



Unlicensed Medicines

Information for patients, relatives and carers

You have been issued with the following unlicensed
medicine(s).....

Please read this leaflet to understand what this means

① For more information, please contact:

Issuing team:.....

Tel:.....

York Hospital Pharmacy Department

Tel: 01904 725736

Scarborough Hospital Pharmacy Department

Tel: 01723 342093

Medicines Information

Tel: 01904 725960

Email: medicines.information@york.nhs.uk

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What is this leaflet about?

You have been given this leaflet because a medicine that you have been prescribed is

- Not licensed in the United Kingdom

Or

- Is licensed in the United Kingdom, but not for the condition/symptoms you are being treated for.

This leaflet is intended to help answer any questions that you may have.

Why are medicines licensed?

Pharmaceutical companies must hold a license for each medicine that they sell in the United Kingdom. The Medicines and Healthcare products Regulatory Agency (MHRA) issue these licenses only after they have assessed information on the quality and safety of the medicine. The license states what conditions/symptoms the medicine has been approved by the MHRA to treat.

Why don't all medicines have licenses?

A medicine will not have a UK product license if:

- It is waiting to be granted a license from the MHRA.
- It is being tested in a clinical trial.
- Usage of the medicine is low and therefore it is not economic for the manufacturers to apply for a license.
- The medicine is only available from abroad and needs to be imported.
- The medicine needs to be made as a 'special' by a Pharmacy manufacturing unit.

A medicine may have a UK product license but not for the condition or symptom it is being used for.

Why are unlicensed medicines used?

In order to provide patients with the best or most suitable treatment, it is sometimes necessary for prescribers to prescribe medicines that are unlicensed or unlicensed for that condition.

A prescriber will only use medicines outside the product license when there is research and experience to back up such use. They will not use an unlicensed medicine unless they believe it to be safe and effective and the best choice for you.

- Research may have shown that this medication/treatment is the best option for you but the manufacturer may not have asked for the treatment to be approved, or may be waiting for a license to be granted.
- No other effective medication/treatment is 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 for a young child.

Are there any groups of patients or conditions where unlicensed medicines are more commonly used?

Unlicensed medicines may occasionally be used by all prescribers, but there are particular conditions/ groups of people where use is more frequent.

People with specific types of pain -

Conventional pain killers like paracetamol will often not be that helpful for specific types of pain caused by damage to a nerve. These types of pain are however often very successfully treated with antidepressants and anti-epileptics (anticonvulsants). These drugs are usually not licensed to treat pain, but their use for this type of pain is well recognised. The manufacturers have not applied for a license for pain as it would not be economic.

Children -

When a manufacturer applies for a license for a medicine, it will usually have only been tested in adult healthy volunteers or patients. Therefore, it will often not have a licence for use in children. A prescriber will only use medicines outside the product license when there is research and experience to back up such use.

Palliative care -

In palliative care, up to a quarter of all prescriptions written are for licensed drugs given for unlicensed indications, and/or via an unlicensed route.

Certain types of pain may respond very well to drugs not licensed to treat pain as already discussed above.

Medicines are often injected subcutaneously (under the skin) rather than into the vein or muscle because it is more comfortable and convenient for the person being treated. They may not be licensed for subcutaneous use, but their use in this way is well recognised for being safe and effective.

Should I be worried about taking unlicensed medicines?

Your prescriber should tell you that the treatment is not licensed. They should explain why it is the preferred treatment for your condition and discuss any side effects.

In some cases your prescriber may give you some separate information about the medicine. If this is supplied please read it carefully, and follow any instructions you are given.

Your prescriber should have explained why they think this medicine is the right one for you. If however you are worried about taking this medicine, talk to your prescriber or pharmacist and explain why you are concerned.

The prescriber can then:

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

If you experience any unpleasant or unexpected side effects whilst taking this medicine, you should report this to the doctor or specialist nurse looking after you.

How do I obtain a further supply?

If you are unsure where to obtain further supplies speak to your prescriber or the hospital pharmacy.

Some unlicensed drugs must only be prescribed by your hospital doctor or nurse. These will be dispensed by one of the pharmacies in the hospital (the main Hospital Pharmacy or Lloyds Pharmacy at York Hospital). If you do not have a hospital appointment contact your Consultant's secretary via the hospital switchboard to arrange a new prescription.

If your GP is going to carry on prescribing for you, the prescription should be taken to your local pharmacy. You should take the original bottle/container with you in case they are unsure how to obtain the drug for you. Many of these medicines have to be made up specially or may take longer to obtain. You will probably need to give your pharmacy one or two weeks' notice to obtain the prescription for you.

It is important that you do not let your supply run out.

What do I do if I want more information?

When a medicine is used outside the product license, the information on the Patient Information Leaflet supplied by the manufacturer may not be relevant to how you are taking the medicine and may not include the reason you are taking the medicine.

If you have any worries or concerns about your medicine or information you have been given, please talk to your prescriber or contact the pharmacy department at York or Scarborough Hospital.

Doctors, nurses and pharmacists will only prescribe/supply an unlicensed medicine when it is considered to be the most appropriate treatment.

Tell us what you think of this leaflet

We hope that you found this leaflet helpful. If you would like to tell us what you think, please contact:
Medicines Information, The York Hospital, Wigginton Road, York, YO31 8HE, telephone 01904 725960 or email medicines.information@york.nhs.uk.

Teaching, training and research

Our Trust is committed to teaching, training and research to support the development of health and healthcare in our community. Healthcare students may observe consultations for this purpose. You can opt out if you do not want students to observe. We may also ask you if you would like to be involved in our research.

Patient Advice and Liaison Service (PALS)

PALS offers impartial advice and assistance to patients, their relatives, friends and carers. We can listen to feedback (positive or negative), answer questions and help resolve any concerns about Trust services.

PALS can be contacted on 01904 726262, or email pals@york.nhs.uk.

An answer phone is available out of hours.

Leaflets in alternative languages or formats

Please telephone or email if you require this information in a different language or format, for example Braille, large print or audio.

如果你要求本資 不同的 或 式提供 , 電
或發電

Jeżeli niniejsze informacje potrzebne są w innym języku lub formacie, należy zadzwonić lub wysłać wiadomość e-mail

Bu bilgileri değişik bir lisanda ya da formatta istiyorsanız lütfen telefon ediniz ya da e-posta gönderiniz

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