

Patient information

Unlicensed Medicines and Medicines for Unlicensed Indications ('Off-Label' Use)

Pharmacy - Liverpool University Hospitals Foundation Trust

You have been given a supply of:

.....

This medicine is:

1. An unlicensed medicine

A licensed medicine being used off-label

In the United Kingdom (UK), most medicines are licensed but some are not. To help you understand what this means, we have given you this leaflet which answers some of the most frequently asked questions and explains why medicines are licensed and why some useful medicines do not have licences.

Your pharmacist may also give you another leaflet which is specific to your medicine.

Why do medicines have a licence?

In the UK, all medicines are checked to make sure they work and are safe. These checks are normally part of a clinical trial. The Medicines and Healthcare Products Regulatory Agency (MHRA) gives a product licence to medicines which have passed these checks. The product licence, also called a market authorisation, will say which condition or conditions that medicine can be used to treat.

What is meant by an unlicensed medicine?

An unlicensed medicine is a medicine which does not have a product licence. A medicine might be unlicensed for various reasons.

Some examples of unlicensed medicines are:

- A medicine that has to be imported because it is not available in the UK.
- A specially prepared liquid medicine for patients who cannot swallow tablets or capsules.

Sometimes prescribers may use a medicine in a way that is not part of its product licence. You may hear this being called an 'off-label' use of a licensed medicine.

Examples of 'off-label' uses include:

- Using a medicine to treat a condition which is not listed in the product licence.
- Using a medicine in an age group which is not mentioned in the product licence.
- Using a medicine at a different dose than that recommended in the product licence.

Why are some medicines unlicensed?

There are many different reasons why a medicine might be unlicensed.

These include:

- Manufacturers may decide not to try to get new uses for a medicine added to the product license because it is very expensive to complete the necessary clinical trials.
- The number of people with a particular condition is too small to allow clinical trials to be completed.
- The medicine is still going through the licensing process, which can take some time.

How do I know these medicines are safe and will work?

Your prescribers will have considered all the options for treating your condition before deciding to give you an unlicensed or off-label medicine. The prescriber will have thought carefully about the best medicine for you and your condition.

Prescribers have a lot of experience with medicines. They will have read specialist information about the unlicensed or off-label medicine and may have talked to other experts about your treatment.

How will I know that my medicine is not licensed?

Your prescriber should discuss this with you before giving you the medicine.

If your medicine is being used 'off-label', you may notice that the leaflet in the box does not talk about the condition that you have. It is important that you take your medicine as the prescriber or pharmacist has told you. The dose should be printed on the label stuck on the box by pharmacy.

What if I don't want to take an unlicensed medicine?

This is your choice to make. Talk it over with your prescriber. Tell them what you are worried about. They will be able to give you more information and advice about the medicine.

Your prescriber will also be able to discuss alternative treatments with you and explain why they think this option is the best for you.

Where can I find out more information?

If the leaflet given to you with the medicine does not talk about the condition you have, please ask your prescriber for more information.

If the medicine comes from another country and the packaging and leaflet are not in English, ask your pharmacist if they can give you a leaflet that has been translated into English.

How do I obtain further supplies of this medicine?

Your prescriber or pharmacist should explain this to you when you are given your medicine.

If you need to continue with your medicine after leaving hospital, you may need to continue to obtain it via the hospital. Alternatively your hospital prescriber may ask your GP to prescribe this medicine for you. Your GP will then give you a prescription which you can take to a community pharmacy.

Feedback

Your feedback is important to us and helps us influence care in the future.

Following your discharge from hospital or attendance at your outpatient appointment you will receive a text asking if you would recommend our service to others. Please take the time to text back, you will not be charged for the text and can opt out at any point. Your co-operation is greatly appreciated.

Further information

If you would like further information about your medicine, please telephone the pharmacy department using the details below and ask to speak to the Responsible Pharmacist or the Medicines Information Department (Aintree):

- **Royal Liverpool Hospital: 0151 706 2085**
- **Aintree Hospital: 0151 529 3226**

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