
- Do not take more than 4 tablets in 24 hours.

- Do not exceed the stated dose.
- Do not take with other paracetarnol containing products.
- Do not give to children under 16 years.
  If you take too many tablets immediate medical advice should be sought in the event of an overdose, even if you feel well because of the risk of delayed serious liver damage.

- If symptoms persist consult your doctor.

If you take more *Paracetamol* 1000 mg Tablets than you should

Immediate medical advice should be sought in the event of over dosage because of the risk of irreversible liver damage. It is important to contact your doctor even if you feel well.

Contact your nearest hospital emergency department or tell your doctor immediately and say exactly how much you have taken. Your doctor will advise you what to do.

Remember to take the pack and any remaining tablets with you. This is so the doctor knows what you have taken.

Symptoms of *Paracetamol* overdose in the first 24 hours are paleness of the skin, feeling sick (nausea), vomiting, lack of appetite, and abdominal pain. Liver damage may become apparent 12 to 48 hours after taking *Paracetamol*.

If you forget to take *Paracetamol* 1000 mg Tablets

If you forget to take a dose at the right time, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose. You must allow at least 4-6 hours between doses.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, *Paracetamol* film coated tablets cause side effects, although not everybody is affected. The frequency of these side effects is not known but experience indicates that side effects with *Paracetamol* are rare and serious reactions are very rare

Stop taking *Paracetamol* 1000 mg Tablets and see a doctor or go to a hospital straight away if:

- you experience a serious allergic reaction (anaphylaxis) such as swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing
- you have serious illness with blistering of the skin, mouth, eyes and genitals or an itchy, lumpy, skin rash.

The following side effects have also been reported. If you experience any of the following please tell your doctor or pharmacist:

- blood problems (such as agranulocytosis or thrombocytopenia), increased risk of bleeding, bruising more easily than usual or getting more infections than usual
- difficulty in breathing or wheezing (particularly if you have asthma and are allergic to aspirin or anti-inflammatory medicines (NSAIDs)
- liver problems.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE *PARACETAMOL* FILM COATED TABLETS

Keep out of the sight and reach of children.

This medicine does not require any special storage condition. Do not use after the expiration date of *Paracetamol* film coated tablets as indicated on the package.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What is *Paracetamol* film coated tablets

Active ingredient is *Paracetamol*.

Each ***Paracetamol* 1000 mg film coated tablets** contains 1000 mg of

Paracetamol

The other ingredients are: Pregelatinized starch, Maize starch, Povidone, Magnesium stearate, Hypromellose (E464), Titanium Dioxide (E171), Macrogol (E1521)

What *Paracetamol* film coated tablets looks and contents of the pack

***Paracetamol* 1000 mg film coated tablets**

White coloured, caplet shaped, film coated tablets, with 'K', Bisect break line '02'on one side and break line on the other side.

***Paracetamol* 1000 film coated tablets** are available in Blister packs of 12, 16 & 100 tablets and HDPE Bottles of 32, 100, 300 & 500 tablets.

Marketing Authorization Holder

Dawa Limited

5 Sandridge Close

Harrow

Middlesex

HA1 1XD

UK

Manufacturer

Drugsrus Limited

5 Sandridge Close

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This leaflet was last revised on 05/2015.

AMOXICILLIN

PACKAGE LEAFLET: INFORMATION FOR THE USER

Amoxicillin 500mg Capsules

Amoxicillin Trihydrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Amoxicillin Capsules are and what they are used for

What Amoxicillin Capsules are

Amoxicillin Capsules is an antibiotic. The active ingredient is amoxicillin. This belongs to a group of medicines called 'penicillins'.

What Amoxicillin Capsules are used for

Amoxicillin Capsules are used to treat infections caused by bacteria in different parts of the body.

Amoxicillin Capsules may also be used in combination with other medicines to treat stomach ulcers.

- **What you need to know before you take Amoxicillin Capsules.**

Do not take Amoxicillin Capsules:

- If you are allergic (hypersensitive) to amoxicillin, penicillin or any of the other ingredients of this medicine (listed in section 6).
- If you have ever had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face or throat.

Do not take Amoxicillin Capsules if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Amoxicillin Capsules.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Amoxicillin Capsules:

- If you have glandular fever (fever, sore throat, swollen glands and extreme tiredness)
- If you have kidney problems
- If you are not urinating regularly.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Amoxicillin Capsules.

Blood and urine tests

- If you are having urine tests (glucose) or blood tests for liver function
- If you are having oestriol tests (used during pregnancy to check the baby is developing normally).

Tell your doctor or pharmacist that you are taking Amoxicillin Capsules. This is because Amoxicillin capsules can affect the results of these tests.

Other medicines and Amoxicillin Capsules

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

- If you are taking allopurinol (used for gout) with Amoxicillin Capsules, it may be more likely that you will have an allergic skin reaction.
- If you are taking probenecid (used for gout) your doctor may decide to adjust your dose of Amoxicillin Capsules.
- If you are taking medicines to help stop blood clots (such as warfarin), you may need extra blood tests.
- If you are taking other antibiotics (such as tetracycline) Amoxicillin Capsules may be less effective
- If you are taking methotrexate (used for the treatment of cancer and severe psoriasis) Amoxicillin Capsules may cause an increase in side effects.

Pregnancy and breast-feeding

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

Driving and using machines

Amoxicillin Capsules can have side effects and the symptoms (such as allergic reactions, dizziness and convulsions) may make you unfit to drive.

Do not drive or operate machinery unless you are feeling well.

3. How to take Amoxicillin Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Do not chew the capsules. Swallow the capsules with water without opening capsule.
- Space the doses evenly during the day, at least 4 hours apart.

Children weighing less than 40 kg

All doses are worked out depending on the child's body weight in kilograms.

- Your doctor will advise you how much Amoxicillin Capsules you should give to your baby or child.
- The usual dose is 40 mg to 90 mg for each kilogram of body weight a day, given in two or three divided doses.

- The maximum recommended dose is 100 mg for each kilogram of body weight a day.

Adults, elderly patients and children weighing 40 kg or more
The recommended dose of Amoxicillin Capsules is 250 mg to 500 mg three times a day or 750 mg to 1 g every 12 hours, depending on the severity and type of infection.

- **Severe infections**: 750 mg to 1 g three times a day.
- **Urinary tract infection**: 3 g twice daily for one day.
- **Lyme disease (an infection spread by parasites called ticks)**: Isolated erythema migrans (early stage – red or pink circular rash): 4 g a day, Systemic manifestations (late stage – for more serious symptoms or when the disease spreads around your body): up to 6 g a day.
- **Stomach ulcers**: one 750 mg or one 1 g dose twice a day for 7 days with other antibiotics and medicines to treat stomach ulcers.
- **To prevent heart infection during surgery**: the dose will vary according to the type of surgery. Other medicines may also be given at the same time. Your doctor, pharmacist or nurse can give you more details.
- The maximum recommended dose is 6 g per day.

Kidney problems

If you have kidney problems the dose might be lower than the usual dose.

