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The design of information on Ibuprofen

A minor headache?

Keywords: medicine information, pain killer, information design

This article shows and describes the information about an ordinary pain killer—Ibuprofen—presented in medicine packaging, labels and leaflets. The article discusses both the contents and design, and guestions whether this combination of information is the most appropriate way to communicate with a person who has a minor headache. The article is divided into two parts. The first part provides a step-by-step description, whereas the second part summarizes the main patterns of the pain killer (Ibuprofen) information communication. The main conclusions are: the contents are incorrectly structured, repetitive, conflicting and hard to apply; the language used is confusing, vague and at some parts inappropriate; the visual design does not enable people to find and understand information, and the information does not really help patients to make appropriate decisions. These conclusions could be used as a starting point for the development of information about Ibuprofen which would really enable people to act appropriately.

1. Context: A prior warning

The text below was written to answer a question asked by an employee of a Regulatory Agency of medicine information in the United Kingdom (UK). She was convinced that medicine packaging and the labelling of all over-the-counter medicines in the UK followed the highest possible standards. The information and design were approved by her Agency, and it was therefore 'clear, understandable and easy to use'. My personal experience—which is substantially influenced by several years of talking with patients about medicine information—deviated substantially from her views. This article reports my experience of taking a pain killer when in England, and is, therefore, written in a personal style. The analysis of the medicine information and its design was presented at the IIID's Vision Plus Symposium at Birmingham City University.

In order to discuss and make some observations on the medicine information, I use a specific package of Ibuprofen, which is made by Boots Company PLC and marketed by Galpharm Healthcare Ltd in the UK. I purchased the medicine in a drugstore where the pharmacist was helpful and gave me accurate advice. The quality of the medicine itself is not related to the quality of its visual information. I am aware of the regulations, the guidelines, the registration procedures

and the discussions with the regulatory authorities. I am also aware of the difficulties of combining commercial, marketing, production, ethical, and legal requirements across Europe. The combination of all the requirements results in information about a simple medicine that is very hard to read and understand, not very convincing, and nearly impossible to apply. The photographs in this article show the package and the package leaflet as patients see them. They have not been modified or changed in any way. The poor quality in contrast, color, and folding, represents common usage as close as possible.

2. What patients see

On a recent trip to England, I got a mild headache. I went into a pharmacy and looked for a pain killer. I found the available selection of pain killers, among them Ibuprofen. I had taken Ibuprofen before, but I was unfamiliar with the brand and the long lasting capsules available in that shop. I took a package and checked if that particular medicine would be suitable for my headache. I needed to base some of my decisions on the information provided on the outer packaging. Figure 1 shows all sides of the package. Could this medicine help to alleviate my headache?

2.1 Question 1: What is this medicine for? ('The indications')

The front of the medicine package does not really make clear where I should start reading. At least four items are equally prominent. None of these prominent ones—Boots pharmaceuticals; IBUPROFEN; LONG LASTING; 200 mg capsules—meant very much to me. The text in the smallest type is the most relevant. It states: 'Relieves pain, inflammation and fever' (Figure 2). This is part of a list of two items. The visual design implies that

both items on the list belong to the same group, and have a similar type of meaning. The information suggests that, apart from considering the reasons to take a medicine, it is also important to consider the way in which it should be taken.

I was not sure if 'Relieves pain' also includes headaches, so I turned the package around. The first sentence on the back of the pack is 'Read all of the enclosed leaflet for full instructions' (Figure 3). However, customers are not usually allowed to open the packages before buying the product. Does this mean that I have to base my decision on incomplete instructions, and check the full instructions after I have bought the medicine?

The information on the pack continues (Figure 3): 'Uses: A slow release capsule for the relief of headaches, rheumatic and muscular pain, backache, migraine, period pain, dental pain and neuralgia. It can also be used to reduce fever and relieve the symptoms of colds and flu.' When I compare this information with the information on the package front (Figure 2), they seem to be different. I can see the relation between different kinds of pain, but I do not see the term 'inflammation' on the list on the back. I do not see 'relieves the symptoms of colds and flu' written on the front either. Why does the information on the front of the package seem to be different from the information on the back?

Then, I took the easy way out: I approached the pharmacist for advice. The pharmacist confirmed that I had made the right choice as Ibuprofen helps to alleviate minor headaches. To make sure that Ibuprofen was really suitable to me, the pharmacist asked me if I had any stomach problems. If I had any, I should take paracetamol; if not, Ibuprofen would be a good choice.

After purchasing Ibuprofen and back to my hotel room, I read the information provided on the package (Figure 1), in the package leaflet (Figures 4 and 5), and on the blister packs (Figures 6 and 7). The front of the package leaflet has a prominent logo of the pharmacy,



Figure 1. Six sides of the package. The braille on the back of the package (bottom left) states: 'boots Ibuprofen long lasting 200 mg capsules'. The dimensions are 86 by 71 mm. The height is 23 mm.

