Patient information: pharmacy service

Unlicensed medicines FAQ’s

This leaflet is for patients who have been prescribed an unlicensed medicine and answers frequently asked questions some people may have. Please speak to the pharmacist if you have any further questions after reading this leaflet.

I have been prescribed an unlicensed medicine. What does this mean?

You have been prescribed an unlicensed medicine as there is no licensed alternative that will meet your needs. There are several reasons for prescribing an unlicensed medicine. For example, it could be that you are allergic to the licensed medicine, that it is not available in the UK or it has been withdrawn from the market. Your doctor will have thought very carefully about prescribing the most appropriate medicine for you.

What is the difference between licensed and unlicensed medicines?

To sell a medicine in the UK, the manufacturer must apply for a product licence from the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA will only agree a product licence if:
- tests have proved that the medicine successfully treats the condition for which it was developed.
- the medicine does not have too many side effects.
- the medicine is made to a high standard.
- the licence will be for the medical condition(s) for which it was developed.

An unlicensed medicine is one that does not have a product licence. The reasons for this are:
- if only a very small number of people would use a medicine, there might be little commercial interest in marketing that medicine.
- the medicine might be waiting for approval from the MHRA.
- your doctor might prescribe your medicine in a form that is not readily available, so that it has to be made up as a special preparation by your local pharmacy.

Below are some examples of when an unlicensed medicine may be used:
- your doctor might believe that a medicine would work well for your condition, even though it has not been licensed for that condition.
• your doctor may prescribe a liquid medicine that is only licensed in tablet form – medicines like this are often prescribed for children if they find it difficult to take adult medicine.

Should I be worried about taking unlicensed medicines?
Your doctor will have explained to you why they think that this medicine is the right one for you. If you are worried about taking this medicine, talk to your doctor or pharmacist about your concerns. They might be able to give you further information.

What if I don’t want to take unlicensed medicines?
Talk it over with your doctor (or pharmacist) and tell them what you are worried about. They can tell you more about the information or advice they have about the medicine. They can also tell you about other treatments if these are available and why they think this is the best one.

What else do I need to know?
Sometimes it will take longer for the pharmacist to order in an unlicensed medicine, so you should allow one or two weeks for the pharmacist to obtain further supplies of your medicine. You should bear this in mind, if you need to get a repeat prescription from your doctor.

Authors: Amani El Bushra, associate chief pharmacist, Aadil Ismail, lead pharmacist for clinical services
Revision number: 3
Approval date: December 2019
Review date: December 2022