If you take more Amoxicillin Capsules than you should

If you have taken too much Amoxicillin Capsules, signs might be an upset stomach (feeling sick, being sick or diarrhoea) or crystals in the urine, which may be seen as cloudy urine, or problems urinating. Talk to your doctor as soon as possible. Take the medicine to show the doctor.

If you forget to take Amoxicillin Capsules

- If you forget to take a dose, take it as soon as you remember.
- Do not take the next dose too soon, wait about 4 hours before taking the next dose.
- Do not take a double dose to make up for a forgotten dose.

How long should you take Amoxicillin Capsules for?

- Keep taking Amoxicillin Capsules for as long as your doctor has told you to, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.
- Once you finish treatment, if you still feel unwell you should go back to see the doctor.

Thrush (a yeast infection of moist areas of the body which can cause soreness, itching and white discharge) may develop if Amoxicillin Capsules is used for a long time. If this occurs tell your doctor.

If you take Amoxicillin Capsules for a long time, your doctor may perform additional tests to check your kidneys, liver and blood are orking normally.

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

4. Possible side effects

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

Stop taking Amoxicillin Capsules and see a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

Very rare: may affect up to 1 in 10,000 people

- Allergic reactions, the signs may include: skin itching or rash, swelling of the face, lips, tongue, body or breathing difficulties. These can be serious and occasionally deaths have occurred
- Rash or pinpoint flat red round spots under the skin surface or bruising of the skin. This is due to inflammation of blood vessel walls due to an allergic reaction. It can be associated with joint pain (arthritis) and kidney problems
- A delayed allergic reaction can occur usually 7 to 12 days after having Amoxicillin Capsules, some signs include: rashes, fever, joint pains and enlargement of the lymph nodes especially under the arms
- A skin reaction known as ‘erythema multiforme’ where you may develop: itchy reddish purple patches on the skin especially on the palms of the hands or soles of the feet, ‘hive-like’ raised swollen areas on the skin, tender areas on the surfaces of the mouth, eyes and genitals. You may have a fever and be very tired
- Other severe skin reactions can include: changes in skin colour, bumps under the skin, blistering, pustules, peeling, redness, pain, itching, scaling. These may be associated with fever, headaches and body aches
- Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- Fever, chills, a sore throat or other signs of an infection, or if you bruise easily. These may be signs of a problem with your blood cells
- The Jarisch-Herxheimer reaction which occurs during treatment with Amoxicillin Capsules for Lyme disease and causes fever, chills, headache, muscle pain and skin rash
- Inflammation of the large bowel (colon) with diarrhoea (sometimes containing blood), pain and fever
- Serious liver side effects may occur. They are mainly associated with people having treatment over a long period, males and the elderly. You must tell your doctor urgently if you get:

  Severe diarrhoea with bleeding

  Blisters, redness or bruising of the skin

  Darker urine or paler stools

  Yellowing of the skin or the whites of the eyes (jaundice). See also anaemia below which might result in jaundice.

These can happen when having the medicine or for up to several weeks after.

If any of the above happens stop taking the medicine and see your doctor straight away.

Sometimes you may get less severe skin reactions such as:

- A mildly itchy rash (round, pink-red patches), ‘hive-like’ swollen areas on forearms, legs, palms, hands or feet. This is uncommon (may affect up to 1 in 100 people).

If you have any of these talk to your doctor as Amoxicillin Capsules will need to be stopped.

The other possible side effects are:

Common: may affect up to 1 in 10 people

- Skin rash
- Feeling sick(nausea)
- Diarrhoea.

Uncommon: may affect up to 1 in 100 people

- Being sick (vomiting).

Very rare: may affect up to 1 in 10,000 people

- Superficial tooth discolouration that can usually be removed by brushing.
- Thrush (a yeast infection of the vagina, mouth or skin folds), you can get treatment for thrush from your doctor or pharmacist
- Kidney problems
- Fits (convulsions), seen in patients on high doses or with kidney problems
- Hyperactivity
- Crystals in the urine, which may be seen as cloudy urine, or difficulty or discomfort in passing urine. Make sure you drink plenty of fluids to reduce the chance of these symptoms
- The tongue may change to yellow, brown or black and it may have a hairy appearance
- An excessive breakdown of red blood cells causing a type of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes
- Low number of white blood cells
- Low number of cells involved with blood clotting
- The blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself.
- Dizziness

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: http://www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Amoxicillin Capsules:

- Keep this medicine out of the sight and reach of children.
- Store in the original package.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Do not use this medicine if there are visible signs of deterioration.
- Keep container tightly closed.
- Do not store above 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information
What Amoxicillin Capsules contain

The active substance in this medicine is called amoxicillin and is present as amoxicillin trihydrate.

Amoxicillin 500mg capsules contain 500mg amoxicillin trihydrate.

The other ingredients are colloidal anhydrous silica and magnesium stearate.

The capsule shells contain; gelatin, titanium dioxide (E 171) erythrosine (E 127), black Iron Oxide (E 172), red iron oxide (E 172), iron oxide yellow (E 172)

What Amoxicillin Capsules look like and contents of the pack
Amoxicillin 500 mg Capsules are maroon and yellow capsules which are supplied in blister packs of 3, 6, 12, 15, 21, 50 capsules and pots of 100 capsules (500 mg) Not all pack sizes may be marketed.

PL 44041/0002

Marketing Authorization Holder:

NOUMED LIFE SCIENCES LIMITED Noumed House, Shoppenhangers Road Maidenhead, Berkshire, SL6 2RB, United Kingdom

Manufacturer:

MEDREICH PLC

Warwick House, Plane Tree Crescent,

Feltham TW13 7HF, UK

E-mail : info@medreich.co.uk

This leaflet was last revised in September 2017

Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, 020 33998960 (UK only)

Please be ready to give the following information:

Product name	**Reference number**
Amoxicillin 500mg capsules	**PL 44041/000**

Ennogen Healthcare

PACKAGE LEAFLET: INFORMATION FOR THE USER

Acetylcysteine 600mg Effervescent Tablets

(Acetylcysteine)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT ACETYLCYSTEINE EFFERVESCENT TABLETS ARE AND WHAT THEY ARE USED FOR

Acetylcysteine Effervescent Tablets contain a medicine called Acetylcysteine. This belongs to a group of medicines called mucolytics. It works by making the mucus (phlegm) less sticky which makes the mucus easier to cough up. Acetylcysteine is used for problems with the breathing passages (respiratory tract).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACETYLCYSTEINE EFFERVESCENT TABLETS

Do NOT take Acetylcysteine Effervescent Tablets if you:
- **Are allergic (hypersensitive) to acetylcysteine** or any of the other ingredients of this medicine (listed in section 6)
- Are under 14 years of age.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Acetylcysteine Effervescent Tablets:
- If you have asthma
- If you have a history of stomach ulcers
- If you are allergic to histamines
- If you are on a restricted salt diet (see Acetylcysteine Effervescent Tablets contain sodium)
- If you have hereditary problems with some sugars (see Acetylcysteine Effervescent Tablets contain sorbitol)
- If you have liver or kidney problems.