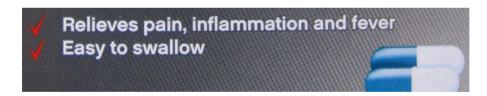


Figure 2. The design suggests that 'Easy to swallow' is nearly as important as the reasons to take Ibuprofen.

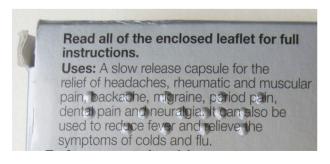


Figure 3. It is fairly hard to read the text on the back of the package. The type is (1) small, (2) condensed, (3) a light version, and (4) there is very little space between the lines. The text is (5) printed in black ink on a silver-grey background, (6) the cardboard is shiny and reflective, and (7) the Braille dots are pushed right through the text which distorts the shape of the letters. According to the literature about legible typography, each of these factors influences legibility in a negative way. The combination of those seven (!) detrimental factors make the text very hard to decipher.



Figure 4. The front of the package leaflet. The dimensions are 135 by 209,5 mm. Typographical details: x-height: 1,50 mm; line space: 3,18 mm (= about 9 point); ranged left; line length: 52 mm or 48 characters maximum. Total number of words: 1215.

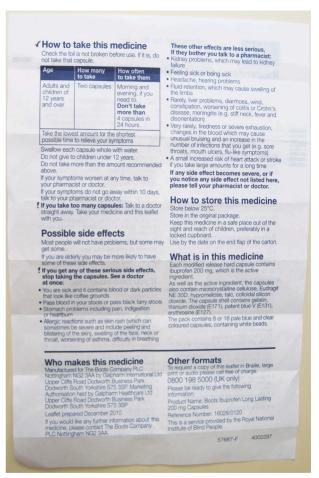


Figure 5. Back of the package leaflet.



Figure 6. Front of a blister pack.

and seems to have two headings (Figure 8). The first one is smaller and states: 'Information for the user'. I am not sure why such a statement is necessary, and I wonder if this leaflet could possibly be for anyone else.

There is a second heading which states the full name of the medicine: 'Ibuprofen Long Lasting 200 mg Capsules' (Figure 8). The type size indicates that this is the main heading. The following sentence reinforces the instructions on the back of the package: 'Read all of this leaflet carefully because it contains important information for you.' This seems rather patronizing to me. I have to read 'all of the leaflet', I have to read it 'carefully', and they tell me that it is 'important for me'. Those are usually things that I can decide for myself.

The patronizing tone continues throughout the first paragraph (Figure 9). 'This medicine is available without prescription to treat minor conditions. However, you still need to take it carefully to get the best results from it.' Not only do I have to read the leaflet 'carefully,' I also must



Figure 7. Back of a blister pack.

take the capsules 'carefully'. The following sentences confirm the patronizing attitude towards the user. 'Keep this leaflet, you may need to read it again.' I am not sure if there are any other reasons to keep the leaflet. The text continues: 'Ask your pharmacist if you need more information or advice. It is strange to put this advice in the package leaflet, because this can only be read after the user has opened the pack. I have not even started reading the text, and it is already suggested that I might need to go back to the pharmacist to get more information. At the same time, I wonder if there could be 'more' information. There are 428 words on the outer packaging and 1,215 words in the leaflet. How much more information could there be? If I need more information I might want to check a website, or make a phone call, or write an e-mail before I walk back to the pharmacy. Unfortunately, there are no websites, phone numbers or e-mail addresses on the package nor on the leaflet.

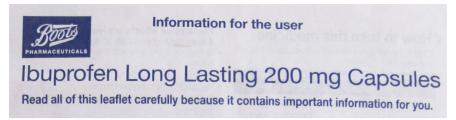


Figure 8. The two headings and a subheading relate the medicine, the patient, and the leaflet. The name of the medicine is most salient and the leaflet contains 'important information'. There are two instructions for patients: 'to read all' and 'to read carefully'. The balance between medicine, leaflet and patient becomes evident: the medicine is the most important element, followed by the leaflet, and the patient comes last.

The first section of the leaflet 'What this medicine is for' starts with a long sentence about Ibuprofen and a group of related medicines (Figure 10). It is not clear why this information is so important that it must be mentioned first. Based on the title, I had expected something like: 'This medicine relieves different kinds of pain. It also reduces fever, and relieves the symptoms of colds and flu.' Instead, the text in the leaflet prefers to describe the effects of a group of medicines 'which acts to relieve pain and reduces swelling'. This seems to suggest that Ibuprofen has both these effect as well. It is, therefore, surprising that 'swelling' is not mentioned on the outer package.

