

On Product Warnings

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Abstract. *Patient information leaflet (PIL) is the official label for the written information that accompanies medicines and that is intended to maximize the effective use of the medicine (van der Waarde, 2004). However, studies show that this information is not simply inefficiently conveyed (Pander Maat and Lentz, 2011) but that it can even introduce health risks. This article examines the adequacy of the PILs included in a sample of over-the-counter medicines sold in the UK and in Brazil. The analysis focuses on textual characteristics of the warning sections of the PILs, in order to assess their readability and intelligibility. We also note that there are occasions when a consumer, although able to read and understand the text, may not realise the significance or the importance of the warning, as it is not expressed sufficiently strongly. In examining this problem we draw on Tiersma's (2002: 55) observation that a good warning "is one in such form that could reasonably be expected to catch the attention of a reasonably prudent [person] in the circumstances of its use and whose content is understandable". Results are presented to show that, despite the structural differences between the Brazilian and the English PILs, both present problems due to the overuse of indirect, complex and vague language, which can lead the reader to infer information that is inaccurate, incomplete and at times just plain wrong. In addition, it will be shown that the headings of some sections are an inadequate guide to their content, particularly as far as the location of warnings is concerned. Results strongly suggest that one major purpose of PILs is to help the manufacturer to avoid litigation.*

Keywords: *Patient Information Leaflets (PILs), warnings, efficiency, intelligibility.*

Resumo. *As bulas de remédios são informações escritas que acompanham os medicamentos com o objetivo principal de aumentar o uso efetivo dos medicamentos (van der Waarde, 2004). Entretanto, vários estudos apontam que estas informações não são simplesmente ineficientemente transmitidas (Pander Maat and Lentz, 2011), mas podem até mesmo trazer riscos à saúde do consumidor. Este artigo examina a adequação das bulas de uma amostra de remédios sem a necessidade de prescrição vendidos no Reino Unido e no Brasil. A análise focaliza as características textuais da seção de advertências das bulas, a fim de acessar a legibilidade e inteligibilidade. Notamos que também há ocasiões onde o consumidor, apesar de ser capaz de ler e entender o texto, não percebe a significância*

ou importância da advertência, visto que não é enfatizada adequadamente. Após averiguar este problema, nos referimos à observação de Tiersma Tiersma, 2002: 55 onde uma boa advertência “é de tal forma que poderia razoavelmente ser esperado que ela chame a atenção de uma pessoa razoavelmente prudente e que seu conteúdo seja inteligível”. Os resultados apontam que apesar da diferença estrutural das bulas brasileira e inglesas, elas apresentam os mesmos problemas referentes ao uso excessivo de informações indiretas, complexas e incompletas que podem levar o leitor a inferir informações, que são imprecisas, incompletas e às vezes, claramente desacertadas. Além disso, será mostrado que os títulos de algumas seções guiam inadequadamente aos seus conteúdos, principalmente quando a localização das advertências estão em questão. Os resultados sugerem nitidamente que ajudar o fabricante a evitar litígios é um objetivo principal das bulas.

Palavras-chave: *Bulas, advertências, eficiência, inteligibilidade.*

Introduction

Various linguistic and non-linguistic solutions have been proposed to cope with the dangers associated with specific products and the use of Warnings is only one of them. As Wogalter (2006) notes, warnings should not be seen as a substitute for both a) good design that can avoid, or at least reduce, hazards and b) for some kind of formal or informal training that will enable users to handle the product safely. Only when these strategies are insufficient to remove all the potential risks, should verbal warnings be considered necessary to “inform people about hazards so that undesirable consequences are avoided or [at least] minimized” (Wogalter, 2006: 3).

Legally, it is the product manufacturers who are responsible for hazard prevention and therefore who are liable if the consumer and/or his/her possessions suffer any harm, injury or damage. However, paradoxically, warnings seem designed specifically to change this relationship, because in fact they place the responsibility for most hazard prevention firmly on the shoulders of the customer. This seems to contravene at least the spirit of the law, especially when frequently the warnings are either vague or fail partly or entirely to inform customers about the potential risks and how to avoid them.

For example, the warning below, taken from a Patient Information Leaflet (PIL) accompanying a widely available non-prescription medicine, is a classic example of vagueness,

Take special care with this medicine if you have:

–liver problems, including those due to drinking too much alcohol.

The direction ‘take special care’ is opaque; what action(s) should the patient take or not take and what are the risk(s) that can be avoided or at least minimized by taking ‘special care’? Consequently, the message could easily be interpreted as meaning something very different from what the writer intended and indeed could lead the patient to actually adopt unsafe behavior. Furthermore, the expression ‘too much’ is equally vague. Within the semantic vacuum of non-specificity ‘too much’ is likely to be interpreted in the light of the patient’s current behaviour, rather than objectively and the resulting quantity could be very different from what a medical professional regards as ‘too much’. Hence the shock that greeted a BBC news item (25.01.15) titled “*Drinking three alcoholic drinks a day can cause liver cancer*”.

Dumas (1992) and van der Waarde (2008) observe that warnings and medicine leaflets, respectively, have a dual role: they do not simply provide information for the user, but also help the manufacturer to avoid litigation. This second role is evident in many warnings similar to the one quoted above, where the information required by the particular regulatory agency is provided, but the intended message is not conveyed successfully. The objective of this article is to examine a series of medicine leaflets, in order to assess the success with which warning messages are conveyed. In order to meet this objective, we will first provide a definition of warnings and the characteristics that influence their adequacy, then discuss how target readers are conceptualised. Next, we will describe and compare some English and Brazilian Patient Information Leaflets (PILs), and analyze the warnings contained in them. Finally, we will report two legal cases that involved patients who had suffered side effects after taking medicines, in order to illustrate the consequences of inadequate messages.

Warnings

Any attempt to describe or categorize warnings has to cope with uncertainty and ambiguity. Dumas (1992: 267) asserts that “no discipline recognizes a clear, unambiguous definition of warning”. Moreover, a closer examination reveals that *warnings* share some characteristics with *threats* and *promises*. All can be made in several different ways: they can be direct, indirect or conditional and many of them are context dependent. So, we can assume that sometimes intended recipients may fail to recognize a piece of text as a warning, which raises the question of what constitutes an efficient and effective warning.