If you notice any changes to your skin or mucus membranes such as the inside of your nose, mouth and lips, you should **STOP taking these tablets IMMEDIATELY and seek medical advice** (see section 4 Possible side effects).

Effervescent tablets can be a choking hazard if swallowed whole, especially in the elderly. Ensure that tablet is fully dissolved before you take it.

Other medicines and Acetylcysteine Effervescent Tablets:

Please tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. In particular:
- Antitussives: cough-relieving agents
- Antibiotics: some antibiotics may not work as well when taken at the same time as Acetylcysteine Effervescent Tablets. All antibiotics should be given at a different time to Acetylcysteine Effervescent Tablets at least 2 hours apart
- Glyceryl trinitrate: used to treat angina (chest pain).

Acetylcysteine Effervescent Tablets with food, drink and alcohol

Acetylcysteine Effervescent Tablets should be taken after food.

Pregnancy and breast-feeding

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

Acetylcysteine Effervescent Tablets should not be taken during pregnancy or breast-feeding.

If you are unsure you should talk to your doctor before taking these tablets.

Driving and using machines

Acetylcysteine Effervescent Tablets should not affect your ability to drive or use machinery.

Acetylcysteine Effervescent Tablets contain sodium

Acetylcysteine Effervescent Tablets contain 356.8 mg of sodium per tablet. This should be taken into consideration if you are on a controlled salt diet. Sodium is part of salt (sodium chloride).

Acetylcysteine Effervescent Tablets contain sorbitol

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

3. HOW TO TAKE ACETYLCYSTEINE EFFERVESCENT TABLETS

Always take Acetylcysteine Effervescent Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.
For oral administration only. Acetylcysteine Effervescent Tablets should be dissolved completely in a glass of water before use and taken after food.

Adults and children aged 14 years and over:

The usual dose is 1 tablet, once daily.
Dissolve the tablet in a glass of water and take after food.

This medicine can be taken for up to 5 days for acute respiratory problems. Longer-term treatment may be needed for chronic respiratory disorders.

Children under the age of 14 years
Acetylcysteine Effervescent Tablets are not suitable for children under the age of 14.

If you take more Acetylcysteine Effervescent Tablets than you should
If you take more Acetylcysteine Effervescent Tablets than you should, talk to your doctor or contact your nearest hospital casualty department immediately. Take your tablet pack with you. You may have diarrhoea, heartburn, stomach ache or feel sick.

If you forget to take Acetylcysteine Effervescent Tablets
If you have forgotten to take a dose, leave out that dose completely. Take your next dose at the normal time, do not take a double dose. If you have trouble remembering to take your tablets, tell your doctor or pharmacist.

If you stop taking Acetylcysteine Effervescent Tablets
You should talk to your doctor or pharmacist before stopping taking these tablets.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Acetylcysteine Effervescent Tablets can cause side effects, although not everyone gets them.

Stop taking Acetylcysteine Effervescent Tablets and see a doctor or contact your nearest hospital casualty department immediately:
- If you have swelling of the lips, throat or tongue, difficulty in swallowing or breathing. This could be a sign of an allergic reaction
- Any changes to the skin or mucus membranes (such as your nose, mouth, lips and genitals) including skin rashes, blistering or peeling of the skin. These may be accompanied by flu-like symptoms. These could be signs of serious skin reactions such as Stevens Johnson Syndrome or Lyell's Syndrome.

Other side effects reported with this medicine are shown below:

Uncommon (affects less than 1 person in 100)
- Headache
- Ringing in the ears (Tinnitus)
- Increased heart rate
- Feeling sick and being sick
- Diarrhoea
- Stomach pains
- Swelling in the mouth and swelling of the lips
- Skin rashes and itching
- Fever
- Low blood pressure.

Rare (affects less than 1 person in 1,000)
- Indigestion
- Shortness of breath.

Very rare (affects less than 1 person in 10,000)
- Bleeding in the upper respiratory tract.

Frequency unknown
- Swelling of the face.

Laboratory tests:
Your doctor may want to perform some laboratory tests while you are taking these tablets.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ACETYLCYSTEINE EFFERVESCENT TABLETS

Keep out of the sight and reach of children.

Store below 25°C. Store in the original package to protect from moisture and light. Keep the tube tightly closed.

Check the expiry date found on the blister and carton or label. The expiry date refers to the last day of that month. Do not use after the expiry date stated.
Do not use this medicine if you notice discolouration of the tablets.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Acetylcysteine Effervescent Tablets contain:
Acetylcysteine Effervescent Tablets contain the active substance acetylcysteine 600mg in each tablet.

The other ingredients are: Ascorbic acid (Vitamin C), Citric acid, Sodium hydrogen carbonate, Sodium carbonate, Sorbitol (E420), Macrogol 6000, Sodium citrate, Sodium saccharin, Flavour (Lemon).

What Acetylcysteine Effervescent Tablets look like and contents of the pack
Acetylcysteine Effervescent Tablets are white flat-faced tablets with bevelled edges 25mm in diameter.

They are available as follows:
Tubes containing 12 tablets with tamper evident plastic caps with inbuilt dessicant.
A carton containing 10 tablets packed into individual sachets.
A carton containing 20 tablets packed into individual sachets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Ennogen Healthcare Limited
Unit G4, Riverside Industrial Estate,
Riverside Way, Dartford, DA1 5BS, UK

This leaflet was last revised in May 2016

Diazepam 5mg Tablets

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking these tablets

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

In this leaflet:

1. What Diazepam Tablets are and what they are used for

Diazepam belongs to a group of medicines called benzodiazepines. It works by depressing activity in the part of the brain that controls emotion, by promoting the action of a chemical called gamma-aminobutyric acid (GABA). Diazepam is used in the treatment of anxiety, including that associated with alcohol withdrawal, for sedation before minor medical procedures and in conjunction with other medicines to relieve muscle spasm. It may also be used in the management of cerebral spasticity and as part of a treatment for epilepsy. In children it is also used to treat night terrors and sleepwalking.

2. Before you take Diazepam Tablets

Do not take Diazepam Tablets:

- If you are allergic (hypersensitive) to diazepam or any of the other ingredients in diazepam tablets.
- If you have breathing difficulties.
- If you suffer from any mental illness such as obsessions, phobias (irrational fears) or schizophrenia.
- If you suffer from depression or anxiety associated with depression.
- If you have a rare metabolic condition called porphyria.
- If you have myasthenia gravis (very weak muscles)

Take special care with Diazepam Tablets:

Tell your doctor before you start taking these tablets:

- If you have severe liver disease.
- If you have severe kidney disease.
- If you suffer from memory loss (amnesia).
- If you have a personality disorder.
- If you have a history of alcoholism or drug abuse.
- If you have suffered a loss or bereavement (diazepam can affect the way you react to this).
- When diazepam is used for a long period of time as there is a risk of becoming dependent on the drug and there is also a risk of withdrawal symptoms when you stop taking it.

