



# Unlicensed use of medicines in children

This leaflet explains:

- what we mean by the unlicensed use of a medicine
- why the use of many medicines in children is unlicensed
- when unlicensed use is considered safe and acceptable.

Many different healthcare professionals can prescribe medicines in addition to doctors. We use doctor here to mean anyone who prescribes a medicine.

## What is a licence?

Pharmaceutical companies conduct clinical trials to show that a medicine works and that it is safe to use. Based on the evidence obtained from these trials, the manufacturer can obtain a licence – also known as a marketing authorisation. The licence states:

- the illness(es) or condition(s) the medicine can be used for
- how the medicine is given (e.g. by mouth)
- the dose (how much can be given)
- which group(s) of patients it can be used for.

The pharmaceutical company can only promote the medicine for the uses stated on the licence.

Children are rarely included in clinical trials (for many reasons) so they are rarely included in the licence.

## What does “unlicensed use” mean?

It means giving a medicine in a different way from that described on the licence. This may also be called ‘off-licence’ or ‘off-label’ use.

The following are examples of unlicensed use:

- use for an age group that is not included in the licence (e.g. children or elderly patients)
- use for an illness that is not included in the licence
- use of a medicine that has to be imported from abroad (it may have a licence in other countries)

Unlicensed use also includes medicines that have been made specifically to meet the needs of an individual patient (called “specials” or “extemp”). For example, a patient may not be able to swallow tablets or capsules (which are licensed) but pharmacists can make a liquid medicine (unlicensed)

## Why are medicines used unlicensed in children?

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 consider using the medicine in children (at a lower dose) or for a different illness or condition.

An unlicensed medicine may have advantages over licensed option.

- There may not be any medicines for a particular condition that are licensed for use in children.
- Doctors may believe that an unlicensed medicine will work better for your child than the licensed options (e.g. if it is new medicine).
- The unlicensed medicine may be in a form that your child can take more easily (e.g. liquid medicine instead of tablets).
- The unlicensed medicine may be considered safer than a licensed one.

Unlicensed use gives doctors more options for treating their patients.

**Your doctor will only suggest an unlicensed medicine if they believe that it is the best treatment for your child.**

## Is unlicensed use in children safe?

Most medicines that are prescribed for children have a licence for use in adults. This means that it has been shown to work well and is safe to use in adults. A lower dose will be prescribed for children, usually based on the body weight and the prescriber’s experience.

## 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 it may say that the medicine is not suitable for children. This does not mean that it cannot be used safely in children. The manufacturer is not allowed to promote or give information about use in children if this is not in the licence.
- If you want to know whether a medicine is licensed for use in children, ask your doctor, nurse or pharmacist.

## Are unlicensed medicines hard to get?

This depends on the medicine. If it is widely used for adults, there shouldn’t be any difficulty getting the medicine.

If your child needs an imported medicine or one that is specifically made by a manufacturer or pharmacist, it may take longer to get (1–2 weeks or more).

Some specially prepared medicines have a short shelf-life (often less than 2 weeks).

- Check the information on the medicine label and make a note of the “use by” or expiry date.
- Order new supplies in plenty of time – your pharmacist will tell you how long they need.
- Do not use medicines after their “use by” or expiry date.

- Ask your pharmacist to record where they got the medicine from and the exact ingredients. This will be helpful if you need to get future supplies from a different pharmacy.
- It may be helpful to give the prescription and the container of your current supply to your local pharmacy.

### What if my child has side-effects?

- We use medicines to make our children better, but sometimes they cause effects that we don't want (side-effects).
- Your doctor will tell you about any common side-effects your child may get.
- If you notice anything unusual and are concerned, contact your doctor or the person who prescribed the medicine.
- You can report any suspected side-effects to the UK safety scheme at [yellowcard.mhra.gov.uk](https://yellowcard.mhra.gov.uk)
- More information on the possible [side effects from medicines](#) can be found on the Medicines for Children website.

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

- Your doctor or pharmacist will be able to tell you more about the medicine.
- The [Medicines for Children website](#) provides leaflets about medicines used for children – many of which are not licensed for use in children.

- There may be 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.**

### Who to contact for more information

Your doctor, pharmacist or nurse will be able to give you more information about medicines used to treat your child's conditions.

You can also get useful information from:

#### England: NHS 111

Tel 111 [www.nhs.uk](https://www.nhs.uk)

#### Scotland: NHS 24

Tel 111 [www.nhs24.scot](https://www.nhs24.scot)

#### Wales: NHS 111 Wales

Tel 111 [www.111.wales.nhs.uk](https://www.111.wales.nhs.uk)

#### Northern Ireland: NI Direct

[www.nidirect.gov.uk](https://www.nidirect.gov.uk)

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