The text goes on to explain that Ibuprofen is released in the body slowly over 12 hours. It is not clear if there is a difference between 'Long lasting', 'Lasts up to 12 hours' (Figure 1, top left), 'slow release capsule' (Figure 3), and 'The Ibuprofen in the capsule is released slowly over 12 hours' (Figure 10). What is released slowly? The capsule or the Ibuprofen? It seems that the Ibuprofen in the capsule dissolves over a period of up to 12 hours. It does not seem necessary to me to use four different ways to explain that.

This medicine is available without prescription to treat minor conditions. However, you still need to take 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

Figure 9. The typography of the leaflet shows a certain disdain for readers too. The typeface is condensed, light, and printed in dark blue ink. There is little space between the lines, and the paper is so thin that the text that is printed on the back shines through. Each one of these factors reduces the legibility of a text if compared to an optimal design as it is suggested in the typographic literature.

In the third and fourth sentences the reasons to take Ibuprofen are mentioned again. This is the same information which is given on the package. So, a combination of all the indications of Ibuprofen into a single list shows that it can be used to:

- relieve different kinds of pain,
- reduce fever,
- relieve inflammation,
- reduce swelling, and
- relieve symptoms of colds and flu.

I find it odd that the items on this list are mentioned in three different places. A simple headache is now described as a specific type of pain, and I get the treatment for another four indications as well. 'Have I bought the wrong medicine?' 'Isn't there a medicine which just treats headaches?'

What this medicine is for

This medicine contains Ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory medicines, which act to relieve pain and reduce swelling. The Ibuprofen in the capsule is released slowly over 12 hours. It can be used to relieve headaches, rheumatic and muscular pain, backache, migraine, period pain, dental pain and neuralgia. It can also be used to reduce fever and relieve the symptoms of colds and flu.

Figure 10. The first sentence is 25-word long and uses an awkward 'which-which' construction—in linguistic terms: 'multiple embedded non-restrictive clauses'. Such constructions are particularly difficult for poorer readers, and for those who are reading quickly. There is also a substantial amount of information in the paragraph that is unrelated to the heading. There are two paragraphs separated by some white space. This separates lines 1 to 4, and lines 5 to 10. As both paragraphs are about the same topic, why are they separated? The term 'non-steroidal anti-inflammatory medicines' confuses me. I don't have an inflammation, just a headache. If this information is relevant, it should be explained, and might need to appear on the package.

2.2 Question 2: Who is it for? Can I use it? ('Contra-indications and warnings')

In the section 'Before you take this medicine', there are two lists. The first list mentions groups of people who should not use Ibuprofen ('Do not take'). The second list describes situations in which a patient should seek the advice of a pharmacist or a doctor before taking Ibuprofen. I expect that it might be beneficial to me to check both lists to see if any of these apply to me.

The back of the package and the leaflet mention six things that I must consider before I take Ibuprofen (Figure 11). These are mentioned under the heading 'Do not take'. The list in the package leaflet (Figure 12) is identical to the list on the back of the package. In figures 11 and 12, these are indicated by numbers. After some careful reading, I can only be sure about the first and the sixth items: they do not apply to me. I am not so sure about the other four items.

A number of situations when a consumer should ask a doctor or pharmacist for advice are also mentioned. The outer package provides three points (Figure 13). The package leaflet formulates this list slightly differently by spreading similar information over five bullet points (Figure 14). In contrast with the list under 'Do not take' which was copied verbatim, these lists are not identical.

Three things that appear in the leaflet are not mentioned on the outer package: other allergic diseases, if you use any other pain killers, and if you receive regular treatment from your doctor.

The section 'Talk to your pharmacist or doctor' contains three references (Figure 14). The first reference points to the section 'Do not take'. This section just adds 'severe kidney and liver failure' (see Figure 11, item 5), which seems to suggest that I should be able to distinguish between 'severe kidney or liver failure' and 'other



Figure 11. The outer package and the package leaflet provide the same six bullet points advising not to take Ibuprofen. Four bullets are a bit unclear:

- Bullet 2: Could Ibuprofen—as part of this group—cause perforation and a bleeding stomach? Is this a potential side effect? And is 'a bleeding stomach' the same as 'bleeding of the stomach' described in bullet 1?
- Bullet 3: I need to check if I am allergic to Ibuprofen or if
 I am allergic to any of the other ingredients. Unfortunately,
 these 'other ingredients' are not mentioned on the
 package. They can only be found in the leaflet, and
 therefore I cannot find out what 'the other ingredients'
 are before I purchase Ibuprofen.

