

Unlicensed medicines

Most medicines used in the UK have a licence (sometimes known as a 'Marketing Authorisation') that states how it 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
- 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 may be used for unlicensed medicines:

- **special** (specially manufactured)
- **extemp** (specially prepared by the pharmacist)
- **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 what is included in its licence).

In this leaflet we refer to doctors as the people who prescribe your child a medicine. However, **many healthcare professionals in the UK can prescribe medicines** and might be responsible for your child's health care. These include 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, a drug company must conduct clinical trials to show that the medicine works and that it is safe to use. Trials are almost always done with adults first. To obtain a licence for use in children, clinical trials involving children are required. However, this can be difficult to do for many reasons.

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. Clinical trials are carefully regulated in the UK.

What do we mean by unlicensed use?

- Most licences for medicines are given once clinical trials have shown they are effective and safe for use in adults.
- After a medicine has been used for some time in adults, more is known about how it works and its possible side-effects (effects that we don't want).

- Doctors may then want to use it to help other illnesses or conditions, or in other groups of patients, for example, elderly patients or children.
- Giving a medicine in a different way from that described in its licence, is called 'unlicensed' or 'off-licence' use
- The following are examples of unlicensed use:
 - » use of a licensed medicine for an age group that is not included in 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 given to children are used in a way that is 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 difficult, especially when the illness is rare in children.

Often, doctors have to choose a medicine that is unlicensed for (use in) your child.

This may be because there is no licensed medicine for your child's illness. An unlicensed medicine may have advantages over the licensed one for a number of reasons including:

- it might be in a form your child can take more easily
- your doctor may think it will work better for your child's illness
- the 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 a short shelf life. Make a note of when your child's medicine will become too old to use (this is shown on the label as 'do not use after' or 'expiry date') as shown on the example table below.

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	04/08/20	03/11/20	14 days	20/10/20

- Do not use expired medicine. Make sure 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 until the expiry date. If the medicine's shelf life is 2 weeks or less, check if your child's doctor can 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 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 (use of) medicines

Is it safe for my child to have a medicine that is being used in an unlicensed way?

Most medicines that are prescribed for children 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 to be safe and effective for use in children because they have used it many times, they may prescribe it for a child.

 **Your doctor will only suggest using a medicine 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 common side-effects 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 a medicine is licensed for use in children?

- 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 is not allowed to promote or give information about use in children.
- If you want to know whether a medicine is unlicensed for use in 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 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

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 the information also applies to children and is useful to parents/carers.

 **Always follow your doctor's instructions about how much medicine to give.**

You can also get useful information from:

[RCPCH and NPPG statement about unlicensed medicines](#)

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

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.