

### 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 licence may be the best way for you to get maximum benefit from medication with minimum unwanted effects.

### Any Further Questions?

If you are still worried or unsure about your prescription, please do talk to your prescriber or the pharmacist who dispenses your medication

Further Information: NHS Choices

<http://www.nhs.uk/Conditions/Medicinesinfo/Pages/Safetyissues.aspx>

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## Patient Information Leaflet

### “Unlicensed” and “Off-Label” Medicines

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## 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 licence.**

While no medicine is completely safe, a licence indicates all the proper checks have been carried out and the benefits of a medicine are believed to outweigh the risks.

This licence is also known as a marketing authorisation.

## What is Off-Label use of medication?

Off-label’ use means that the manufacturer of the medicine has not applied for a licence for it to be used to treat your condition.

## Unlicensed medicines

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

## Why do some medicines not have a licence?

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

- It may be waiting for a licence to be granted by the Medicines and Healthcare Products Regulatory Agency (MHRA)
- 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 licence (which is an expensive process)
- The medicine may be licensed in another country, and needs to be imported to the UK
- The medicine needs 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 licence 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 licence, or they may be in the process of having a licence 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 licence 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 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.