XDo not take:

- 1 If you have a stomach ulcer, perforation or bleeding of the stomach, or have had one in the past (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools)
- 2 If you have had perforation or a bleeding stomach after taking a non-steroidal anti-inflammatory medicine
- 3 If you are allergic to ibuprofen or any other ingredients in the product, aspirin or other non-steroidal anti-inflammatory medicines (you have ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
- If you are taking aspirin with a daily dose above 75 mg, or other non-steroidal anti-inflammatory medicines
- 5 If you have severe heart, kidney or liver failure
- 6 If you are pregnant

Figure 12. The package leaflet.

- Bullet 3: I find it strange to mention aspirin as a separate medicine. I thought that aspirin belonged to the group of medicines that are called Non-Steroidal Anti-Inflammatory Medicines (NSAIMs). Why is it separated out here?
- Bullet 3: Do I need to recall if I have ever had asthma, a runny nose, itchy skin, or swelling of the lips, face, or throat? Are they trying to tell me that ibuprofen might cause all these allergic reactions?
- Bullet 4: Do I take more than 75 mg of aspirin or of NSAIMs per day? These capsules are 200 mg each and I could take two capsules twice a day. That is 800 mg in total. Would there be a dangerous difference between 800 and 875 mg? Why would 75 mg per day—less than 10%—really matter?
- Bullet 5: Do I have a severe heart, kidney, or liver failure?
 Fortunately, I do not have any of these, but how can I know if these are severe or not? Are there also minor liver failures, or negligible heart failures?

! Talk to your pharmacist or doctor:

- If you have, or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney, stomach or bowel problems
- If you smoke
- If you are elderly

Figure 13. The sentence after the first bullet point is ambiguous. Also some sentences are not accurate – e.g., 'If you have had diabetes,' as some forms of diabetes are incurable at the moment. Other sentences are not clear – e.g., 'If you have had a heart' or 'If you have had a stomach', as it takes some effort to relate 'heart', 'liver', 'kidney', and 'stomach' to 'problems'. The use of a swung dash (~) would have been helpful.

kidney and liver problems. The second reference suggests that the elderly can find more information on back of leaflet. The text on the front says: 'you may get more side effects' whereas the one on the back says: 'you may be more likely to have some of these side effects' (see Figure 21). These two sentences do not have the same meaning. 'More' or 'more likely' in comparison to what? Furthermore, the term 'elderly' seems fairly vague to me. Does this mean over 75 or over 90? The third reference only points to two lines further down in the next section. None of these three references is very helpful. The first paragraph in the section 'Other important information' provides instructions which are too general and applicable to all: 'take the lowest amount for the shortest possible time to reduce the risk' (Figure 15).

This is followed by two items about breastfeeding and becoming pregnant. Although probably vital for female patients, I cannot see how this information can be classified as 'other important information'. It is unlikely that women for whom this information is

! Talk to your pharmacist or doctor:

- If you have asthma, a history of asthma or other allergic disease, stomach or bowel problems
- If you have other kidney or liver problems (see "Do not take")
- If you are elderly you may get more side effects (see back of leaflet)
- If you are taking any other painkillers or receiving regular treatment from your doctor
- If you have had a stroke, or have heart problems, high blood pressure, diabetes, high cholesterol, or you smoke - see 'Risk of heart attack or stroke' below

Figure 14. The precautions section in the package leaflet differs slightly from the information on the package.

- Should a patient/consumer be able to compare these lists?
- I am not sure if I can distinguish between 'if you have had asthma' (package) and 'If you have a history of asthma' (leaflet). I was not aware that asthma was an allergic disease either.
- In these five points, there are three different ways of visually indicating a reference: a) (see "Do not take");
 b) (see back of leaflet); and c) see 'Risk of heart attack or stroke' below. There is no typographic consistency in the use of double quotation marks (or single), roman (or bold), and the use of brackets.

relevant will look at a section entitled 'Other important information.' Also, this information should have been given on the outer package too, because it is relevant for the user before they buy Ibuprofen.

The next section in the package leaflet is called 'If you take other medicines' (Figure 16). It provides advice about potential interactions with other medicines. The first sentence states that 'Before you take these capsules, make sure that you tell your pharmacist about ANY other medicines you might be using at the same

Other important information

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.

Women of childbearing age: If you take this medicine, it may reduce your ability to become pregnant. This effect will be reversed when you stop the medicine.

Figure 15. The title 'Other important information' does not give any indication about the contents of this section. It lists three unrelated items which require very different reactions. The first item suggests to take the lowest amount for the shortest time, the second states that it is suitable for breastfeeding mothers, and the third one warns of a possible unwanted effect.

time, The information only appears in the leaflet, and none of this information is mentioned on the package. This is surprising because this could influence the purchase decision.

The general advice seems to be: 'if you take any other medicines, talk to your pharmacist.' If that is the case, than it is not necessary to list several 'other medicines' because ANY medicine needs to be mentioned to the pharmacist. Practically, it would be difficult to tell a pharmacist because the leaflet can only be read after purchasing this medicine.