Much of the current research in the area of warnings evaluates effectiveness in terms of the legibility and readability of the text provided; these are obviously essential characteristics of any informative text that accompanies a product or service. And there is also the need to examine the relationship between what is actually included and what should be included. Even then, assuming the consumer has read and understood the information in the warning, s/he can choose not to comply with it. For this reason a third characteristic seems to be necessary, the ability to both attract the purchaser’s attention and then convey the importance of the information. An adequate warning, according to Tiersma (2002: 55), “is one in such form that could reasonably be expected to **catch the attention** of a reasonably prudent [person] in the circumstances of its use and whose content is **understandable**”.

Pragmatic features of a warning also have an influence on the efficiency with which the message is transmitted. Tiersma (2002) suggests that there are two major types of warning: *informative* and *imperative*. While the first type provides information about risk, for example, “This product is flammable” or “Some people may have problems with their eyes such as blurred vision, while they are being treated with Voltarol Ophtha”, the second type details necessary actions to avoid the risk, such as “Do not spray it near flames or ignition sources” or “If you are affected, you should not drive or use machines”. Tiersma discusses the relative efficiency of both types of warning and concludes that it depends ultimately on the situation. Ideally, both types should be used, but as writers may have space constraints, Tiersma suggests that imperatives are preferable, because they clearly tell the reader what s/he should do or avoid doing, even though they do not inform directly about the nature of the risk. He also emphasises that if consumers are

not informed explicitly, they may not know how to avoid a particular risk and so make wrong inferences.

Imagined and Real Readers

In approaching warning texts we must always keep in mind how writers produce and how readers actually process texts of this kind. First, let us consider the writer(s). In a chapter entitled 'Evaluating Texts', one of us (Coulthard, 1994) observed that, in order to compose any kind of written text, a writer must first create, at least subconsciously, an Imagined Reader to whom s/he attributes certain knowledge and ignorance of the topic in question and certain linguistic and text-processing skills; only then, on this basis, can the writer construct her/his text.

One frequent major communicative problem with all kinds of informative texts is that the Writer fails to conceptualise sufficiently clearly the Imagined Reader and as a result makes inconsistent or even incorrect assumptions; a second problem is that, knowing what s/he intends the text to communicate, the writer may not realise that the text does in fact allow or worse, favour, other interpretations.

A third major and crucial problem is that once created the warning texts are in fact read by Real Readers, who may be significantly different, in terms of knowledge and text processing abilities and strategies, from the writer's Imagined Reader. Thus for example the author of an instruction leaflet writes:

“... we recommend that you read this entire booklet before your first use”.

But it is very clear that many people, being the proud possessors of newly acquired equipment, typically use the accompanying *Instructions* text only to find answers to specific questions – few, if any, actually read the 'entire booklet' before starting to use a new piece of equipment, however expensive and complicated it may be. For this very important reason, all instruction and warning texts must allow the user to search for and find correct answers to questions as and when necessary.

A further complicating factor with instruction and warning texts is that they may themselves be communicatively problematic – the world is full of bad writers – and that raises the question of what the reader should do when faced with contradictory information, which the writer, (and the editor if indeed there was one), has allowed to creep into the text.

As Real Readers we are, of course, quite accustomed to finding contradictions in texts and having to infer interpretations and conclusions on the balance of probabilities. Here is an example from a Brazilian Product Information Leaflet (PIL) for a medicine requiring a doctor's prescription. Coulthard, suffering from a persistent cough, was prescribed some anti-allergic medicine. There was a doubt about whether the medicine caused drowsiness and whether it was permissible to drive, even though the doctor hadn't mentioned either as potential problems. The medicine was accompanied by a very detailed 4-column, two-sided PIL produced in a very small font.

Near the beginning of the leaflet was the clear assertion “The medicine does not cause drowsiness” and shortly afterwards under a general heading of *Warnings* was the information “No effects on the capacity to drive cars and operate machines were observed”. So one could deduce apparently categorically, that there would be no problems. However, further down the same column, if indeed the reader had bothered to continue, under a heading of *Cautionary Advice* – what one wonders is the pragmatic difference

between a *Warning* and *Cautionary Advice* in the Real World and would any non-linguist reader attach any significance to the distinction – the leaflet cautioned:

“During treatment the patient should **not drive vehicles** or operate machines,
as his (sic) ability and attention could be prejudiced [our highlighting]”.

How is the reader to square this observation with the earlier one which noted that “no effects on the capacity to drive cars ... were observed”? Was this just an example of the manufacturers protecting themselves from legal responsibility, because they hadn't actually bothered to test? Subsequently, the identical warning with identical wording was discovered in instructions for another medicine, so it would appear to be a standard sentence, but, in the case of this medicine, dangerously confusing. Even more disquieting was the fact that, hundreds of words later in the PIL in a section entitled *Technical Information for Health Professionals* – which, in principle, is a section that is specifically written for the medicine-taker **not** to read and probably only accessed by text-obsessed linguists – the same sentence was repeated word-for-word

“During treatment the patient should not drive vehicles or operate machines, as his ability and attention could be prejudiced”

Word-for-word, *except* that it had been metalinguistically upgraded to the status of a *Warning*! The important question here is, what is the status of *cautionary advice* as opposed to a *warning* or are the two in free variation in the real world of medical leaflets. And, if the patient had driven, become drowsy and had an accident would there be any basis for a claim against the manufacturer for inadequately advising about the danger? Could they be prosecuted for either not bothering to test for, or for failing to observe, ‘effects on the capacity to drive cars’?

PILs accompanying Medicines

There are many factors and characteristics that make warnings, and thus PILs complex. Askehave and Zethsen observe that PILs are ‘mandatory genres’ that “emanate from a legal directive and are introduced into the community by regulatory force” (2008: 170). In the case of PILs, the communicative purpose, the content and the structure are defined by official documents. This creates an additional challenge for the writer, who needs to adapt the official language to the ordinary reader, that is, to ‘translate’ the technical content into plain language. In fact the PILs analyzed in this article present many communicative problems that can impede their intended purpose, which is “to increase the effective use of medicines” (Donnelly, 1991, as cited in van der Waarde, 2004: 75). To use a medicine properly, the patient must have some knowledge about side effects, storage, warnings and treatment, that is, how much medicine s/he should take and how often s/he can take it safely, that is avoiding toxicity.

The following sections of the article will describe and compare the organs responsible for overseeing the structure and content of PILs’ in the UK and in Brazil.

