

INFORMATION FOR PATIENTS

Unlicensed medicines

Most medicines prescribed in this country are approved for use ('licensed') by the Government's Medicines and Healthcare Products Regulatory Agency (MHRA).

This leaflet is intended to explain why healthcare prescribers may sometimes prescribe medicines used outside this approval process.

This leaflet is being given to you because your healthcare prescriber may prescribe for you an unlicensed medicine. Your healthcare prescriber will explain what this is, but this leaflet gives you more information. For the purpose of this leaflet the term healthcare prescriber is used to cover doctors, nurses, midwives and pharmacists who have been trained to prescribe medicines.

Why are medicines usually officially approved?

With a few exceptions, medicines prescribed or sold in this country are approved for use by the Government's Medicines and Healthcare Products Regulatory Agency (MHRA). This helps ensure that medicines:

- Are effective
- Do not cause too many side effects
- Are produced under good conditions.

To provide patients with the best or most suitable treatment, it is sometimes necessary for healthcare prescribers to supply medicines that have not gone through this approval process. They will not do this unless they believe the medicine to be safe and effective. It is also sometimes necessary to use medicines for uses other than those for which they have been approved.

In this leaflet, medicines that have not gone through this approval process are called unlicensed medicines.

Why do healthcare prescribers prescribe/use unlicensed medicines?

- Research may have shown that the special medicine is better than a medicine that has been officially approved, but the manufacturer may not have asked for the medicine to be approved, or may be waiting for approval.

- It may be that no other effective treatment is available. This is often the case with some rare diseases.
- A medicine may only be approved for use in one group of patients, e.g. adults, but doctors may have found it also works for others, e.g. children. Healthcare prescribers may wish to use it for these patients if it is felt to be the most appropriate treatment available.
- The medicine may not have gone through the approval process because it is one that needs to be made up specially, e.g. a liquid medicine that has to be made so that a child can swallow it easily.

What differences might I notice if I am prescribed/supplied with a special medicine?

You may notice that a manufacturer's information leaflet supplied with the medicine is not quite right. For instance, you may notice it does not include information about the condition for which you are being treated or about the use of the medicine for children. It might also state a dose different from that which your healthcare prescriber has prescribed for you. Many of these medicines have to be made up specially or may take longer to obtain than other medicines. Your pharmacist may therefore need to make special arrangements for the supply of the medicine so it may be necessary for you to ask the prescriber for another prescription up to two weeks before the next supply of the medicine is needed.

Healthcare prescribers will prescribe/supply a special medicine only when it is considered to be the most appropriate treatment.

The fact that a medicine has not gone through the Government's official approval process does not mean it is less effective, less safe or of a poorer quality than one that has.

What do I do if I want more information?

If you have any concerns about any medicine, or information you have been given with the medicine, or just want more information, please talk to your healthcare prescriber. They have lots of knowledge and experience with medicines and will be pleased to answer your queries.

What if I am unhappy about taking/using a special medicine?

If you have any concerns at all, talk them over with your healthcare prescriber. Tell them what you are worried about and why. He/she can:

- Give you more information about the medicine.
- Explain why it is believed to be the most suitable.
- Discuss other treatments that may be available.

Nobody can force you to take or use any medicine that you do not want.

Contact details

Pharmacy - Medicines Information: Telephone 01623 672213.

Further information

Patient Experience Team (PET) - PET is available to help with any of your compliments, concerns or complaints, and will ensure a prompt and efficient service.

King's Mill Hospital: 01623 672222

Newark Hospital: 01636 685692

Email: sfh-tr.PET@nhs.net

If you would like this information in an alternative format, for example large print or easy read, or if you need help with communicating with us, for example because you use British Sign Language, please let us know. You can call the Patient Experience Team on 01623 672222 or email sfh-tr.PET@nhs.net.

This document is intended for information purposes only and should not replace advice that your relevant health professional would give you. External websites may be referred to in specific cases. Any external websites are provided for your information and convenience. We cannot accept responsibility for the information found on them. If you require a full list of references (if relevant) for this leaflet, please email sfh-tr.patientinformation@nhs.net or telephone 01623 622515, extension 6927.

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