Taking other medicines:

Please tell your doctor if you are taking any of the following medicines:

- Tranquillisers used to treat anxiety (e.g. *chlordiazepoxide*).
- Sleeping tablets (e.g. *temazepam*)
- Medicines used for depression (e.g. *amitriptyline*).
- Strong pain killers known as narcotics including *codeine, morphine, methadone, fentanyl, oxycodone, meperidine, hydromorphone* and *hydrocodone* as it can cause you to become more sedated and may affect your breathing and heart.
- *Anaesthetics* as it can cause you to become more sedated and may affect your breathing and heart.
- Medicines used to treat mental disorders (e.g. *thioridazine*).
- Medicines used to treat epilepsy (e.g. *phenytoin*).
- *Cimetidine*, a drug used to treat ulcers of the stomach and duodenum.
- *Rifampicin* a drug used in the treatment of tuberculosis.

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

Taking Diazepam Tablets with food and drink:

Diazepam should not be taken with alcohol as it will increase the sedative effects of this medicine and therefore should be avoided.

Pregnancy and Breastfeeding:

Tell your doctor if you are, you think you might be or are planning to become pregnant. You should not use Diazepam tablets if you are breast-feeding or are planning to breast-feed your baby.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

Do not drive or operate machinery when taking this medicine as it may make you sleepy or affect your concentration.

Important information about some of the ingredients of Diazepam Tablets:

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

3. How to take Diazepam Tablets

Always take Diazepam Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The tablets should be swallowed with a drink of water.

Adults

Anxiety: the usual dose is 2mg three times daily. Do not exceed 30mg per day, in divided doses. For sleeping problems (insomnia) associated with anxiety, take 5 to 15 mg at bedtime. This medicine should only be used to treat insomnia when it is severe, disabling or causing extreme distress.
Alcohol withdrawal: 5 to 20mg, repeated if necessary after two to four hours.
Muscle spasm: The usual adult dose is 2 to 15mg daily in divided doses.
Muscle spasm in tetanus: 3 to 10mg per kg of bodyweight daily.
Management of cerebral spasticity: The usual dose in 2 to 60mg daily in divided doses.
Epilepsy: 2 to 60 mg daily in divided doses.
Sedation before medical procedures: 5 to 20mg.

Children

Night terrors and sleep walking in children: 1 to 5mg at bedtime.
Management of cerebral spasticity: for tension and irritability a dose of 2 to 40mg daily in divided doses should be taken.
Muscle spasm in tetanus: 3 to 10 mg per kg of bodyweight daily. *Sedation before medical procedures:* 2 to 10mg.

Elderly or very ill patients

The dose should not exceed half the adult dose.

If you take more Diazepam Tablets than you should:

If you swallow too many tablets or someone else accidentally

takes your medicine contact your doctor, pharmacist or nearest hospital straight away.

The symptoms of overdose may include poor coordination in the arms and legs, slurred speech, difficulty swallowing, shaking, increased drowsiness and unusual excitement. In severe overdose there may be decreased function of the lungs and heart, difficulty breathing and coma.

If forget to take Diazepam Tablets:

Try to take Diazepam Tablets daily as prescribed. If you forget to take a dose, take it as soon as you remember, then go on as before. Never take a double dose to make up for a forgotten dose.

If you stop taking Diazepam Tablets:

Do not stop taking Diazepam Tablets suddenly. Always ask your doctor first.

Long term treatment with diazepam may lead to dependence and the side effects of treatment withdrawal include depression, nervousness, sleeping difficulties, irritability, sweating, diarrhoea, confusion and convulsions (fits).

If you have any further questions on the use of Diazepam Tablets ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, Diazepam Tablets can cause side effects, although not everyone gets them.

Contact your doctor or pharmacist as soon as possible if you have these side effects:

Rare: (between 1 in 1000 patients and 1 in 10,000 patients)

- Yellowing of the skin and whites of the eyes, as this may indicated you have a problem with your liver (e.g. Jaundice).

- Problems passing water.
- Stomach or bowel upset.
- Blurred vision or dizziness.
- Changes in libido (sexual desire).
- Skin rashes.
- Headaches.
- Low blood pressure.

- Changes in blood cells, which may appear as changes in bleeding times (e.g. increased bleeding times), nosebleeds, bruising easily, frequent or persistent infections or weakness and pale skin.

The following side effects may be mild and occur at the beginning of the treatment. Contact your doctor if you are concerned about these side effects.

Common: (between 1 in 10 patients to 1 in 100 patients)

- ☐ Sedation (increased drowsiness)
- ☐ Drowsiness
- ☐ Unsteadiness
- ☐ Poor coordination in the arms and legs
- ☐ Slurred speech
- ☐ Difficulty swallowing
- ☐ Shaking
- ☐ Trembling hands
- ☐ Confusion

If any of the side effects gets serious, or if you notice and side effects not listed in this leaflet please tell your doctor or pharmacist.

ACICLOVIR

PATIENT INFORMATION LEAFLET

Aciclovir 200mg and 400mg Dispersible Tablets (Aciclovir)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. (See Section 4).

What is in this leaflet:

1 What Aciclovir is and what it is used for

Aciclovir 200mg and 400mg Dispersible Tablets (referred to as Aciclovir throughout this leaflet) belongs to a group of medicines called anti−virals.
Aciclovir can be used:

- to treat herpes simplex infections of the skin and mucous membranes e.g. cold sores and genital herpes (excluding newborn babies and children with low immune systems and severe herpes simplex infections)
- to prevent recurrent attacks of herpes simplex
- to help prevent those who have low immune systems from getting herpes infections
- to treat chicken pox (varicella infection) and shingles (herpes zoster infection)

2 What you need to know before you take Aciclovir

Do not take Aciclovir:
If you are allergic (hypersensitive) to aciclovir, valaciclovir or any of the other ingredients in these tablets (see Section 6 "Contents of the pack and other information")

Warnings and precautions
Talk to your doctor before taking Aciclovir:

- If you are taking other nephrotoxic medicines (medicines that may cause kidney failure) such as cyclosporin and tacrolimus (See "Other medicines and Aciclovir" section)
- If you suffer from kidney problems [including if you have dialysis therapy] (as you may need a lower dose of aciclovir − see Section 3 "How to take aciclovir")
- if you are elderly (as you may need a lower dose of aciclovir − see Section 3 "How to take aciclovir")
- if you have a severely low immune system and need to have this medicine over a long period of time or in repeated doses .

Other medicines and Aciclovir
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

Medicines which may interact with Aciclovir:

- Probenecid (used to treat gout)
- Cimetidine (used to reduce stomach acid)
- Mycophenolate mofetil (used to prevent transplant rejection)

- Medicines which may affect the kidneys e.g. cyclosporin, tacrolimus (nephrotoxic medicines)
- Theophylline (used to treat breathing problems, such as asthma)

Aciclovir with food and drink
It is important that you drink plenty of fluids while you are taking Aciclovir to prevent you becoming dehydrated, especially if you are elderly, suffer from kidney problems, receiving Aciclovir via injection or are taking a high dose of Aciclovir.