The UK Medicines and Healthcare Products Regulatory Agency

The UK Medicines and Healthcare products Regulatory Agency (MHRA) “is responsible for regulating all medicines and medical devices in the UK” (home page: <http://www.mhra.gov.uk>). These UK guidelines follow the European Community template, set out by the European Medicine Agency (EMA). The template takes into account four aspects:

1. Content, which is based on the Summary of Product Characteristics (SPC);
2. Sequencing of information;
3. Headings; and
4. Wording.

The European Union directive for Patient Information Leaflets (PILs) states that they have to include six sections (see Appendix 1 for an example of a complete PIL).

1. What the drug is and what it is used for;
2. What you need to know before you take it;
3. How to take it;
4. Possible side effects;
5. How to store it;
6. The contents of the pack and other information.

The content of all PILs must be based faithfully on the Summary of Product Characteristics (SPC), which is essentially a report of clinical studies, written by medical professionals and addressed to other medical professionals. This report contains a detailed summary of the medicine, as well as its effects and side effects. According to Askehave and Zethsen (2003: 32), “the law requires a close relationship between these two texts [the SPC and the PIL] in the name of consumer protection”. However, as the authors point out, this ‘close relationship’ can cause significant communication problems, since the recipients of the two texts, which belong to markedly different genres, are also markedly different. Whereas the intended recipients of the PILs are ordinary readers, who may possess little previous knowledge about the content, effects and side effects of the particular PIL and indeed may not even be competent readers, the recipients of the SPC are experts. Thus, there can be a major conflict between the two requirements: faithfulness to the original text and effective communication with the target readership. Thus the document that emerges from the text conversion process can be highly deficient communicatively when read by the target lay audience.

Brazil – ANVISA (Agência Nacional de Vigilância Sanitária)

In Brazil ANVISA (*Agência Nacional de Vigilância Sanitária* / the National Sanitary Surveillance Agency) is responsible for producing the guidelines for medicine leaflets and in 2009 introduced RDC 47 (*Resolução da Diretoria Colegiada* / the Resolution of the Board of Direction) aiming to improve the quality of the documentation. Whereas the British PILs have six sections the Brazilian PILs distribute information into only three sections:

- Identification of the medicine;
- Information to the patient;
- Legal Information

The second section, specifically addressed to the patient, is the most important and is organized into 9 question/answer items, obviously intended to facilitate the reader’s understanding (see below).

1. What is this medicine used for?
2. How does this medicine work?
3. When should I **not** take this medicine?
4. What should I know before taking this medicine?

5. Where, how and for how long should I keep this medicine?
6. How should I use this medicine?
7. What should I do if I forget to take this medicine?
8. What side effects can this medicine cause?
9. What should be done if someone takes a higher dose of this medicine than recommended?¹

This directive is clearly concerned with how the message is conveyed, as can be seen in Art. 6, below:

Art 6

In relation to the content, the insert must have the information provided in attachment 1 of this directive, following the established order and items.

§ 1. The patient package inserts must include items related to: medicine identification, information for the patient, and legal information and the text must;

I – be organized in a question / answer format;

II – be clear and objective without repeating information;

III – be written in accessible language, with concise and clear wording, according to the guidelines for writing inserts, with the aim of enabling patient comprehension.

IV – have explanatory terms following technical terms when these are employed and if necessary an explanation to aid patient comprehension²

Although there is a concern with the readability of inserts, the term ‘clear wording’ is problematic for at least two reasons which are intrinsically linked: 1) each writer may interpret the term in a different way; 2) the definition of what is ‘clear’ will depend in part on the readers, whose level of content and linguistic knowledge can vary widely. As one might expect there is no consideration of communicative problems caused by reader variation.

Comparison

As is evident, there is a significant difference between the English and the Brazilian PILs regarding the organization of the information, even though in principle both are setting out with the same communicative intention. The English PILs have an initial section, which first alerts the reader about the importance of the PIL and then indicates the content. After this initial section, the English PILs contain the 6 sections, presented above. The Brazilian PILs, on the other hand, do not have this initial section and are organized into only three main sections. The second section ‘Information to the patient’, corresponds to the first five sections of the English PIL, while the first section of the Brazilian PIL, ‘Medicine identification’, which brings information related to the medicine, corresponds to the final section ‘Further information’ of the UK one. To us it does seem more reasonable to provide information related to the ingredients of the medicine at the beginning of the document. The final section of the Brazilian PILs is devoted to legal text, that is, information regarding the manufacturer, the pharmacist and the registration number at the Ministry of Health. The English version presents information about the manufacturer, but there is nothing related to the pharmacist or the registration number.

The specific pattern of the PILs might benefit the readers who know the genre, facilitating comprehension (Pander Maat and Lentz, 2011). Moreover, some problems emerge from adopting a specific format, especially, when it is far from being reader-friendly.

Pander Maat and Lentz (2009) investigated the pattern of medicine leaflets and concluded that they presented ‘findability’ issues, that is, readers experience difficulties in finding the information they want, especially when the heading does not correspond with the information contained in the section. The Beechams Powders leaflet (Appendix 1) is an example of such a problem, given that Section 6, which is located under the heading ‘further information’, provides information about the medicine’s ingredients, whereas readers might reasonably expect to find this kind of information in Section 1, ‘what the drug is’.

In fact, many of the headings adopted in this PIL are problematic. Pander Maat and Lentz point out that in general “there is a mismatch between the wording of the headings and readers’ interpretations” (2011: 197). One problem derives from the fact that the headings are “phrased very generally”, for example, information on alcohol use and allergies is located counter-intuitively under the heading ‘before you take it’ in both the English and the Brazilian PILs. In addition, as mentioned before, warnings are not explicitly labelled as such and are placed in more than one section, which complicates their identification, and consequently minimizes compliance.

Sequencing of information can be another serious problem that impairs comprehension. As Shuy observes (1990: 296) ‘simply having all the proper pieces of information is not enough’, since they should be presented in such a way as to facilitate both comprehension and findability. Thus, one would expect the most important information, such as the most serious and frequent risks, to be presented first, because the reader will expect to find them at the beginning.

