

When an unlicensed medicine is prescribed to you

Department of Pharmacy

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Information for Patients, Carers and Parents

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Introduction

When you are told that the medicine you are being prescribed is unlicensed you may be unsure what this means. This leaflet answers some of the questions you may have. If you have any further questions please speak to your health care professional or pharmacist.

Why do medicines have a licence?

In the UK, all manufacturers of medicines have to apply for a product licence from the government and European Union Agency in order to market them. To gain a product licence the company has to test the medicine through clinical trials on human volunteers. The licence then applies to a specific medical condition and specific doses of the medicine.

When and why is an unlicensed medicine used?

There are times when your health care professional will advise you to take a medicine which is classified as unlicensed. There are a number of reasons for this:

- Your health care professional thinks a particular medicine would work well for your condition even though it is licensed for a different condition. When a medicine is used for a condition not stated in the product licence, it is said to be being used "off licence".
- The medicine does not have a UK product licence. The medicine may have been bought from a country with which the UK has a mutual agreement on standards of licensing, or it may be specially manufactured (in the UK).
- The medicine is normally made in one form, such as a liquid or tablet and at times your doctor will recommend for your comfort that you take the medicine in a different form, which is not licensed. This means it will be made as a "special" formulation which is unlicensed.

**Health information and support is available at www.nhs.uk
or call 111 for non-emergency medical advice**

Visit www.leicestershospitals.nhs.uk for maps and information about visiting Leicester's Hospitals
To give feedback about this information sheet, contact InformationForPatients@uhl-tr.nhs.uk

Why are so many children's medicines unlicensed?

A lot of medicines in the UK and other countries are only tested with adult volunteers. Therefore, they will not have a licence for children.

We use specific reference books to assist our health care professionals in deciding on the best medicines to give to children and young people. Your health care professional or pharmacist will be able to tell you if the medicine prescribed for your child is one commonly used for children.

More information about unlicensed medicines for children can be found on the website www.medicinesforchildren.org.uk

What does this mean for me or my family member?

Your health care professional will consider all medical evidence available when prescribing an unlicensed medicine.

There may be a separate patient information leaflet available with your unlicensed medication which will explain the effects of the medicine.

Your health care professional will tell you about any expected common side effects. There may, on occasions, be other side effects that are unknown. If you notice anything unusual or are concerned, contact your health care professional or pharmacist.

You can also report any suspected side effects to the Medicines and Healthcare products Regulatory Agency (MHRA) - UK safety scheme: <http://www.mhra.gov.uk/yellowcard>

Your unlicensed medication details

The unlicensed medication that has been prescribed is: _____

It has been obtained from (company name): _____

(Other suppliers may be able to supply this medicine).

Contact details

If you have any questions please contact the Pharmacy Department. The telephone number can be found on the label of your medication.

اگر آپ کو یہ معلومات کسی اور زبان میں درکار ہیں، تو براہ کرم مندرجہ ذیل نمبر پر ٹیلی فون کریں۔
على هذه المعلومات بلغة أخرى، الرجاء الاتصال على رقم الهاتف الذي يظهر في الأسفل
જો તમને અન્ય ભાષામાં આ માહિતી જોઈતી હોય, તો નીચે આપેલ નંબર પર કૃપા કરી ટેલિફોન કરો

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Aby uzyskać informacje w innym języku, proszę zadzwonić pod podany niżej numer telefonu

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