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

Driving and using machines
Aciclovir is not likely to affect you being able to drive or use machinery. However, if you experience any difficulty or

symptoms, it may be necessary to avoid driving or operating machinery or pursuing any activity in which full attention is required

3 How to take Aciclovir

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- These tablets are to be taken orally, dissolved in at least 50mls of water or swallowed whole with a glass of water.
- The score line (present only in 400mg dispersible tablets) is not intended for breaking the tablet

The recommended doses are:

Adults
Treatment of Herpes Simplex infections
- 200mg five times a day for 5 days at approximately 4 hour intervals (leaving out the night time dose)
- Patients with severe infections, may need to take this medicine for more than 5 days
- For patients with a severely low immune system (e.g. after a bone marrow transplant) or those suffering from gut absorption problems, a higher dose of 400mg five times a day may be given or alternatively, dosing via injection may be considered

For treatment of infections in patients with a low immune system:
- 200mg four times a day at approximately 6 hour intervals
- This dose may be changed to 400mg twice a day at approximately 12 hour intervals, 200 mg three times a day at approximately 8 hour intervals or twice a day at approximately 12 hour intervals
- For patients with a severely low immune system or those suffering from gut absorption problems, a higher dose of 400mg four times a day may be given at approximately 6 hour intervals or alternatively, dosing via injection may be considered
- Treatment should be interrupted at intervals of 6−12 months, in order to see if there are any possible changes in the natural history of the infection

For prevention of infections in patients with a low immune system:
- 200mg five times a day for 5 days at approximately 4 hour intervals (leaving out the night time dose)
- For patients with a severely low immune system (e.g. after a bone marrow transplant) or those suffering from gut absorption problems, a higher dose of 400mg five times a day may be given or alternatively, dosing via injection may be considered
- The length of treatment will depend on the infection and its severity

Shingles (Herpes Zoster infection) and Chickenpox (Varicella infection)
- 800mg five times a day for 7 days at approximately 4 hour intervals (leaving out the night time dose)
- For patients with a severely low immune system (e.g. after a bone marrow transplant) or those suffering from gut absorption problems, dosing via injection may be considered
- Treatment of shingles should start as soon as possible after the start of the rash
- Treatment of chickenpox in patients with a low immune system should start within 24 hours after the start of the rash

Children
Treatment of Herpes Simplex infections and prevention of Herpes Simplex infections in children with a low immune system
- 2 years and over: adult dose
- Under 2 years: half the adult dose

Chickenpox (Varicella infection)
- 6 years or over: 800mg four times a day for 5 day
- 2−5 years: 400mg four times a day for 5 days

- Under 2 years: 200mg four times a day for 5 days
- Different dosage may be prescribed based on 20mg per kg of body weight (max of 800mg) four times a day

Elderly and patients suffering from kidney problems Herpes Simplex Infections
- 200mg two times a day at approximately 12 hour intervals is recommended

Shingles (Herpes Zoster infection)
- 800mg two times a day at approximately 12 hour intervals for patients suffering from severe kidney problems
- 800mg three times a day at approximately 8 hour intervals for patients suffering from moderate kidney problems

It is especially important if you are elderly, suffering from kidney problems or are taking a high dose of Aciclovir that you drink plenty of fluids.

If you take more Aciclovir than you should
If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department immediately for advice. Remember to take this leaflet or any remaining tablets with you.
Symptoms of overdose include: feeling and/or being sick, headache, confusion, seeing or hearing things that are not real (hallucinations), feeling agitated, fits, loss of consciousness/coma.

If you forget to take Aciclovir
Take it as soon as you remember, unless it is time for your next dose.
If you miss a dose do not take a double dose to

make up for a forgotten dose.

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

4 Possible side effects

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

Seek medical advice immediately if you develop the following symptoms:
- Allergic reactions: skin rashes, itching, swelling of the face, tongue or throat, breathlessness, difficulty in breathing, dizziness

Common side effects: (may affect up to 1 in 10 people)
- Headache
- Dizziness
- Feeling sick (nausea) or being sick (vomiting)
- Diarrhoea
- Stomach pains
- Severe itching (pruritus), skin rashes
- Abnormal sensitivity of the skin to sunlight (photosensitivity)
- Tiredness (fatigue)
- Fever

Uncommon side effects: (may affect up to 1 in 100 people)
- Red, raised, itchy skin rash (urticaria)
- Hair loss (alopecia)

Rare side effects: (may affect up to 1 in 1,000 people)
- Shortness of breath (dyspnoea)
- Increases in bilirubin and liver−related enzymes (reversible)
- Swelling of the deeper layers of the skin caused by a build−up of fluid (angioedema)
- Effects on blood and urine tests

Very rare side effects: (may affect up to 1 in 10,000 people)
- Agitation
- Confusion

- Shakiness (tremors)
- Lack of voluntary co−ordination of muscle movements (ataxia)
- Difficulty with speech (dysarthria)
- Hallucinations
- Mental health problems
- Fits
- Sleepiness (somnolence)
- Disorder of the brain (encephalopathy)
- Coma

The side effects listed above are generally reversible and usually reported in patients with kidney problems or with other pre−existing factors (See Section 2, "Warnings and precautions").

- Looking pale and feeling tired (anaemia)
- A reduction in white blood cells (leukopenia)
- A reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytophenia)
- Inflammation of the liver (hepatitis)
- Yellowing of the skin or whites of the eyes (jaundice)
- Kidney problems, failure or pain

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the internet at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Aciclovir

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister/carton after "EXP". The expiry date refers to the last day of that month.
- Store below 25°C.
- Store in original package.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

These measures will help to protect the environment.

6 Contents of the pack and other information

What Aciclovir contain:

- Each tablet contains either 200mg or 400mg of active ingredient aciclovir
- The other ingredients are potato starch, gelatin, microcrystalline cellulose, sodium starch glycollate, sodium stearyl fumarate and colloidal anhydrous silica

What Aciclovir looks like and contents of the pack
Aciclovir 200mg Dispersible: white/almost
white, round, convex tablet of 9.5mm diameter, marked " HF 200" on one side

- Aciclovir 400mg Dispersible: white/almost

white, oval, convex, scored tablet of 8mm x 16mm, marked " HD 400" on one side

Aciclovir is available in:
Aciclovir Dispersible is available in packs of:

- 200mg: 25 and 100
- 400mg: 25, 30, 56, 60, 70 and 100

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Tillomed Laboratories Ltd. 3 Howard Road,
Eaton Socon, St. Neots, Cambridgeshire
PE19 8ET

United Kingdom

Product Licence Numbers:
Aciclovir 200mg Dispersible Tablets PL 11311/0201 Aciclovir 400mg Dispersible Tablets PL 11311/0202

Date of last revision: December 2013

Hard to Read? Phone 0800 970 6115 for help

PACKAGE LEAFLET: INFORMATION FOR THE USER

GLUCOSAMINE SULPHATE 1500mg

POWDER FOR ORAL SOLUTION

Glucosamine sulphate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, ask your doctor or pharmacist.**
- **This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.**
- **If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.**

What is in this leaflet:

1. What Glucosamine sulphate Powder is and what it is used for

The full name of your medicine is Glucosamine sulphate 1500mg Powder for oral solution, but within the leaflet it will be referred to as Glucosamine sulphate Powder.