Pander Maat and Lentz (2011: 197) investigated readers’ preferences related to both information and sequencing. Their results showed that the preferred sequence would be “goal of the medicine – directions for use – potential problems – packaging and storage”, instead of goal of medicine – potential problems – directions for use – packaging and storage. (See the complete PIL in Appendix 1). However, one could argue that it is better to place information related to potential problems before directions for use, given that most of them are warnings that the patient should be aware of before taking the medicine.

Warnings in the English PILs

It is surprising that neither the English nor the Brazilian PIL pro-forma contains a section entitled ‘warnings’, (although until recently the Brazilian one did), and this, it could be argued, reduces their efficacy. As already noted, if risks are not highlighted, they may lose their visibility and consequently, the reader’s attention. For this reason, we argue that signal words are fundamental, because they not only inform about a possible risk, but also indicate the level of this risk (Coulthard and Hagemeyer, 2013). As we noted there the US guidelines, ANSI -Z535 4, strongly recommend the use of the following signal words, Danger, Warning, Caution, and Notice, also, if possible, colour coded:

DANGER indicates a hazardous situation, which, if not avoided, will result in death or serious injury.

WARNING indicates a hazardous situation, which, if not avoided, could result in death or serious injury.

CAUTION, used with the safety alert symbol, indicates a hazardous situation, which, if not avoided, could result in minor or moderate injury.

NOTICE used to address practices not related to personal injury. (Kundinger, 2008: 15).

Even though not signalled as such, most warning messages in the English PIL are placed in the second section which is headed ‘What you need to know before you take this medicine’, a very general and anodyne label – some patients may even fail to infer that this section includes warnings.

A corpus was created consisting of leaflets from 17 over-the-counter paracetamol products available in the UK, in July 2014. This corpus will be used to examine the nature of the warnings – 6 of these leaflets come from medicines specifically produced for children and 4 of them come from medicines that can be used by both children and adults, while 7 are produced specifically for adults. All the second sections of these 17 leaflets are divided into several subsections, varying in number from 3 to 8, (see Appendices 1 and 2).

Some brands contain more information and/or subdivide the section into a greater number of sub-sections – a fact which demonstrates that there is in fact no consensus about the optimum communicative strategy, despite the pro-forma. The apparently highly important subsection below, for instance, appears in only one of the 17 leaflets:

‘Paracetamol Oral Solution with food and drink

Do not drink alcohol whilst taking Paracetamol Oral Solution. This is because taking alcohol and paracetamol together can increase the risk of liver damage’
(Paracetamol - A17)

Although this heading predicts a general statement about food and drink, the warning in fact mentions no food and only one category of drink, alcohol. Clearly, a more appropriate heading would be ‘Taking Paracetamol Oral Solution with/and alcohol’ and might then attract more of the target readers. That said, this is actually a good warning, despite not being labelled as such, because it includes both of Tiersma’s types: *imperative* and *informative*: first a direction to avoid the risk, then a statement about the risk of non-compliance: liver damage.

Interestingly, this particular leaflet chooses to provide information about liver problems on 5 separate occasions sprinkled over 3 sub-sections. But the second sub-section, which mentions the risk 3 times, includes a confusing contradiction. It first warns the patient not to take paracetamol if they have a ‘liver disorder’.

Do not take paracetamol oral solution if:
- *you know that you are allergic to paracetamol, or any of the other ingredients (refer to section 6 below)*
- *a liver disorder (sic)*

but follows this immediately with a second warning that appears to allow the patient to take Paracetamol provided s/he takes special care (see below).

Take special care and tell your doctor or pharmacist before taking Paracetamol Oral Solution if:

- *you have liver problems, including those due to drinking too much alcohol*
- *you have kidney problems.*

Do not take more than the recommended dose. (Paracetamol A17)

Worryingly, firstly this section fails to specify exactly what liver/kidney ‘problems’ are and how to recognise or discover whether you actually have a liver/kidney problem and secondly does not make it clear whether it is always better to approach your doctor before taking the medicine, just in case s/he knows you have a ‘problem’. Finally, it does not clarify whether it is only this particular sub-set of patients who must not exceed “the recommended dose”, or whether “*Do not take more than the recommended dose*”, is actually a badly misplaced general warning – as indeed it is.

One can at least safely conclude that Paracetamol and alcohol is a dangerous combination that can increase the risk of liver damage, but it is therefore surprising that the risk of this combination is not made explicit in all the leaflets. And although the term *alcohol* appears 20 times in the corpus, only 7 of the 11 leaflets aimed at adult users specifically direct the patient to not consume alcohol. As mentioned before, 6 of the medicines are said to be specifically for children and for this reason, one would assume they would not need to include warnings related to alcohol abuse. However, in fact one PIL does provide a section for any adults who do intend to take the medicine and does warn about alcohol:

Information for adults intending to take this medicine

This medicine may be harmful if you are dependant on alcohol or have alcoholic liver disease. Do not drink alcohol (wine, beer, spirits) whilst taking this medicine. (Paracetamol A7)

Even so, it both fails to give information about the nature of the risk and modalises the risk itself “may be harmful”. And, one wonders, if one manufacturer assumes adults do sometimes use children’s medicines, shouldn’t all manufacturers (be constrained to) make the same assumption?

Subsections entitled: ‘Do not take/give this medicine if (...)’ appear in all 17 PILs, although the specific warnings included differ not only in number but also in content. For example, while all 17 PILs warn about the risk of allergies, only 4 characterise and/or exemplify the symptoms, as in the example below:

‘[If] you are allergic (hypersensitive) to paracetamol or any of the other ingredients in your medicine (listed in Section 6: *Further information*) Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue’
(Paracetamol A15)

Requiring the patient to read a different section – “listed in Section 6: *Further information*” – in order to have the complete message is a recurrent characteristic of medicine PILs, and this can significantly reduce their effectiveness. The patient could wrongly deduce that a given piece of information is not particularly important, because if it were, it would be included in the same section.

Also, as already noted, the writer should always bear in mind that readers rarely read the whole PIL, but rather scan it searching for specific pieces of information. Silva *et al.* (2006) investigated with 1829 subjects, reader strategies and discovered that only 22% claimed to read the entire document, while the remaining 78% reported reading only for specific information, such as indications, contraindications, instructions for use and side effects.

