

## Unlicensed medicines

Most medicines used in the UK have a licence that says exactly how the medicine can be used. However, this licence may not include use in children or in a particular illness or condition.

This leaflet explains what we mean by the unlicensed use of a medicine, why the use of many medicines in children is unlicensed, and why this is safe and acceptable.



This leaflet has been written specifically about medicines in children. Please read this leaflet carefully. Keep it somewhere safe so that you can read it again.

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The term medicine refers to any substance used to prevent or treat a medical condition: tablets, capsules, liquid medicine, liquid given by injection, inhalers, suppositories, creams, ointments and patches.

### What is a licence?

A drug company must have a licence to advertise and sell a medicine. The licence states which illness the medicine can be used for, what doses (how much) can be used, how the medicine should be given (e.g. by mouth, by injection) and which group of patients it can be used for – this is usually adults.

To get a licence, the drug company must prove that the drug works and that it is safe to use, which is done during clinical trials. Trials are usually done in adults but may be done in children if a medicine is to be used for them.

### What do we mean by unlicensed use?

When doctors know more about how a medicine works and its possible side-effects (unwanted effects), they may then want to try using it for other illnesses or conditions, or in other groups of patients, such as elderly patients or children.

If a medicine is used in a way that does not meet the strict rules set out in the licence, this is described as 'unlicensed use' (it may also be called off-label or off-licence use). This includes giving a medicine in a way that is different from that described in the licence.

Here are some examples of unlicensed uses:

- use of a licensed medicine for an illness that is not covered by the licence
- use of a medicine that is only available from abroad and has to be imported (it may have a licence in other countries)
- a medicine that needs to be made specially because it cannot be obtained easily; for example, a patient may not be able to swallow a (licensed) tablet or capsule and would prefer a liquid (unlicensed) version of the medicine.

Many medicines that are widely used in children's hospitals and neonatal units are unlicensed. This gives doctors more choice about which medicine to use than if they could only use licensed medicines.

### Why is use in children often unlicensed?

To get a licence to use a medicine in children, the drug company would have to do clinical trials in children. This can be difficult, especially for a rare illness.

Once a medicine is widely used, the drug company may do clinical trials in children. This allows them to get a licence so that they can market the medicine for this age group.

### Is it OK to use an unlicensed medicine?

Most medicines that are prescribed for a child will have a licence for use in adults, and so clinical trials have been done to prove that it is OK to use in adults.

Your doctor will only suggest using a medicine for your child if he or she thinks that it is the best thing to help your child. Your doctor will tell you about any side-effects that your child may get.

It is important to understand that if your doctor prescribes a medicine for your child, it is because they think that the benefit of taking the medicine will be greater than the risk of not treating your child's illness.

### How do I know whether my child's medicine is unlicensed?

Your doctor or pharmacist may tell you that the medicine is not licensed for use in children. The leaflet that comes with the medicine may not say anything about its use in children, or may say that the medicine is not suitable for children.


This **does not** mean that it cannot be used safely in children – it means that the drug company does not have a licence for use in children and so is not allowed to recommend this use.

### Where can I get information about unlicensed medicines?

Your doctor or pharmacist will be able to tell you more about the medicine. Medicines for Children produces leaflets that are written specially for parents and carers.

Many of these are about medicines that are unlicensed for use in children. You can get the leaflets from our website, [www.medicinesforchildren.org.uk](http://www.medicinesforchildren.org.uk)

You will probably get an information leaflet with your child's medicine, which describes what the medicine is used for, how to take it, and any side-effects. This information may have been written about use of the medicine in adults. However, a lot of it will be relevant to children and useful to parents/ carers, although the doses recommended in this leaflet may not be right for children.

 You should always follow your doctor's instructions about how much to give.

**Remember, your doctor will never prescribe a medicine that is not thought to be safe.**

[www.medicinesforchildren.org.uk](http://www.medicinesforchildren.org.uk)



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The primary source for the information in this leaflet is the British National Formulary for Children. For details on any other sources used for this leaflet, please contact us through our website, [www.medicinesforchildren.org.uk](http://www.medicinesforchildren.org.uk)

We take great care to make sure that the information in this leaflet is correct and up-to-date. However, medicines can be used in different ways for different patients. It is important that you ask the advice of your doctor or pharmacist if you are not sure about something. This leaflet is about the use of these medicines in the UK, and may not apply to other countries. The Royal College of Paediatrics and Child Health (RCPCH), the Neonatal and Paediatric Pharmacists Group (NPPG), WellChild and the contributors and editors cannot be held responsible for the accuracy of information, omissions of information, or any actions that may be taken as a consequence of reading this leaflet.