The remark in the second bullet about 'other pain killers' worries me. I need to know that there are other pain killers. Could there be steroidal pain killers? Or pro-inflammatory ones? This requires very detailed knowledge, thus the assistance of a doctor or a pharmacist becomes really essential.

If you take other medicines

- Before you take these capsules, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:
- Aspirin 75 mg (to prevent heart attacks and strokes) - the protection may be reduced when you take ibuprofen
- Other pain killers
- Medicines to thin your blood (e.g. warfarin)
- Mifepristone (for termination of pregnancy) do not take ibuprofen if you have taken mifepristone in the last 12 days
- Water tablets (diuretics), medicines to treat high blood pressure, medicines for heart problems
- · Corticosteroids, lithium, methotrexate, zidovudine
- · Quinolone antibiotics (for infections)
- Medicines for depression
- Ciclosporin or tacrolimus (given after transplant surgery, or for psoriasis or rheumatism)

 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 yourself, including herbal and homeopathic remedies.

Figure 16. Information in the leaflet is only available after purchasing the package and will therefore be read later. The advice to 'tell your pharmacist about ANY other medicines' comes too late. This is something that should have been mentioned on the package.

- The sequence in which the items appear in the list is odd. Usually, these lists are in order of importance with the most important elements appearing at the top. Are aspirin and other pain killers really the most important items?
- The grouping of the medicines in each item seems a little odd too. Why put medicines against bipolar disorders (lithium), together with medicines against cancer (methotrexate), and HIV/AIDS (zidovudine)?
- The first line starts 'Before you take these capsules ...'. Should this not be included in the section 'Before you take this medicine'?

The list of reasons for not using this product is not finished yet. Two other reasons are given and these appear in different locations:

Reason 1: 'Do not take this medicine if the foil is broken' is stated on the package and on the leaflet (Figure 17). It is an odd way of describing 'medicine use', because it considers 'pressing a capsule through the foil' as 'using the medicine'. Replacing 'it' in the second sentence shows the problem: 'If the foil is broken before use, do not take that capsule'. Of course the foil is broken before I take a capsule. There is no other way to get to the capsule.

Reason 2. 'Do not take his medicine after the expiry date'. The statement in the leaflet reads: 'Use by the date on the end flap of the carton'. (Figure 18). I am not sure if there is a difference between 'package' and 'carton'. The expiry date is also stated on the blister itself, but neither the package nor the leaflet refers to this. The reference would not be necessary if the description and the dates/batch number appeared together on the package.

To summarize this section, I can confirm that I do not have any of the medical problems mentioned in the medicine packaging and leaflet and I do not use other

How to take this medicine

Check the foil is not broken before use. If it is, do not take that capsule.

√ How to take this medicine

Check the foil is not broken before use. If it is, do not take that capsule.

Figure 17. Identical information is given on the package and in the leaflet. This information is only relevant just before taking the capsules. It is not relevant while at the pharmacy.

medicines. I do not smoke, I am not pregnant, and I am over 12 years old. The foils are still intact, and the expiry date is in 2016. All seems fine, so I can take Ibuprofen. However the section questioning my health condition has started to worry me. I cannot answer some of the questions because I do not know if I have 'other kidney or liver problems', and I do not know if these are 'severe ones'. I do not know if I have 'high blood pressure', or 'high cholesterol.' I do not know what 'perforation' is, and I cannot make a judgement about 'why more than 75 mg aspirin is relevant' or 'what a severe heart, kidney, or liver failure' means. Personally, I have difficulties to distinguish between 'severe heart failure', a 'stroke', 'heart problems', and a 'heart attack'.

Use by the date on the end flap of the carton.

Use by the date on the end flap of the carton.



Figure 18. References to the expiry date are made on the box (top) and in the leaflet (center). There is no explanation on the actual side where LOT and EXP are pressed into the cardboard (Figure 1). The batch number and expiry date on the blister pack are not mentioned (bottom). The reference to 'end flap of the carton' is strange. In the section 'What is in this medicine' the text refers to 'the pack', not 'carton'.

It took me quite some time to consider all the points about taking Ibuprofen. The presentation of the information does not really help me to make decisions. Furthermore, it is not clear why most of this information appears on both the package and in the leaflet, why some of the information is partially copied, and why some is not mentioned at all.

2.3 Question 3: How do I take it? ('Instructions')

Until now, I have established that Ibuprofen is suitable to treat my headache, and that I am not in one of the groups of people that should not take it. Now the next task looms: How to take the capsules:

 The instructions are provided on the package and in the package leaflet. The instructions on the package (Figure 19) are provided as a list of separate sentences, whereas the instructions in the package

Adults and children of 12 years and over: Take two capsules in the morning and evening, if you need to.

Don't take more than 4 capsules in 24 hours.