This next extract has a different problem

‘Paracetamol 10mg/ml Solution for Infusion **may be used** during pregnancy, however, the doctor must evaluate if the treatment is advisable’. (highlighting in **bold** added)
(Paracetamol A13)

It apparently allows the patient to take the medicine, “may be used”, if she is pregnant; but if she reads to the end of the sentence – although she may well not bother to if she is simply looking for confirmation that she can take the medicine – she will discover that the second part of the sentence imposes a condition – the doctor’s prior evaluation. And, of course, this requirement is only presented in informative, and not in Tierma’s preferred imperative form: *Do not use ... without your doctor’s permission*. Also, there is no reference to, let alone a specification of the risk(s) and for this reason the text does not have the characteristics of a warning, which, as we have argued, should inform about an unwanted future event. It appears that the manufacturer is transferring the responsibility for any problems caused by taking the medicine to the doctor, or worse is simply covering against any claims from users who didn’t bother to consult their doctor.

At this point, we want to draw attention again to the comparative absence of signalling words. An analysis of a larger corpus of 85 medicine leaflets revealed that the word ‘warning(s)’ appeared in only 29 of the PILs, and then almost always just once in the subsection of the second section titled ‘What you need to know before you take it’. This markedly infrequent use of the term ‘warning’ is strange, given that the term is widely and frequently used on UK labels for many other products, such as food and domestic cleaning liquids.

And finally, as already noted above, the reader’s comprehension problems are too often compounded by the need to cope with badly written text. For example, the two extracts below alert the reader to ‘additional’ or ‘other important’ warnings, despite the fact that nothing has previously actually been labelled as a warning. So, the patient has to infer which piece(s) of text already processed was/were intended by the writer to count as warning(s).

This product is intended for use by children under 6 years old. However, the following **additional warnings** are included in case an adult is taking this medicine. (highlighting in **bold** added)
(Paracetamol A6)

Other **important warnings**: taking painkillers for headaches too often or for too long can make them worse. (highlighting in **bold** added)
(Paracetamol A10)

Warnings in Brazilian PILs

Section 2, subsection 4 of the Brazilian pro-forma is devoted to warnings, although, interestingly, just like the UK leaflets, there are no longer any signal words; instead it reads ‘What should I know before taking this medicine?’. An analysis of 23 Brazilian paracetamol PILs shows that the term ‘warning’ (*advertência*) appears only 3 times and then in only one PIL:

Overdose **warning**: taking more than the recommended dose can cause serious health problems. In case of an overdose, look for medical help immediately. Rapid medical attention is critical for both adults and children even if you yourself do not note any signs or symptoms.³ (highlighting in **bold** added)

Although this warning does not specify the nature of the risks, they are at least characterized as ‘serious’, (*sérios*), thereby attracting the patient’s attention and the lexemes ‘immediately’ (*imediatamente*) and ‘rapidly’ (*rápido*) convey urgency. Even so, the warning fails to specify how many ‘more than’ doses one needs to have taken before it is characterized as an overdose, nor does it list symptoms that would help the patient recognise that they have overdosed. Even worse, this leaflet actually includes information about these very symptoms in a later sub-section, reproduced below, but the first warning does not refer the reader forward to the later section and thus a panicking potentially overdosed reader who is looking for specific help would be totally and dangerously unaware of its existence.

Subsection 9. What should be done if someone takes a higher dose of this medicine than recommended? The initial signs and symptoms that follow the ingestion of a large quantity of paracetamol, possibly hepatotoxic are: nausea, vomiting, intense sweating and general malaise. Arterial hypertension, cardiac arrhythmia, jaundice, hepatic and renal insufficiency are also observed. (Paracetamol B 22)⁴

The above warning clearly employs many technical terms, ‘hepatotoxic’, ‘hepatic’, ‘arterial hypertension’ and ‘cardiac arrhythmia’, which not only prejudice the understanding of most ordinary readers, but are also in specific contravention of RDC 47 – 2009, art. 6 IV, which, as mentioned above, clearly tells the writer that there must be “explanatory terms after technical terms, when these are employed and if it is necessary also an explanation for the patient’s comprehension”. Furthermore, while subsection 4 adopts the term ‘overdose’ (*superdosagem*), subsection 9 instead uses the term ‘a large amount’ (*uma grande quantidade*); are these actually synonymous and if so will the general reader realise this?

Vague Language

While all the PILs contain the basic information that is required by the regulatory agencies (MHRA and ANVISA), the way in which the information is conveyed frequently leaves a lot to be desired. This is in no small part due to the number of vague phrases, sometimes whole sentences, that can raise doubts and at times even allow for multiple interpretations. For example: the warning “Drinking alcohol at the same time as taking aspirin increases the risk of bleeding”, in the second section of the English PIL reproduced in Appendix 1, under the title “**Take special care with Beechams Powders**”, contains a great deal of implicit information. The patient first has to infer what type of ‘special care’ needs to be taken, given that the term ‘special’ is not defined and then has to cope with the phrase ‘risk of bleeding’. Patients are likely to evaluate ‘bleeding’ as something serious and caused specifically by the combination of paracetamol with alcohol, but a closer reading reveals that there is already a risk of bleeding associated with the medicine even when it is taken without alcohol, otherwise the risk could not be ‘increased’ by the alcohol. This creates a dilemma for the patient: should the medicine in fact be avoided completely, because apparently it is inherently dangerous, or is bleeding in fact not particularly worrying because it is a normal and accepted, if not acceptable, consequence of taking the medicine? And if so, perhaps the increased risk of bleeding is also not particularly worrying.

But, the linguist asks, can we rely on the wording here? Should some of the words have been reordered? Should the text actually warn that not that there is ‘an increased

risk of bleeding’ but rather a ‘risk of increased bleeding’ and it is this increase that is problematic? As is evident this vague warning fails to inform about the scale of the risk, the consequences of any associated bleeding and of an increase in bleeding. Finally, there is no information about how the patient can find out if, with or without drinking alcohol, there is bleeding and if so how serious it is. Once again the reader is required to make multiple inferences, and runs the risk of making the wrong ones, which consequently, could lead him/her to make wrong decisions with serious consequences.

