

# When an unlicensed medicine is prescribed to you

Department of Pharmacy  
Information for Patients

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## Introduction

When you are told that the medicine you are being prescribed is unlicensed. You may not know what this means. This leaflet answers some of the questions you may have. If you have any more 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.

Visit: <http://www.nhs.uk/Conditions/Medicines-information> or scan the QR code for more information on why some medicines are unlicensed and what this might mean for you.



## 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. Your doctor may 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.

## 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 help 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.

Visit: [www.medicinesforchildren.org.uk](http://www.medicinesforchildren.org.uk) or scan the QR code for more information about unlicensed medicines for children.



## What does this mean for me or my family member?

Your health care professional will think about all the 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 be sometimes 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> or scan the QR code.



## Contact details

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

Health information and support is available at [www.nhs.uk](http://www.nhs.uk) or call 111 for non-emergency medical advice  
Visit [www.uhleicester.nhs.uk](http://www.uhleicester.nhs.uk) for maps and information about visiting Leicester's Hospitals.  
To give feedback about this information sheet, contact [uhl-tr.informationforpatientsmailbox@nhs.net](mailto:uhl-tr.informationforpatientsmailbox@nhs.net)

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જો તમને અન્ય ભાષામાં આ માહિતી જોઈતી હોય, તો નીચે આપેલ નંબર પર કૃપા કરી ટેલિફોન કરો.

If you would like this information in another language or format such as EasyRead  
or Braille, please telephone 0116 250 2959 or email [uhl-tr.equalitymailbox@nhs.net](mailto:uhl-tr.equalitymailbox@nhs.net)

**We are a research hospital and you may be asked to take part in research**