Glucosamine sulphate Powder contains glucosamine sulphate which belongs to a group of medicines called non-steroidal anti-inflammatory and anti-rheumatic agents.

Glucosamine sulphate Powder is used to relieve symptoms of mild to moderate osteoarthritis of the knee.

2. What you need to know before you take Glucosamine sulphate Powder

DO NOT take Glucosamine sulphate Powder:

- **if you are allergic (hypersensitive) to glucosamine or to any of the other ingredients (listed in section 6)**
- **if you are allergic (hypersensitive) to shellfish, as glucosamine is manufactured from shellfish**
- **if you suffer from phenylketonuria, as Glucosamine sulphate Powder contains aspartame, a source of phenylalanine.**

Warnings and precautions

Tell your doctor or pharmacist:

- **if you suffer from impaired glucose tolerance. More frequent controls of your blood glucose level may be necessary when starting the treatment with Glucosamine sulphate Powder**
- **if you have liver and/or kidney problems**
- **if you suffer from asthma. When starting on Glucosamine sulphate Powder, your asthma may get worse.**

Other medicines and Glucosamine sulphate Powder

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor before taking Glucosamine sulphate Powder if you are taking any of the following:

- **medicines to thin your blood (anticoagulants such as warfarin or acenocoumarol)**
- **tetracycline antibiotics.**

Pregnancy and breast-feeding

Glucosamine sulphate Powder should not be used during pregnancy. The use of Glucosamine sulphate Powder is not recommended during breast-feeding period. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

If you experience dizziness or drowsiness while taking Glucosamine sulphate Powder, you should not drive or operate machinery.

Glucosamine sulphate Powder contains aspartame and sorbitol

This medicine contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. One sachet contains 6.6 mmol (151 mg) sodium. If you have to follow a low-sodium diet, you should take this into account.

3. How to use Glucosamine sulphate Powder

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults (including the elderly)

The dose is 1 sachet (1500 mg glucosamine sulphate) daily. Dissolve the powder from the sachet in a glass of water (250 ml) and drink.

Glucosamine is not used for the treatment of acute painful symptoms. Relief of symptoms (especially pain relief) may not be experienced until after some weeks of treatment or sometimes even longer. If your symptoms do not get better after 2-3 months, consult your doctor or pharmacist, as you may need to consider other treatment.

Children and adolescents

Glucosamine sulphate Powder, should not be used in children and adolescents below the age of 18 years.

If you use more Glucosamine sulphate Powder than you should

If you have taken more Glucosamine sulphate Powder, than you should, you must consult your doctor or a hospital.

If you forget to take Glucosamine sulphate Powder

Take the dose as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop using Glucosamine sulphate Powder

Your symptoms may re-occur. If

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

4. Possible side effects

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

Stop taking the solution and contact your doctor or go to the casualty department of your nearest hospital IMMEDIATELY if you have any of the following:

- swelling of the lips, face, tongue or throat
- difficulty swallowing or breathing
- skin rash or hives.

The symptoms above may mean that you are having a serious allergic reaction to this medicine.

The following side effects have been reported:

Common side effects (occurring in less than 1 in every 10 patients):

- stomach pain, indigestion, diarrhoea constipation, nausea, flatulence
- headache, sleepiness or drowsiness, tiredness.

Uncommon side effects (occurring in less than 1 in every 100 patients):

- rash, itching, patchy inflammation of the skin.

Other side effects:

Allergic reaction, dizziness, visual disturbances, hair loss and hypercholesterolemia (increased cholesterol levels in blood) have also been reported occasionally.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Glucosamine sulphate Powder

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

DO NOT use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Glucosamine sulphate Powder contains:

- The active substance is glucosamine sulphate sodium chloride. Each sachet contains 1884 mg glucosamine sulphate sodium chloride, equivalent to 1500 mg glucosamine sulphate or 1178 mg glucosamine.
- The other ingredients are: anhydrous citric acid (E330), macrogol 4000, aspartame (E951), and sorbitol (E420).

What Glucosamine sulphate Powder looks like and contents of the pack

Glucosamine sulphate Powder is a white to slightly yellowish powder contained in single dose sachets.

Each carton contains 30, 60 or 90 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Crescent Pharma Limited,

Units 3 & 4, Quidhampton Business Units,

Polhampton Lane, Overton,

Hants RG25 3ED

United Kingdom

Manufacturers

Alcala Farma S.L.

Avenida de Madrid, 82
28802 Alcala de Henares, Madrid
Spain

Rafarm S.A.

Thesi Pousi-Xatzi Agiou Louka,
19002 Paiania Attiki,
Greece

This leaflet was last revised in 01/2016.

Code	Grasshopper Sistemas de Informação	Date
AW.CRC.36.03.V09	geral@gsiportugal.com www.gsiportugal.com GRASSHOPPER SISTEMAS DE INFORMAÇÃO	2016-01-07

Customer	Description
Crescent PHARMA LIMITED	GLUCOSAMINE SULPHATE 1500mg POWDER FOR ORAL SOLUTION (PACKAGE LEAFLET)

Size	Colours	Notes
115x450 mm	Pantone Reflex Blue C Keyline	NO GOOD FOR COLOR PROOF

60 mm

amneal® PHARMACEUTICALS

Package leaflet: Information for the user

Memantine 10 mg film-coated tablets
Memantine 20 mg film-coated tablets
Memantine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read itagain.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Memantine is and what it is used for

How does Memantine work

Memantine belongs to a group of medicines known as anti-dementia medicines. Memory loss in Alzheimer's disease is due to a disturbance of message signals in the brain. The brain contains so-called N-methyl-D-aspartate (NMDA)-receptors that are involved in transmitting nerve signals, important in learning and memory. Memantine belongs to a group of medicines called NMDA-receptor antagonists. Memantine acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

What is Memantine used for

Memantine is used for the treatment of patients with moderate to severe Alzheimer's disease.

2. What you need to know before you take Memantine

Do not take Memantine

- if you are allergic to memantine hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Memantine:
- if you have a history of epileptic seizures.
- if you have recently experienced a myocardial infarction (heart attack), or if you are suffering from congestive heart failure or from an uncontrolled hypertension (high blood pressure).

In these situations the treatment should be carefully supervised, and the clinical benefit of Memantine reassessed by your doctor on a regular basis.

If you suffer from renal impairment (kidney problems), your doctor should closely monitor your kidney function and if necessary adapt the Memantine doses accordingly.

The use of medicinal products called amantadine (for the treatment of Parkinson's disease), ketamine (a substance generally used as an anaesthetic), dextromethorphan (generally used to treat cough) and other NMDA-antagonists at the same time should be avoided.

