

# Use of unlicensed “specials” and off-label medicines



You have been given this leaflet because you have been prescribed a medicine that does not have a licence or is being used differently to what is described in its licence (off-label).

## What are licensed, unlicensed “specials” and off-label medicines?

For a medicine to be sold in the UK, it must have marketing authorisation or be “licensed”. The licence describes how the medicine should be used including:



- Who it can be given to
- What condition(s) it can be used to treat
- How much should be taken (the dose)
- What form it is in (e.g. tablet, capsule, liquid)



An unlicensed medicine doesn't have a UK licence. It may be licensed in another country and imported to the UK, or be made specially (known as a “special” medicine).

If a licensed medicine is used differently to their licence, this is called “off-label” use of the medicine. Examples of off-label uses include:



- treating a different condition
- treating a different group of patients such as children or during pregnancy
- using a different dose

This leaflet uses the term “unlicensed” to describe both off-label and unlicensed ‘specials’ medicines.

## Why are unlicensed medicines used?

Usually you will only be prescribed an unlicensed medicine when there is no suitable licensed alternative to treat your condition.

Reasons for using an unlicensed medicine include:



A licensed medicine may not be available yet.

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The medicine may be in the process of getting a licence or may still be undergoing testing in a clinical trial.

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There may be a temporary shortage of the licensed medicine.

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The medicine needs to be taken in a form that is not normally available (e.g. liquid), and must be specially made to order.

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The medicine has a license but needs to be given in an unlicensed way. For example, crushing tablets to make them easier to swallow.

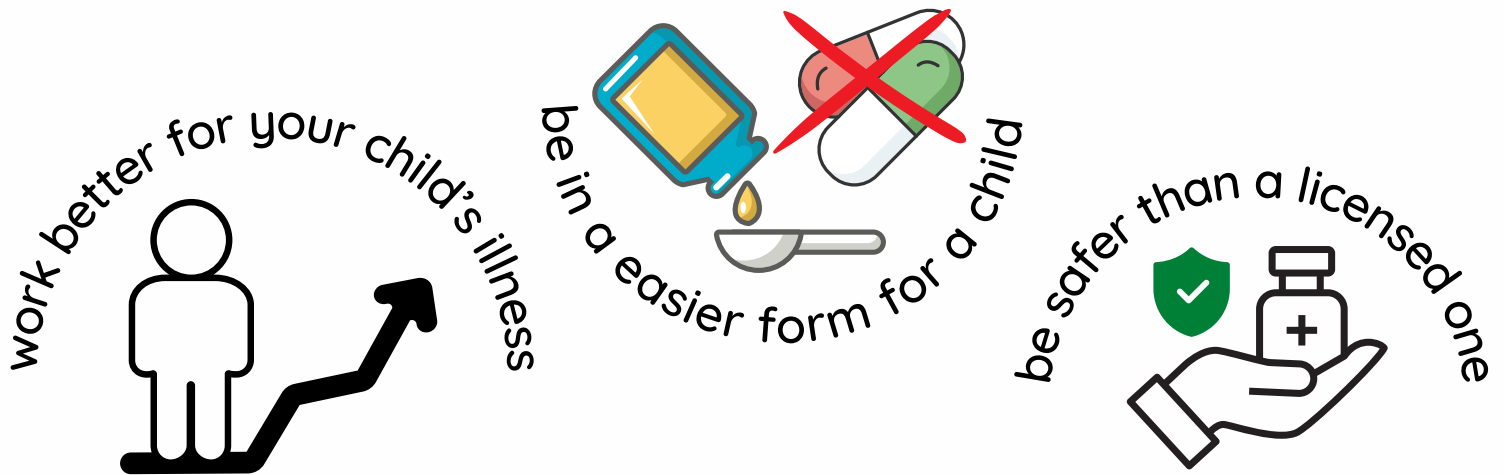
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There is limited information available about treating certain conditions or for certain patient groups.



## Can children be prescribed unlicensed medicines?

Yes. It is not always possible to do clinical trials in children, particularly for rare illnesses, so the prescriber may have to choose an unlicensed medicine. This might have benefits over a licensed one, for example it may:



## Are unlicensed medicines commonly used?

Often, unlicensed medicines have been widely used and their effects are well known. The person treating you will have carefully considered the best choice of medicine for you and will explain:



why the medicine is right for you



and the possible risks

They will review the medicine regularly to make sure it remains the best one for you.



If you do experience any unpleasant or unexpected effects whilst taking the medicine, you should tell your prescriber or pharmacist. You can also report any suspected side effects to the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/>

If you are worried about taking the medicine, talk to your prescriber or pharmacist about your concerns.

## How can I make sure I always have enough of my unlicensed medicine?



Unlicensed medicines often have short expiry dates. Check the expiry date so you will know when you need to order it.

It may take longer for the pharmacy to get an unlicensed medicine, up to one to two weeks. Tell the pharmacy in plenty of time.



If the pharmacist thinks that you may run out of your medicine, for example due to a supply issue, tell your prescriber. They may need to monitor you until your next supply arrives.

**Do not take less medicine than advised unless you discuss this with your prescriber first. Do not take any medicine that may have been compromised (e.g., spilled or damaged).**

### For further information

The NHS website also has information about licensed and unlicensed medicines: <https://www.nhs.uk/conditions/medicines-information/>

Information leaflets about using unlicensed medicines in children, specifically aimed at parents can be found on the Medicines for Children website: <https://www.medicinesforchildren.org.uk/>

Alternatively, you can contact the Welsh Medicines Advice Service: <https://www.wmic.wales.nhs.uk/>

Access this leaflet on your phone:

