

## Unlicensed medicines

Most medicines used in the UK have a licence that says exactly how the medicine should 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 when it is considered safe and acceptable to use unlicensed medicines.



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.

The following terms are all used to describe different unlicensed medicines:

- **special** (specially manufactured)
- **extemp** (extemporaneously and specially prepared)
- **import** (an imported medicine that is usually licensed for use in the country it is manufactured in)
- **off-licence** or **off-label** (using a medicine in a different way to its licence).

Throughout this leaflet we refer to doctors as being the people who prescribe your child a medicine. It is important to remember that **many healthcare professionals in the UK can prescribe medicines** and might be responsible for your child's health care. This includes nurses, pharmacists, dentists and optometrists. They are sometimes collectively called 'prescribers'.

### What is a licence?

A drug company must have a licence to promote a medicine. The licence states:

- which illness(es) 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)
- which group of patients it can be used for.

To get a licence, the drug company must prove that the medicine works and that it is safe to use, by testing it during clinical trials. Trials are almost always done with adults first. To obtain a licence for use in children, clinical trials involving children are required.

A clinical trial is a test of the medicine. A clinical trial may be used to test how much of the medicine to give to a child, if it works, or how safe it is. All clinical trials are carefully regulated in the UK.

### What do we mean by unlicensed use?

- Most licences for medicines are given after trials have shown they are effective and safe for use in adults.

- After a medicine has been used for some time in adults, doctors – and other prescribers – will know more about how it works and its possible side-effects (effects that we don't want).
- Once the medicine has been shown to work in adults, your doctor may want to use it to help other illnesses or conditions, or in other groups of patients, for example, elderly patients or children.
- If a medicine is used in a way that is different from that described in its licence, this is called 'unlicensed' 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 age group that is not covered by its licence
- use of a licensed medicine for an illness that is not included in its licence
- use of a medicine that is only available from abroad and has to be imported (it may have a licence in other countries)
- use of 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 tablet or capsule (which is licensed) and needs a liquid (unlicensed) version of the medicine.

Many medicines that are widely used are unlicensed. This gives doctors more choice about which medicine to use than if they could only use licensed medicines.

### Why is use of medicines for children often unlicensed?

To get a licence to promote the use of a medicine in children, the drug company has to do clinical trials involving children. There are steps in place to help make this happen but it can be very difficult, especially when the illness is rare.

**In many cases, doctors have to choose a medicine that is unlicensed for your child.**

This is because there is not a licensed medicine for the illness your child has. Another reason could be that the unlicensed medicine has some advantages over the licensed one, like being in a form your child can take more easily, because the doctor thinks that it works better for your child's illness, or because an unlicensed medicine is safer than a licensed one.

## How can I make sure I always have enough of my child's off-license medicine?

- Unlicensed medicines often have short shelf lives. Please check and make a note of when your child's medicine becomes too old to use (this is normally shown on the label as 'do not use after' or 'expiry date' as shown on the example table).

Name and strength of medicine	Date medicine received	Expiry date	Time needed to order medicine	Date to order medicine next
(for example) Spironolactone liquid 50mg/5mL	05/09/14	04/12/14	14 days	20/11/14

- Do not use expired medication. It is important that you get a new prescription from your doctor in plenty of time before the medicine runs out.
- Mark the date in your diary or put a reminder in your mobile phone or smart device calendar to help you remember.
- Take the prescription and the container of your current supply to your local pharmacy. It can take your pharmacist one or two weeks to obtain the medicine, so make sure you allow for this.
- If your child's medicine has a short shelf life, only order enough to last till the expiry date. If the medicine's shelf life is two weeks or less, check if your child's doctor would be able to write separate prescriptions to cover a month's supply.

Ask your pharmacist to record where they got the medicine from. They may also find it useful to note on the back of this leaflet the exact ingredients of your child's medication. This will ensure that you can obtain future supplies easily and consistently.

## Questions and further information about unlicensed medicines

### 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 they are effective and safe to use in adults. If a doctor believes a medicine is safe and effective for use in children, because they have used it many times previously, they may continue to prescribe it for a child.

 **Your doctor will only suggest using a medicine for your child if they think that it is the best thing to help your child.**

## Are there side-effects from using unlicensed medicines?

- Your doctor will tell you about any expected common side-effects that your child may get.
- There may, sometimes, be other side-effects that are not known. If you notice anything unusual and are concerned, contact your doctor, nurse, pharmacist or the person who prescribed your child the medicine.
- You can also report any suspected side-effects to a UK safety scheme at: <http://www.mhra.gov.uk/yellowcard>.

## 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 of the medicine in children and so is not allowed to promote or give information about use in children.
- If you want to know whether a medicine is unlicensed or off-label for children, ask your doctor, nurse or pharmacist.

## 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. Although this may have been written about use in adults, a lot of it will be the same for children and useful to parents/carers.

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

You can also get useful information from:

**RCPCH and NPPG statement about unlicensed medicines**  
[www.rcpch.ac.uk/medicines#Unlicensed\\_medicines\\_statement](http://www.rcpch.ac.uk/medicines#Unlicensed_medicines_statement)

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