Memantine is not recommended for children and adolescents under the age of 18 years.

Other medicines and Memantine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, Memantine may change the effects of the following medicines and their dose may need to be adjusted by your doctor:
- amantadine, ketamine, dextromethorphan.
- dantrolene, baclofen.
- cimetidine, ranitidine, procainamide, quinidine, quinine, nicotine.
- hydrochlorothiazide (or any combination with hydrochlorothiazide).
- anticholinergics (substances generally used to treat movement disorders or intestinal cramps).
- anticonvulsants (substances used to prevent and relieve seizures).
- barbiturates (substances generally used to induce sleep).
- dopaminergic agonists (substances such as L-dopa, bromocriptine).
- neuroleptics (substances used in the treatment of mental disorders).
- oral anticoagulants.

If you go into hospital, let your doctor know that you are taking Memantine.

Memantine with food and drink

You should inform your doctor if you have recently changed or intend to change your diet substantially (e.g. from normal diet to strict vegetarian diet) or if you are suffering from states of renal tubulary acidosis (RTA, an excess of acid-forming substances in the blood due to renal dysfunction (poor kidney function)) or severe infections of the urinary tract (structure that carries urine), as your doctor may need to adjust the dose of your medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. The use of Memantine in pregnant women is not recommended.

Women taking Memantine should not breast-feed.

Driving and using machines

Your doctor will tell you whether your illness allows you to drive and to use machines safely. Also, Memantine may change your reactivity, making driving or operating machinery inappropriate.

3. How to take Memantine

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The recommended dose of Memantine for adults and elderly patients is 20 mg once a day.

In order to reduce the risk of side effects this dose is achieved gradually by the following daily treatment scheme. For up-titration other tablet strengths are available.

week 1	half a 10 mg tablet
week 2	one 10 mg tablet
week 3	one and a half 10 mg tablet
week 4 and beyond	two 10 mg tablets or one 20 mg tablet once a day

The usual starting dose is half a 10 mg tablet once a day (5 mg) for the first week. This is increased to one 10 mg tablet once a day (10 mg) in the second week and to 1 and a half 10 mg tablet once a day in the third week. From the fourth week on, the usual dose is two 10 mg tablets or one 20 mg tablet once a day (20 mg).

At the beginning of treatment you will start by using 5 mg once a day. This dose will be increased weekly by 5 mg until the recommended (maintenance) dose is reached. The recommended maintenance dose is 20 mg once a day, which is reached at the beginning of the 4th week.

Dosage in patients with impaired kidney function

If you have impaired kidney function, your doctor will decide upon a dose that suits your condition. In this case, monitoring of your kidney function should be performed by your doctor at specified intervals.

Administration

Memantine should be administered orally once a day. To benefit from your medicine you should take it regularly every day at the same time of the day. The tablets should be swallowed with some water.

The tablets can be taken with or without food.

Duration of treatment

Continue to take Memantine as long as it is of benefit to you. Your doctor should assess your treatment on a regular basis.

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If you take more Memantine than you should

- In general, taking too much Memantine should not result in any harm to you. You may experience increased symptoms as described in section 4. "Possible side effects".
- If you take a large overdose of Memantine, contact your doctor or get medical advice, as you may need medical attention.

If you forget to take Memantine

- If you find you have forgotten to take your dose of Memantine, wait and take your next dose at the usual time.
- Do not take a double dose to make up for a forgotten dose.

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

1. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
In general, the observed side effects are mild to moderate.

Common (may affect up to 1 in 10 people):

- Headache, sleepiness, constipation, elevated liver function tests, dizziness, balance disorders, shortness of breath, high blood pressure and drug hypersensitivity.

Uncommon (may affect up to 1 in 100 people):

- Tiredness, fungal infections, confusion, hallucinations, vomiting, abnormal gait, heart failure and venous blood clotting (thrombosis/thromboembolism).

Very Rare (may affect up to 1 in 10,000 people):

- Seizures.

Not known (frequency cannot be estimated from the available data):

- Inflammation of the pancreas, inflammation of the liver (hepatitis) and psychotic reactions.

Alzheimer's disease has been associated with depression, suicidal ideation and suicide. These events have been reported in patients treated with Memantine.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Reporting of side effects
If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

2. How to store Memantine

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

Do not use this medicine after the expiry date which is stated on the carton, label and the blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

3. Contents of the pack and other information

The active substance is memantine hydrochloride. Each tablet contains 10 mg /20 mg of memantine hydrochloride equivalent to 8.31 mg /16.62 mg Memantine.

The other ingredients are:

Tablet core: Silica colloidal anhydrous, cellulose, microcrystalline, silicified microcrystalline cellulose, sodium starch glycolate, talc, sodium stearyl fumarate.

Tablet film-coat: Hypromellose, macrogol 6000, talc, titanium dioxide (E 171), iron oxide yellow (E 172) for 20 mg, iron oxide red (E 172) for 20 mg.

What Memantine looks like and contents of the pack
Film-coated tablet.

Memantine 10 mg film-coated tablets:
White to off-white, centrally tapered oblong, biconvex, film-coated tablets with a single break line on both sides and debossed with 'Z' and '03' on either side of break line on one side and plain on other side. The tablet can be divided in equal doses.

Memantine 20 mg film-coated tablets:
Pale-red to grey-red, oval oblong, film-coated tablets debossed with 'Z' on one side arid '06' on other side.

Memantine tablets are available in clear PVC/PE/PVDC/Aluminium lidding foil blisters.

Blister pack:
10 mg: 1, 10, 28, 30, 50, 56, 98, 100 and 112 tablets
20 mg: 10, 28, 30, 42, 56 and 98 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Amneal Pharma Europe Limited
70 Sir John Rogerson's Quay,
Dublin 2,
Ireland.

Manufacturer
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate,
Hal Far, Birzebbugia, BBG 3000
Malta

This leaflet was last revised in 09/2014

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PACKAGE LEAFLET: INFORMATION FOR THE USER

VALSARTAN 320mg

FILM-COATED TABLETS

Valsartan

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet.You may need to read it again.

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

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Valsartan Tablets are and what they are used for

The full name of your medicine is Valsartan 320mg film-coated tablets, but within the leaflet it will be referred to as Valsartan Tablets.

Valsartan Tablets belong to a class of medicines known as angiotensin II receptor antagonist, which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. Valsartan Tablets work by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

Valsartan Tablets can be used:

to treat high blood pressure in children and adolescents 6 to 18 years of age. High blood pressure increases the workload on the heart and arteries. If not treated it can damage the blood vessels of the brain, heart, and kidneys, and may result in a stroke, heart failure, or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure to normal reduces the risk of developing these disorders.

2. What you need to know before you take Valsartan Tablets

Do not take Valsartan Tablets:

if you are allergic to valsartan, or any of the other ingredients of this medicine (listed in section 6).

if you have severe liver disease

if you are more than 3 months pregnant (it is also better to avoid Valsartan Tablets in early pregnancy - see pregnancy section).

if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of these apply to you, DO NOT take Valsartan Tablets.