In this same section there is another example of vagueness:

Take special care with Beechams Powders

– Avoid **excessive intake** of caffeine (e.g. coffee, tea and some canned drinks) while taking this product. (highlighting in **bold** added)

‘Excessive’ is a vague relation term which only becomes meaningful when the reader knows what is normal or acceptable – in the absence of any such definition there is no way of knowing how much caffeine one should **not** ingest. Warnings like these flout the Gricean Quantity Maxim, which requires the instructions to be “as informative as is required”. The Maxim is multiply violated in the following example:

Side effects **may be minimized** by using the **lowest effective** dose for the **shortest duration necessary**. (highlighting in **bold** added)

In principle, the warning tells patients about how to minimize the side effects. However, firstly, there is no information about which side effects ‘may be minimized’, given that they are numerous and of course a sophisticated reader can see that the sentence allows ‘may not be minimised’ as an equally legitimate meaning – in other words, whatever the patient does may be of no avail. Secondly, there are two terms that can generate differing interpretations and neutralise the effect of the medicine: ‘lowest effective’ and ‘shortest duration’ – they fail to specify both the quantity of the medicine and the period of the treatment.

The warning below is even more problematic – although it is clear in relation to the risk – ‘risk of heart attack or stroke’ – it is totally unclear about what to do to avoid the risk, because of the vagueness of the terms: ‘may’, ‘large amounts’, ‘small’, ‘long time’, ‘lowest amount’ and ‘shortest possible time’.

Risk of heart attack or stroke: Ibuprofen **may increase the risk** if you take **large amounts** for a **long time**. The risk is **small**. Take the **lowest amount** for the **shortest possible** time to **reduce** this risk. (highlighting in **bold** added)

By contrast, the warning below is very precise about the quantity of alcohol that the patient can ingest safely, up to 3 doses, although, even so, it does not define ‘dose’ nor say if this is a daily or weekly limit. But, having said that, it goes on to suggest that the patient might be able to ingest more doses of alcohol, if the doctor is contacted, again implying that this may not be a very serious risk. Those patients said to certainly be in danger are the chronic drinkers, but this category is not defined; is it perhaps composed of drinkers of ‘3 or more’ or those who drink considerably in excess of this? And what does the ‘3-a-day drinker’ do when he discovers that he is apparently included in both the safe and the unsafe groups. For the reader coping with these interpretive problems the water is further muddied by the observation that liver disease is only a possible risk – ‘can present’ – and then only associated with overdosing.

If you take 3 or more doses of drinks, you should consult your doctor to know if you can take paracetamol + cloridrato pseudoephedrine or any other painkiller. Chronic drinkers **can** present a **higher** risk of liver disease if a **higher** dose than the recommended one of paracetamol + cloridrato pseudoephedrine is ingested. (Paracetamol B 12)⁵ (highlighting in **bold** added)

Court Cases

We mentioned at the beginning of this article that warnings, no matter how clear and efficient they are, in fact function to transfer the responsibility of hazard prevention onto the reader's shoulders. And this transferred responsibility is evident in two Brazilian court cases that will be briefly presented below.

The plaintiff, in *Maria Rodrigues v. ABBOTT Laboratórios do Brasil LTDA*, had an allergic reaction resulting in angioedema in the left eye, after taking the medicine Bio-press, and she alleged that the PIL had failed to provide adequate information. She compared the Brazilian and American PILs, and highlighted differences, for example: the item 'other allergic reactions' was omitted from the Brazilian PIL, which meant the doctor did not anticipate or warn about potential adverse effects. However, the comparison was not accepted because the PILs came from different brands. Furthermore, the defendant pointed out that the PIL did advise, and in upper case, about the 'possibility of unpredictable adverse effects occurring' (p. 114). This warning is obviously totally inadequate for the doctor and the patient, as there is no information about when and why these adverse effects could occur nor about how to avoid them and certainly no mention of angioedema. This warning only serves to defend the manufacturer against litigation and it seems that in this case it served its purpose, because the plaintiff lost.

In another medicine liability case, *Mickozs v. Mantecorp Indústria Química e Farmacêutica LTDA*, the plaintiff, a 12 year-old teenager, took the medicine 'Coristina D' and suffered serious adverse effects: strong nausea and gastric haemorrhaging and had to undergo cauterization. 'Coristina D' is a widely advertised over-the-counter painkiller and antipyretic. The plaintiff claimed that the adverse effects were aggravated for two main reasons: firstly, the medicine was sold without a PIL, which meant that the plaintiff did not have access to any information. Secondly, even if the plaintiff had been able to access the PIL, it would not have advised him about the hazards he actually suffered, given that the PIL included no information about gastrointestinal risks and the advisability of consulting a doctor before taking the medicine. In this case the jury found for the plaintiff.

Final Remarks

Due to the impossibility of removing all risks from medicines, given that there will always be some individuals that have some kind of reaction to the ingredients, the PILs and the warnings contained in them are of paramount importance to enable the patient to at least to minimize the risks. However, too often the PILs fail to do this. As linguists we have the tools to analyse the problems and improve the communicability of PILs, the difficulty is rather to gain access. Peter Tiersma managed to participate in the committee that rewrote the Californian Pattern Jury Instructions, we now need linguists to gain access to the committees who control the structure and content of PILs.

Notes

- ¹ 1. PARA QUE ESTE MEDICAMENTO É INDICADO?
2. COMO ESTE MEDICAMENTO FUNCIONA?
3. QUANDO NÃO DEVO USAR ESTE MEDICAMENTO?
4. O QUE DEVO SABER ANTES DE USAR ESTE MEDICAMENTO?
5. ONDE, COMO E POR QUANTO TEMPO POSSO GUARDAR ESTE MEDICAMENTO?
6. COMO DEVO USAR ESTE MEDICAMENTO?
7. O QUE DEVO FAZER QUANDO EU ME ESQUECER DE USAR ESTE MEDICAMENTO?
8. QUAIS OS MALES QUE ESTE MEDICAMENTO PODE ME CAUSAR?
9. O QUE FAZER SE ALGUÉM USAR UMA QUANTIDADE MAIOR DO QUE A INDICADA DESTE MEDICAMENTO

²Art. 6º

Quanto ao conteúdo, as bulas devem contemplar as informações preconizadas no Anexo I desta resolução, seguindo a ordem das partes e itens estabelecida.

§ 1º As bulas para o paciente devem conter os itens relativos às partes Identificação do Medicamento, Informações ao Paciente e Dizeres Legais e os seus textos devem:

I - ser organizados na forma de perguntas e respostas;

II - ser claros e objetivos sem a repetição de informações;

III - ser escritos em linguagem acessível, com redação clara e concisa, conforme proposto no Guia de Redação de Bulas, de forma a facilitar compreensão do conteúdo pelo paciente;

IV - possuir termos explicativos após os termos técnicos, quando eles forem utilizados e se fizer necessária uma explicação para compreensão do conteúdo pelo paciente.

