

“Unlicensed” and “Off-Label” Medicines

Introduction

This leaflet has been produced to give you general information about your medication. Most of your questions should be answered by this leaflet. It is not intended to replace the discussion between you and your doctor, but may act as a starting point for discussion. If after reading it you have any concerns or require further explanation, please discuss this with a member of the healthcare team.

Why have I been given this leaflet?

You have been given this leaflet because you have been prescribed a medicine that is “unlicensed”. This leaflet aims to answer most of the frequently asked questions relating to the use of “unlicensed” medicines.

Medication licensing in the UK

Before a medicine can be widely used in the UK, it must first be granted a license. While no medicine is completely safe, a license indicates all the proper checks have been carried out and the benefits of a medicine are believed to outweigh the risks. This license is also known as a marketing authorisation. The license says what conditions the medicine has been approved to treat.

What is ‘Off-Label’ use of medication?

Off-label’ use means that the medicine has a license for treating some conditions, but that the manufacturer of the medicine has not applied for a license for it to be used to treat your condition. In other words, the medicine may not have undergone clinical trials to see if it is effective and safe in treating your condition.

Unlicensed medications

An unlicensed medicine is one that does not have a product license in the UK.

Why do some medicines not have a license?

There are a number of reasons why a medicine may be unlicensed in the UK.

- It may be waiting for a license to be granted by the Medicines Agency
- It may still be undergoing testing in a clinical trial



- The need for the medicine may be so limited that it is not economic for the manufacturers to apply for a license(which is an expensive process)
- The medicine may be licensed in another country, and needs to be imported to the UK
- The medicine may need to be made up as a 'special product' because it is not readily available. (this is often the case for liquid formulations of medicines which only have a license for the tablet form)

What are the reasons for an unlicensed and/or Off-Label medicine to be used?

To ensure that you have the best possible treatment for your condition, it may sometimes be necessary for unlicensed medicines to be prescribed.

- Clinical trials and research may have shown that the unlicensed medicine is the best treatment for your condition, but the manufacturer has not yet applied for a license, or they may be in the process of having a license granted
- There may be no other effective treatment available
- The medicine may be a special formulation such as a liquid which needs to be manufactured specifically for you.
- Many medicines are only tested with adult volunteers. Therefore, they will not have a license for use in children. There are local processes in place to review medicines and decide on what is best to treat children and younger people
- Syringe pumps are often used to deliver medication subcutaneously (under the skin) to control symptoms. Mixing medicines within the syringe pump makes the resulting mixture unlicensed. This does not mean that they are unsafe.

Are unlicensed and /or Off-Label medicines safe to use?

Your prescriber will consider all medical evidence available before prescribing an unlicensed medication. No medicine is completely free of side-effects and your prescriber will balance any risk of these against any benefits you may get, in consultation with you.

Should I be worried about taking unlicensed and /or Off-Label medicines?

Your prescriber 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 prescriber or pharmacist about your concerns. They may be able to give

you further information or help to put you in touch with a support group for your illness or condition.

If you experience any unpleasant or unexpected effects whilst taking the medicine, you should discuss this with the person responsible for prescribing your medicine or the pharmacy which dispenses it for you.

What else do I need to know?

Sometimes it will take longer for the pharmacy to order and receive an unlicensed medicine, so you should allow one or two weeks for the pharmacy to obtain further supplies of your medicine. You should bear this in mind if you need to get a repeat prescription. Please remember that using a medication outside of its license may be the best way for you to get maximum benefit from medication with minimum unwanted effects.

