



UNLICENSED AND 'OFF-LABEL' MEDICINES

Information for patients, parents and carers

All medicines used in the UK must have a licence. Medicines are licensed by the Medicines and Healthcare products Regulatory Agency (MHRA). The manufacturer takes responsibility when a medicine is used according to its licence. The licence says exactly how the medicine can be used.

The medicine you have been prescribed is '**unlicensed**'. This leaflet explains what an unlicensed medicine is and how to obtain further supplies.

What is an unlicensed medicine?

An **unlicensed medicine** may include the following examples:

- Medicine has a license in other countries but not in the U.K. It has to be imported because it is not available in the U.K
- Medicine is used in clinical trials
- Medicine which is awaiting approval by the MHRA
- Medicine is for a patient who has a special clinical need
- Medicine is needed in a special form (for example a liquid) which has to be specially manufactured

The licence may not include use in an age group (for example in children or in the elderly), or a particular illness or if a tablet is crushed. In these cases the medicine is said to be used **off-label** (unlicensed use).

If a medication is unlicensed or prescribed off-label, the responsibility for any problems that arise remains with the doctor who prescribes the medicine.

Is this medication safe to use?

- It is not unusual or unsafe to prescribe an unlicensed or off-label medicine. There are some conditions which currently only have unlicensed and off-label treatment options.
- When a medicine is used off-label, it is being used in a way different to that in the licence. It will have been through the licensing process to show it is safe to use.
- When a doctor prescribes the medication off-label they will use their own expertise to determine that the treatment is suitable for you at the time.
- If a medication has no licence the doctor will liaise with the pharmacy team to ensure that the medication is safe and appropriate. When ordering an unlicensed



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medication the pharmacy will ensure that it is purchased from a reputable supplier.

- If you have any concerns about being prescribed any medication discuss this with your doctor or pharmacist who will be able to provide you with additional information.

How to obtain a further supply?

Some unlicensed medicines can be difficult for pharmacies to obtain as they are not stocked at the usual suppliers. The details below can be given to your pharmacy to assist them in ordering your medication.



Preferred supplier and contact details:.....
Please give this information to your pharmacy **well before** your supply runs out to ensure your treatment can continue.

Further information?

- The internet can be a very useful source of additional information but remember that anyone can put information on the internet so the information may not be accurate.
- The information leaflet provided with your medication gives details of side effects, storage requirements and the usual doses and conditions for which the medicine is intended. It will not mention conditions or doses if the medicine is being used off-label. If your medicine has been imported from outside the UK, an English translation of the information leaflet will be provided where possible.
- If you have any concerns regarding this medicine please contact the **Pharmacy Department. (Tel 01793 605029 Monday to Friday 2:00pm to 4:00pm)**
- Your local community pharmacy will also be able to provide you with additional information about your medication.

From 1st January 2019 smoking will not be permitted on any NHS site in England. Smoking will not be permitted within any of our buildings or anywhere outside on our sites. Smoking facilities will not be provided. Please be considerate of others when vaping in hospital grounds.

This information sheet is available to order in other languages and formats. If you would like a copy, please contact us on 01793 604031 or email gwh.pals@nhs.net

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