³‘**Advertências** de superdosagem: tomar mais do que a dose recomendada pode causar sérios problemas de saúde. Em caso de superdosagem, procure socorro médico imediatamente. O rápido atendimento médico é crítico para adultos e crianças até mesmo se você não notar quaisquer sinais ou sintomas’

(Paracetamol B 22)

⁴**9. O QUE FAZER SE ALGUÉM USAR UMA QUANTIDADE MAIOR DO QUE A INDICADA DESTE MEDICAMENTO?**

Os sinais e sintomas iniciais que se seguem à ingestão de uma grande quantidade de paracetamol, possivelmente hepatotóxica são: náuseas, vômitos, sudorese intensa e mal estar geral. Hipotensão arterial, arritmia cardíaca, icterícia, insuficiência hepática e renal também são observados.

⁵Se você toma 3 ou mais doses de bebidas alcoólicas, deve consultar seu médico para saber se pode tomar paracetamol + cloridrato pseudoefedrina ou qualquer outro analgésico. Usuários crônicos de bebidas alcoólicas podem apresentar um risco aumentado de doenças do fígado caso seja ingerida uma dose maior que a recomendada (superdose) de paracetamol + cloridrato pseudoefedrina.

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Appendix 1 - Beechams Powders (Adult)



Please read right through this leaflet before you start using this medicine.

- Keep this leaflet, you may need to read it again.
- If you have any questions, or if there is anything you do not understand, ask your pharmacist.

In this leaflet:

1. What Beechams Powders do
2. Check before you take Beechams Powder
3. How to take Beechams Powders
4. Possible side effects
5. How to store Beechams Powders
6. Further information

1. What Beechams Powders do

Beechams Powders provide relief from cold and flu symptoms, including sore throat pain, headache, feverishness and aches and pains.

It also provides relief of mild to moderate pain including migraine, neuralgia, toothache, sore throat, period pain and rheumatic pain.

2. Check before you take Beechams Powders

Do not take:

- if you are allergic to **aspirin** or salicylates, **caffeine**, any other medicines known as **NSAIDs** or to any other ingredient (listed in Section 6).
- if you have had an allergic reaction after taking ibuprofen or aspirin.
- if you have had **asthma** or **shortness of breath** in response to **aspirin** before.
- if you suffer from high blood pressure or heart disease.
- if you have ever had a **stomach ulcer, perforation** or **bleeding of the stomach**.
- if you have **blood clotting disorders** (e.g. haemophilia) or have ever had **gout**
- if you have **liver** or **kidney disease**.
- **Do not give to children under 16 years of age unless your doctor tells you to.**

Take special care with Beechams Powders

- There is a possible association between aspirin and Reye's syndrome when given to children under 16 years. Reye's syndrome is a very rare disease which affects the brain and liver and can be fatal.
- Aspirin may cause bleeding. You must tell your doctor if you experience any unusual bleeding.
- Drinking alcohol at the same time as taking aspirin increases the risk of bleeding.
- Avoid excessive intake of caffeine (e.g. coffee, tea and some canned drinks) while taking this product.

- If you think you are dehydrated (you may feel thirsty with a dry mouth).

Ask your doctor before you take this medicine:

- if you suffer from **high blood pressure, asthma, allergic disease, kidney or liver problems.**
- if you are taking any prescribed medicines; particularly **methotrexate**; blood thinning drugs (**anticoagulants**) or blood pressure lowering treatments (**ACE inhibitors**); **oral hypoglycaemics** (to lower blood glucose) or medicines for treating **gout** such as **probenecid** or **sulfinpyrazone**; **ibuprofen** or other painkillers known as **NSAIDs** (e.g. **diclofenac**); **SSRI antidepressants** (such as **fluoxetine**); treatments for **epilepsy** (such as **phenytoin** or **valproate**); **beta-blockers** (e.g. **atenolol**); **acetazolamide**; if you are taking any water tablets (**diuretics**) or steroid hormones (**corticosteroids**); **antacids**; or have an intolerance to some sugars.
- Severe allergic reactions: Symptoms could include difficulty breathing, skin rash or swollen facial features, or tightening of the chest or asthma attacks in those sensitive to aspirin.

If you are pregnant or breast feeding

Do not take Beechams Powders if you are **pregnant or breast feeding**, except on medical advice.

3. How to take Beechams Powders

Mix the powder with a little water and stir before drinking.

Adults and children aged 16 years and over:

One powder every 3 to 4 hours as needed.

Do not take more than 6 powders in 24 hours.

Do not use for more than 10 days for pain relief (or more than 3 days for fever).

If symptoms persist **see your doctor.**

If you take more than the recommended dose seek medical advice immediately.

4. Possible side effects

Like all medicines, Beechams Powders can cause side effects, although not everybody gets them. **If you experience any of these effects then STOP taking this medicine immediately and contact your doctor or pharmacist:**

- Stomach ulceration or perforation: Symptoms could include severe abdominal pain, nausea and vomiting. People with sensitive stomachs may suffer stomach irritation and may experience bleeding (you may pass blood in your stools, or vomit blood or dark particles that look like coffee grounds).
- Severe allergic reactions: Symptoms could include difficulty breathing, skin rash or swollen facial features, or tightening of the chest or asthma attacks in those sensitive to aspirin.
- Occasionally the blood does not clot well, which may result in bruising or bleeding,

or yellowing of the skin and eyes may occur. Other side effects may include lethargy, weakness, shortness of breath, and generalised swelling or water retention, ringing in your ears or temporary

- High caffeine intake can result in nervousness and dizziness.

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 Beechams Powders

Keep out of the sight and reach of children.

Do not use this medicine after the 'EXP' date shown on the pack. Store below 25°C in a dry place.

6. Further information

Active ingredients Each powder contains:

Aspirin 600 mg and Caffeine 50 mg.

Other ingredients Lactose, maize starch, colloidal anhydrous silica, sodium lauryl sulphate, saccharin sodium, sodium cyclamate and spice flavour.

Packs of Beechams Powders contain either 10 or 20 powders.

The marketing authorisation holder is GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K. and all enquiries should be sent to this address.

