

Guidance on information in the PIL to address areas of potential misuse or abuse of over-the-counter (OTC) antihistamine sleep aid and laxative medicines

1. Purpose

The Patient Information Leaflet (PIL) has a key part to play in providing information to patients about their medicine, to promote safe use of the product. It supports the advice given by healthcare professionals.

Most medicines are used by patients safely and in accordance with the instructions for use on the PIL. There are a very small number of cases where medicines rarely may be misused or abused by patients. In products that are known to be misused in a small proportion of cases, the PIL can help to ensure safe use by including appropriate warning messages. However, it is important to maintain a balance so that messages in the PIL do not direct patients to the possibility of misuse.

The MHRA has already worked with industry to include additional information in PILs for OTC products containing the opioids, codeine and dihydrocodeine. This guidance looks at measures which may be appropriate for antihistamine sleeping aids and laxatives.

This guidance has been developed by the MHRA with advice from the Commission on Human Medicines Expert Working Group on Patient Information and in consultation with industry representatives. Pharmaceutical companies are asked to review the need for additional statements when revising their PILs for OTC antihistamine sleep aids and for laxative products. If PILs are being user tested, then it would be useful to use this to check that users can find and interpret the chosen statements.

The inclusion of these messages is voluntary.

2. Antihistamine sleep aids

Over the counter sleep aids are indicated for short term use only and may contain an antihistamine such as diphenhydramine or promethazine. The sedative effects of antihistamine products are generally short lived and rebound insomnia is common on prolonged use, so patients for whom the initial sleep problem is not resolved may take increasing doses to achieve the desired effect. Existing PILs for authorised products contain warning statements such as:

“This medicine is for short term sleeping problems. It should not be used for more than 7 days without talking to the doctor.”

“Do not take X for more than two weeks. If your sleeping difficulties carry on for more than one week, see your doctor.”

To make the warnings more explicit so that consumers understand why the product is only indicated for short term use, the MHRA recommends that the PIL includes a statement to the effect that:

“This medicine may not work as well if you use it for more than one/two* weeks.”
or

“This medicine may lose its effectiveness if you continue to use it for more than one/two* weeks.”

*The stated duration should be amended to reflect what the SPC says about duration of use.

Wherever possible, this should be combined with the existing warnings on duration of use to give clear instructions with an explanation of reasons, for example as follows:

“This medicine is for short term sleeping problems. It may not work as well if you use it for more than one/two weeks [depending on SPC]. If your problems with sleeping continue for more than one week, see your doctor for advice.”

3. Laxatives

Laxative products may be overused by those perceiving them as a means of controlling weight. Sources such as the Eating Disorders Association advise that the medical evidence is that laxatives do not aid in weight loss (beyond the initial temporary loss of waste and water) and that this may lead to dehydration and be harmful in the longer term¹. Current PILs for authorised OTC laxative products have a variety of statements about duration of use depending on the product. Examples include:

“As with all laxatives, X should not be taken every day for long periods. If you need laxatives every day, or if you have abdominal pain which does not go away, you should see your doctor.”

“Do not take for long periods of time (in general more than a week), unless your doctor tells you to.”

For OTC laxative products that may be subject to overuse, the MHRA recommends that the PIL includes a warning statement to the effect that laxatives do not aid weight loss:

“Laxatives do not help long-term weight loss [and taking them regularly for a long time may harm your health].”

or

“Laxatives should not be used to help you lose weight [and taking them regularly for a long time may harm your health].”

Wherever possible, this should be combined with the existing warnings on duration of use to give clear instructions based on the SPC, for example as follows:

“Do not take for long periods of time (in general more than a week), unless your doctor tells you to. Laxatives do not help long-term weight loss.”

MHRA/VRMM
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¹ <http://www.b-eat.co.uk/YoungPeople/Otherissues/Laxatives>