What is this leaflet about?

You have been given this leaflet because the medication you have been prescribed is not licensed (unlicensed medicine) or is being used in a way that is not covered by the licence (off-label). This leaflet is intended to inform you that the most appropriate medicine has been chosen to treat your condition and to help answer any questions you may have.

Please ensure that you read this information leaflet before you start taking your medicine.

Why are medicines licensed?

In the UK, most medicines go through strict checks to make sure that they are safe and effective. When the medicine passes all the required checks, a marketing authorisation (previously known as a product licence) is granted which means that the medicine can be used in the treatment of specific medical conditions.

Pharmaceutical manufacturers must apply to the official government agency, the Medicines and Healthcare Products Regulatory Agency (MHRA), for a product licence if they want to sell their medicines in the UK. The MHRA only agrees a product licence for a medicine if it has been proven to work for the illnesses it was developed for, does not have too many side-effects or risks and has been made to a high standard.

What is an unlicensed medicine or off-label medicine?

Medicines are usually only licensed for conditions that have been investigated in clinical trials. However, at times a licensed medicine cannot be used, for example:

- a medicine is needed for a rare illness
- where there are no licensed medicines for a particular condition
- when a patient is allergic to the licensed treatments
- a liquid form of a medicine that is only licensed as a tablet.
- a medicine used for a different reason to what is in its licence
- a medicine for a child which only has a license for an adult

In these situations, doctors and pharmacists can use their medical experience and specialist knowledge to recommend the use of unlicensed or off-label medicines. They may choose to use:

- a licensed medicine for a purpose, dose or route that is not covered by the licence – 'off-label' use
- a medicine that is currently undergoing clinical trials but does not yet have a licence
- a medicine that used to be licensed in the UK but is no longer available
- a medicine that is only available from abroad and needs to be imported
- a medicine that needs to be specially made because it is not readily available from a manufacturer

Why have I been given an unlicensed medicine?

The doctor who is treating you has recommended an unlicensed or off-label medicine because no suitable licensed alternative is available to treat your condition.

The name of your unlicensed / off-label medicine is:

_____

_____

Should I be worried about taking unlicensed or off-label medicines?

Doctors only prescribe these because they believe that the benefits of taking the medicines outweigh any risks of taking them.

To ensure that the quality of unlicensed medicines is of the highest possible standard, the pharmacy only obtains them from suppliers who have been approved by the MHRA.

Am I likely to have side-effects?

Like all medicines, the medicine you get may give side-effects. Your doctor or pharmacist will talk to you about these for the particular medicine you have been prescribed. If you do experience any side-effects you should report them to your doctor or pharmacist.

What else do I need to know?

Sometimes it will take longer for the pharmacy to order in an unlicensed medicine. It is therefore best to allow one or two weeks for the pharmacy to obtain further supplies. You should bear this in mind if you need to get a repeat prescription from your doctor.

Any further questions

If you are unsure about any of this advice, please ask your doctor or pharmacist, or call:

QVH Patient Medication Helpline
Tel: 01342 414215

If you'd like to find out how you can support QVH, please visit www.supportqvh.org

QVH CHARITY

Please ask if you would like this leaflet in larger print or a different format.

Pharmacy Department
Issue 4 - Ref. No 0188
Approved by the Patient Information Group
Print March 2022 – Review March 2025

qvh.nhs.uk

NHS
Queen Victoria Hospital
NHS Foundation Trust

Use of Unlicensed and Off-Label Medicines

Information for patients

QVH