Do not give to children under 12 years.

Warning: Do not exceed the stated dose

If your symptoms worsen at any time, or do not go away within 10 days, talk to your pharmacist or doctor.

Figure 19. The package gives instructions in a list of six items. The use of bold type has different functions: as a title: 'Adults and children'; to emphasize: 'Don't take more than...'; as a visual cue to focus attention: 'Warning'. The roles of titles, emphasis, and attention are not visually distinguished.

- leaflet (Figure 20) are given in the format of a table. Again, much of the information is repeated although it appears in a different order. For example, the box starts with 'Swallow each capsule whole with water'. In the leaflet this is mentioned under the table.
- A warning in the leaflet-table (Figure 20) says: 'Take
 the lowest amount for the shortest possible time to
 relieve your symptoms.' (Is this in conflict with the
 instruction 'Take two capsules'? The lowest amount
 would be one capsule?) This warning does not appear
 on the package.
- On the package there is a text in a box with a warning.
 It states: 'Warning: Do not exceed the stated dose'. The leaflet mentions 'Do not take more than the amount

Age	How many to take	How often to take them
Adults and children of 12 years and over	Two capsules	Morning and evening, if you need to. Don't take more than 4 capsules in 24 hours.
Take the lowe possible time	st amount for the to relieve your sy	shortest mptoms
Do not give to	capsule whole vochildren under force than the am	
	oms worsen at ar sist or doctor.	ny time, talk to
If your sympto		way within 10 days, tor.

Figure 20. The Leaflet gives the same six items in a different order and a different format.

recommended above'. Both of these warnings require some 'mental gymnastics' to find out what 'the stated dose' or the 'amount recommended above' is. It seems that the statement: 'Don't take more than 4 capsules in 24 hours' is clearer.

Some questions remain:

- Why is it necessary to always take 2 capsules? Was it not possible to put 400 mg into one capsule? Should patients experiment themselves what an effective dose is? And if that is the case, why is that not stated anywhere?
- Why is the age so important for the dosage? Are other factors, such as asthma, taking other pain killers, and pregnancy less relevant? How does the weight of a patient, or their liver function affect the dosage?

2.4 Question 4: What are the side effects? ('Potential risks')

The section 'Possible side effects' only appears in the leaflet (Figures 21 and 22). The package itself does not mention any side effects. The manufacturer does not provide information about possible risks at the time of purchase. This makes me suspicious, or at least it makes me wonder.

The section starts with a reassuring sentence: 'Most people will not have any problems, but some may get some.' This might be the most appropriate way of formulating the information, but the following sentences are worrying: 'If you get any of these serious side effects, stop taking the capsules. See a doctor at once:' and 'If any side effect becomes severe'. Both these sentences are in bold type to visually emphasize their importance. Some remarks about the possible side effects.

 The separation between 'serious side effects' and 'less serious side effects' does not give any indication of how often these might occur. There are three indicators: "Rarely", "very rarely", and "a small increased risk". The odds of the other side effects are not mentioned. It is notoriously difficult to understand risks in relation to statistical frequencies, but for any risk-benefit decision these indications are essential. I think that kidney failure and heart attacks should not be classified as 'less serious' side effects. For me, they sound fairly serious. If I have one of the serious side effects, I have to see a doctor immediately. If a less serious side effect—such as a heart attack or meningitis as mentioned—bothers me, I need to talk to a pharmacist.

Possible side effects

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

If you are elderly you may be more likely to have some of these side effects.

- ! If you get any of these serious side effects, stop taking the capsules. See a doctor at once:
- You are sick and it contains blood or dark particles that look like coffee grounds
- Pass blood in your stools or pass black tarry stools
- Stomach problems including pain, indigestion or heartburn
- Allergic reactions such as skin rash (which can sometimes be severe and include peeling and blistering of the skin), swelling of the face, neck or throat, worsening of asthma, difficulty in breathing

Figure 21. The Leaflet provides two lists of possible side effects: 'serious' and 'less serious'. The sentence 'See a doctor at once:' ends with a semi colon, but the list does not follow as continuous sentences. The first two bullets probably describe the symptoms of stomach ulcer, a perforation, a bleeding stomach, or stomach bleeding. Strangely, these terms are not mentioned. The potential effect for women of childbearing age (see Figure 15) is not mentioned as a side effect.