Warnings and precautions

Talk to your doctor:

if you have liver disease.

if you have severe kidney disease or if you are undergoing dialysis.

if you are suffering from a narrowing of the kidney artery.

if you have recently undergone kidney transplantation (received a new kidney).

if you have severe heart disease other than heart failure or heart attack.

if you have ever experienced swelling of the tongue and face caused by an allergic reaction called angioedema when taking another drug (including ACE inhibitors), tell your doctor. If these symptoms occur when you are taking Valsartan Tablets, stop taking Valsartan Tablets IMMEDIATELY and never take it again. See also section 4, "Possible side effects".

if you are taking medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin. It may be necessary to check the amount of potassium in your blood at regular intervals.

if you suffer from aldosteronism. This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of Valsartan Tablets is not recommended.

if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water tablets (diuretics)

if you are taking any of the following medicines used to treat high blood pressure:

an ACE inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.

aliskiren.

if you are being treated with an ACE-inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone, eplerenone) or betablockers (for example metoprolol).

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "Do not take Valsartan Tablets".

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

Other medicines and Valsartan Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other.

The effect of the treatment can be influenced if Valsartan Tablets are taken together with certain other medicines. Your doctor may need to change your dose, to take other precautions, or in some cases to stop taking one of the medicines. This applies to both prescription and non-prescription medicines, especially:

other medicines that lower blood pressure, especially water tablets (diuretics), ACE inhibitors (such as enalapril, Lisinopril, etc) or aliskiren (see also information under the headings "Do not take Valsartan Tablets" and "Warnings and precautions");

medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin;

certain type of pain killers called non-steroidal anti-inflammatory medicines (NSAIDs);

some antibiotics (rifamycin group), a drug used to protect against transplant rejection (ciclosporin) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of Valsartan Tablets;

lithium, a medicine used to treat some types of psychiatric illness.

Pregnancy, breast-feeding and fertility

You must tell your doctor if you think that you are (or might become) pregnant. Your doctor will normally advise you to stop taking Valsartan Tablets before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Valsartan Tablets. Valsartan Tablets are not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if they are used after the third month of pregnancy.

Tell your doctor if you are breast-feeding or about to start breast-feeding. Valsartan Tablets are not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Patients who are concerned about their fertility while taking Valsartan Tablets are advised to consult with their doctor.

Driving and using machines

Before you drive a vehicle, use tools or operate machines or carry

out other activities that require concentration, make sure you know how Valsartan Tablets affect you. Like many other medicines used to treat high blood pressure, Valsartan Tablets may in rare cases cause dizziness and affect the ability to concentrate.

3. How to take Valsartan Tablets

Always take this medicine exactly as your doctor has told you in order to get the best results and reduce the risk of side effects. Check with your doctor or pharmacist if you are not sure. People with high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with the doctor even if you are feeling well.

Adult patients with high blood pressure:

The usual dose is 80mg daily. In some cases your doctor may prescribe higher doses (e.g. 160mg or 320mg). He may also combine Valsartan Tablets with an additional medicine (e.g. a diuretic).

Children and adolescents (6 to 18 years of age) with high blood pressure:

In patients who weigh less than 35kg the usual dose is 40mg of valsartan once daily.

In patients who weigh 35kg or more the usual starting dose is 80mg of valsartan once daily.

In some cases your doctor may prescribe higher doses (the dose can be increased to 160mg and to a maximum of 320mg).

You can take Valsartan Tablets with or without food. Swallow Valsartan Tablets with a glass of water.

Take Valsartan Tablets at about the same time each day.

The tablet can be divided into equal doses.

If you take more Valsartan Tablets than you should

If you experience severe dizziness and/or fainting, contact your doctor IMMEDIATELY and lie down.

If you have accidentally taken too many tablets, contact your doctor, pharmacist or hospital.

If you forget to take Valsartan Tablets

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed.

DO NOT take a double dose to make up for a forgotten dose.

If you stop taking Valsartan Tablets

Stopping your treatment with Valsartan Tablets may cause your disease to get worse. DO NOT stop taking your medicine unless your doctor tells you to.

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

4. Possible side effects

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

Some side effects can be serious and need IMMEDIATE medical attention:

You may experience symptoms of angioedema (a specific allergic reaction), such as:

- swollen face, lips, tongue or throat
- difficulty in breathing or swallowing
- hives, itching

If you get any of these symptoms, stop taking Valsartan Tablets and contact your doctor STRAIGHT AWAY (see also section 2 "Warnings and precautions").

Other side effects include:

Common (may affect up to 1 in 10 people):

dizziness

- low blood pressure with or without symptoms such as dizziness and fainting when standing up

decreased kidney function (signs of renal impairment)

Uncommon (may affect up to 1 in 100 people):

- angioedema (see section "Some symptoms need IMMEDIATE medical attention")
- sudden loss of consciousness (syncope)
- spinning sensation (vertigo)
- severely decreased kidney function (signs of acute renal failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
- cough
- abdominal pain
- nausea
- diarrhoea
- tiredness
- weakness

Not known (frequency cannot be estimated from the available data):

blistering skin (sign of dermatitis bullous)

- allergic reactions with rash, itching and hives; symptoms of fever, swollen joints and joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms may occur (signs of serum sickness)
- purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis)
- unusual bleeding or bruising (signs of thrombocytopenia)
- muscle pain (myalgia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)
- decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can lead to anaemia in severe cases)
- increase of level of potassium in the blood (which can trigger muscle spasms and abnormal heart rhythm in severe cases)
- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can trigger yellow skin and eyes in severe cases)

increase of level of blood urea nitrogen and increase of level

- of serum creatinine (which can indicate abnormal kidney function)
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases).

The frequency of some side effects may vary depending on your condition. For example, side effects such as dizziness, and decreased kidney function, were seen less frequently in adult patients treated with high blood pressure than in adult patients treated for heart failure or after a recent heart attack.

Side effects in children and adolescents are similar to those seen in adults.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Valsartan Tablets

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

DO NOT use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

DO NOT store above 30°C.

DO NOT throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Valsartan tablets contain

The active substance is valsartan. Each film-coated tablet contains 320mg of valsartan.

The other ingredients are:

Tablet core: microcrystalline cellulose, silicified, starch, pregelatinised, crospovidone, magnesium stearate, silica, coloidal anhydrous.

Tablet coating: polyvinyl alcohol – part. hydrolysed, titanium dioxide (E171), talc (E553b), talc, macrogol 3350, lecithin (soya) (E322), Indigo carmine aluminium lake/ FD&C Blue #2 (E 132), iron oxide red (E172), iron oxide yellow (E172), iron oxide black (E172).

What Valsartan Tablets look like and contents of the pack

Valsartan Tablets are red-brown, ovaloid, slightly convex film-coated tablets, scored on one side.

Valsartan Tablets are available in PVC/PE/PVDC-Aluminium blister packs containing 28 tablets.

Marketing Authorisation Holder and Manufacturer

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