The manufacturer is QP-Services UK Limited, Yatton, Somerset, United Kingdom. This leaflet was last revised February 2014.

Beechams is a registered trademark of the GSK group of companies.

Appendix 2 = BOOTS Paracetamol (6 Years Plus) (Children)

Information for the user



Paracetamol 6 Years Plus 250 mg/5 ml Oral Suspension

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to treat minor conditions. However, you still need to give it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact a pharmacist or doctor if your child's symptoms worsen or do not improve after 3 days
- The leaflet is written in terms of giving this medicine to your child, but if you are an adult who is intending to take this medicine yourself the information in this leaflet will apply to you as well

What this medicine is for

This medicine contains Paracetamol which belongs to a group of medicines called analgesics and antipyretics, which act to relieve pain and reduce fever. It can be used to relieve mild to moderate pain including toothache, headache and other pains. It can also be used to relieve the symptoms of colds and flu and to reduce fever.

Before you give this medicine

This medicine can be given to children from the age of 6 years and over. However, some children should not be given this medicine or you should seek the advice of their pharmacist or doctor first.

X Do not give:

- **If your child is under 6 years**
- **If your child is allergic to any of the ingredients** (see "What is in this medicine")

· **If your child has an intolerance to some sugars, unless your doctor tells you to** (this medicine contains sorbitol)

! Talk to your pharmacist or doctor:

- If your child has liver or kidney problems
- If your child takes any other medicines (see “If your child takes other medicines”)

Other important information

Information about some of the ingredients in this medicine: Sorbitol may have a mild laxative effect. Each 5 ml spoonful contains 1.1 g of sorbitol. This provides 3 kcal per 5 ml spoonful. Methyl hydroxybenzoate (E218) may cause allergic reactions (possibly delayed).

Information for adults intending to take this medicine

This medicine may be harmful if you are dependant on alcohol or have alcoholic liver disease. **Do not drink alcohol** (wine, beer, spirits) whilst taking this medicine.

Oral contraceptives may reduce the pain relief obtained with this medicine.

If you are elderly your doctor or pharmacist may advise you to take less of the medicine or take the medicine less regularly. In this case follow their instructions.

Pregnancy and breastfeeding: Do not take this medicine, unless your pharmacist or doctor tells you to.

If your child takes other medicines

! This medicine contains paracetamol.

Do not give anything else containing paracetamol while giving this medicine.

Before you give this medicine, make sure that you tell your pharmacist about ANY other medicines you might be giving your child at the same time, particularly the following:

- Domperidone or metoclopramide (for feeling sick or being sick)
- Colestyramine (to reduce blood fat levels)
- Medicines to thin the blood (e.g. warfarin)
- Medicines for epilepsy (e.g. barbiturates)
- Medicines for depression (e.g. tricyclic antidepressants)

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for your child, including herbal and homeopathic remedies.

How to give this medicine

Check the cap seal is not broken before first use. If it is, do not give the medicine.

! Do not give anything else containing paracetamol while giving this medicine.

Check the table on the back of the leaflet to see how much of the medicine to give to your child. Never give more medicine than shown in the table. It is important to **shake the bottle** for at least 10 seconds before use.

Always use the syringe supplied with the pack. The syringe can be used to measure 2.5 ml or 5 ml by drawing the liquid to the correct mark on the syringe.

Give this medicine to your child to swallow.

Age	How much	How often
6 years up to 8 years	5 ml	Up to 4 times in any 24 hours. Leave at least 4 hours between doses
8 years up to 10 years	7.5 ml	
10 years up to 12 years	10 ml	
12 years up to 16 years	10 ml to 15 ml	
Adults and children of 16 years and over	10 ml to 20 ml	
Don't give more than 4 times in any 24 hours		

Do not give to children under 6 years. Do not give more than the amount recommended above.

Do not give this medicine to your child for more than 3 days, unless your doctor or pharmacist tells you to.

If your child does not get better, talk to their doctor.

Directions for using the syringe:

1. Shake the bottle for at least 10 seconds before use.
2. Push the syringe firmly into the plug (hole) in the neck of the bottle.
3. To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark (2.5 ml or 5 ml) on the syringe.
4. Turn the bottle the right way up, and then gently twist the syringe to remove from the bottle plug.
5. Place the end of the syringe into the child's mouth, normally to the side of the mouth between the gums and cheek. Press the plunger down to slowly and gently release the medicine.
6. If the table above advises you to give more than 5 ml of the medicine, repeat steps 2 to 5 to give your child the correct amount of medicine.

After use replace the cap on the top of the bottle tightly. Store all medicines out of the sight and reach of children.

Wash the syringe in warm water and allow to dry.

! If you give too much or if anyone accidentally swallows some of the medicine:

Immediate medical advice should be sought in the event of an overdose, even if your child seems well, because of the risk of delayed, serious liver damage. Go to your nearest hospital casualty department. Take the medicine and this leaflet with you.

Possible side effects

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

! If your child gets any of these serious side effects, stop giving the medicine. See a doctor at once:

· Difficulty in breathing, swelling of the face, neck, tongue or throat (severe allergic reactions)

If your child gets any of the following side effects see your pharmacist or doctor:

- Other allergic reactions (e.g. skin rash)
- Unusual bruising, or infections such as sore throats. This may be a sign of very rare changes in the blood. If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.

How to store this medicine

Do not store above 25°C. Store in the original package. Keep the lid tightly closed.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard. Use by the date on the end flap of the carton or on the label edge. After this date return any unused product to your nearest pharmacy for safe disposal.

What is in this medicine

Each 5 ml of oral suspension contains Paracetamol 250 mg, which is the active ingredient. As well as the active ingredient, the suspension also contains purified water, sorbitol (E420), glycerol (E422), microcrystalline cellulose, carmellose sodium, methyl hydroxybenzoate (E218), acesulfame potassium, hyetellose, strawberry flavour and cream flavour. The pack contains 70 ml or 80 ml of an off white, strawberry-flavoured syrupy suspension. Not all pack sizes may be marketed.

Who makes this medicine

Manufactured by BCM Ltd for the Marketing Authorisation holder The Boots Company PLC Nottingham NG2 3AA
Leaflet prepared March 2013

If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA

Other formats

To request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only) Please be ready to give the following information: Product name: Boots Paracetamol 6 Years Plus 250 mg/5 ml Oral Suspension Reference number: 00014/0860

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