- I would probably not follow this last advice and hope that a doctor can reach me quickly enough.
- 2. All five reasons for taking Ibuprofen are also mentioned as possible side effects. By taking Ibuprofen against pain, you might get stomach pain. If you take it to reduce fever, you might get fever. If you take it to treat a headache, you might get a headache. You can

These other effects are less serious. If they bother you talk to a pharmacist:

- Kidney problems, which may lead to kidney failure
- Feeling sick or being sick
- Headache, hearing problems
- Fluid retention, which may cause swelling of the limbs
- Rarely, liver problems, diarrhoea, wind, constipation, worsening of colitis or Crohn's disease, meningitis (e.g. stiff neck, fever and disorientation)
- Very rarely, tiredness or severe exhaustion, changes in the blood which may cause unusual bruising and an increase in the number of infections that you get (e.g. sore throats, mouth ulcers, flu-like symptoms)
- A small increased risk of heart attack or stroke if you take large amounts for a long time
 If any side effect becomes severe, or if you notice any side effect not listed here, please tell your pharmacist or doctor.

Figure 22. The second list shows 'less serious' side effects. The first bullet suggests that kidney problems might be a possible side effect. How could I notice this? The sixth bullet point mentions 'changes in the blood'. I am not sure how I could become aware of this effect. I might recognize some of the consequences, but I cannot notice changes in my blood.

- get flu-like symptoms as a side effect of a medicine that is taken to relieve the symptoms of cold and flu. You can increase the number of infections if you try to treat an inflammation. Also you can start swelling because you took Ibuprofen against swelling. That is all very strange. And the advice is: 'talk to a pharmacist', or 'tell your pharmacist or doctor'. I am not sure if I would be able to distinguish between the headache I had before I took Ibuprofen, and the headache that is described as a side-effect caused by Ibuprofen.
- 3. In the section 'other important information' (see Figure 15), it is advised to 'take the lowest amount for the shortest possible time to reduce this risk'. The leaflet suggests that 'ibuprofen may increase the risk if you take large amounts for a long time'. In this section it is phrased as 'a small increased risk'. It is unclear 'what the normal risk is, it is unclear what 'large amounts' are, it is unclear what 'a small increase' is, and it is unclear what 'a long time' is. A similar vagueness can be recognized in the sentence 'if you are elderly you may be more likely to have some of these side effects'. Terms such as 'may,' more likely, 'some' give the impression that the manufacturer wants to reduce the number of reactions and comments by elderly people. This overuse of wavering terms does not really inform patients. It just seems to be there to avoid any responsibility or liability.
- 4. 'If you notice any side effects not listed here' is an odd phrase. A patient can notice if something unexpected happens after taking Ibuprofen. However, it is not possible for a patient to determine if this is a 'side effect' or not. Patients should report 'any symptom they are worried about' that occurs after they have taken Ibuprofen.

The four points mentioned above indicate that the lists of side effects are really unhelpful for me. I have no idea if and how I should consider these side effects as

potential risks in relation to my minor headache. If any of these things would happen to me, it is likely that I would go to a doctor anyway. The information provided on these lists also gives me the impression that the benefits of taking Ibuprofen are unreliable, or to a large extend unknown. Ibuprofen might work, but there is a fairly substantial chance that it will not work at all. It could even trigger effects that are worse than my initial problem. The numerous irresolute and vague indications do not increase my confidence either. Also the manufacturer (or the marketing authorization holder?) does not accept much responsibility for this product by stating: 'if something happens and you need help, do not contact us; go to a pharmacist or doctor'.

Still with regard to the information provided in the leaflet, there are four final sections to consider. The first two are:

- 'How to store this medicine'. This section consists of four separate sentences that seem unrelated. The last sentence 'Use by the date on the end flap of the carton' seems odd here. It indicates the maximum storage time but does not mention what to do if after this date. This should be mentioned in the section 'Do not take: after the date on the end flap of the carton'.
- 'What is in this medicine'. These are the 'other ingredients' that are mentioned on the outer package.
 Patients with allergies should be able to check these before they buy a medicine.

The last two sections are separated by a horizontal rule (see Figure 5).

 'Who makes this medicine'. The package says: 'If you need more advice ask your pharmacist'. This is repeated in the second bullet of the leaflet 'Ask your pharmacist if you need more information or advice', together with 'If you would like any further information about this medicine, please contact The Boots Company PLC'. Asking a pharmacist seems a lot more convenient in comparison to writing a letter to the company in Nottingham, where they are located. What is more surprising is that there are no phone numbers, no e-mail addresses, no websites, nor any indication of social media. Although there is a date on the leaflet 'prepared December 2010', it does not provide any digital support.

 'Other formats'. The Royal National Institute for the Blind can provide copies of the leaflet in Braille, large print, or audio.

After reading and considering the information on the package and in the package leaflet, I should now be able to take Ibuprofen. I am aware of its risks and benefits, and I know how much and how to take the capsules. I should therefore have confidence in Ibuprofen, that it will alleviate my headache without causing any adverse effects (I am pleased to say that my headache disappeared very quickly without any negative reactions).

3. Is this an example of effective communication?

The initial question of this article was whether this combination of information is the most appropriate way to communicate with a person who has a minor headache. Does the information on the packaging and the leaflet really enable me to act appropriately?

There are many different ways to consider the information. From a legal perspective, this information is flawless. It conforms to all relevant regulations and guidelines. From an economic perspective it is also fine. The costs of producing a complex combination of capsules, packaging and information is financially viable. However, the step-by-step description indicates that

there are fairly severe problems with each section from the perspective of a patient-consumer.

- It turns out that Ibuprofen can be used for several reasons, but these indications are not mentioned together. It is not very clear in which situations Ibuprofen could be most beneficial.
- 2. There is a substantial amount of information that needs to be checked before I take Ibuprofen. My medical history, any other medicines I may be taking, and any other medical treatment I may be undergoing need to be considered. Some of this is mentioned on the outer pack and in the leaflet, other information is only mentioned in the leaflet. Much of it is unclear or vague, and therefore a cause for concern.
- 3. The dose of Ibuprofen seems to be one-size-fits-all. Should I 'Take 2 capsules' every time, regardless of weight, age, gender, and liver effectiveness? Is one dose always appropriate in every situation?
- 4. Ibuprofen could cause a range of side effects. It is strange that some of the side effects that Ibuprofen could cause correspond exactly to the same symptoms that Ibuprofen might relieve. None of these risks are mentioned on the outer package. This makes it impossible to compare the benefits and the risks when purchasing Ibuprofen.

The problems with each of the four information sections are even more severe due to the unconventional use of language and visual design. It is likely that a detailed linguistic analysis will reveal many more issues, but I found some of the sentences very long, poorly structured, and hard to understand. Moreover, the tone of some of the text is patronizing ('it contains important information for you'), and the terminology is at some points inconsistent. The frequent imprecise advice indicated by the use of words such as 'may' and 'could', and incomparable

lists of risks and benefits also make it difficult for a patient to find their way through this information.

The visual design of the text on the package and in the leaflet does not really support readers either. The small type size, low contrast, condensed and light letter-forms make the text hard to read. Even when the text can be 'deciphered', its visual presentation does not support a comfortable interpretation. The information that is most salient is not the most important. For example the main heading 'information for the user' and the subheading 'Other important information' waste valuable attention. The sequence of the information follows the main steps of use, but this sequence is not very clearly marked. For example, the title 'Other important information' disrupts this sequence. This leads to difficulties in interpreting and understanding information.

3.1 Consequence 1: It takes substantial time to read

The unconventional use of language coupled with an unsupportive visual design makes the information about Ibuprofen hard to read.

- Some of the information in the leaflet and on the package is repeated, whereas other information is not. When repeated, the information is not always identically produced, showing a lack in consistency.
- The references to other sections are hard to follow and do not lead to more detailed information.
- Information appears under headings where I did not expect it. For example, the text 'Before you take these capsules' (Figure 16) is not under the heading 'Before you take this medicine'. This makes the information hard to find and confusing.

Neither the package nor the leaflet seem to have been devised in a way which will help me to increase my knowledge about Ibuprofen.

3.2 Consequence 2: The information does not really help me to make decisions

The information on the package and in the leaflet of Ibuprofen does not optimally help me to use this medicine to alleviate my headache. The balance between the benefits and the potential risks is lost. The benefits are mentioned in three different locations in different words. There are many more side effects than there are benefits, and these are mentioned in the package leaflet only. The information provided does not accurately describe the correct use, it does not help me to make decisions, and it does not stimulate appropriate reactions.

3.3 Consequence 3: The information is very hard to apply

After reading the information on the package and in the leaflet several times, I am still not sure how to follow some of the instructions. At some points, the information does not seem to take a practical situation into account. The package suggests to check the other ingredients, but these ingredients are only mentioned in the leaflet, which cannot be read until the medicine is bought. There is no contact information, such as an e-mail address, a phone number or a website. The information on the package and in the package leaflet seems to point towards each other if a patient asks any further questions. These last points make me suspicious.

4. Main conclusions

The package and leaflet of Ibuprofen do not support patients to purchase it, consider its effects, and take this medicine correctly. It took me a lot of effort and time to read the information provided. The information did not really help me to make decisions, and it did not support my activities. This lack of helpful support, the unclear responsibility for additional information ('ask a pharmacist' or 'ask the manufacturer'), and the complete absence of phone numbers and digital resources are surprising nowadays. Most products for consumers score much better on these aspects.

In order to make the information about Ibuprofen suitable for patients, it might be necessary to shift the main focus from 'providing information about Ibuprofen' to 'enabling patients to act appropriately'. Information for patients should not only adhere to legal requirements and consider financial motivations. Information for patients must start from the actual use by patients. It should be possible to write and design information about Ibuprofen in such a way that I can easily find the actions that are relevant to me, consider them, and undertake them safely and confidently.

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