



# Unlicensed and ‘off-label’ medicines



This document was written by the **All Wales Therapeutics and Toxicology Centre** and the **All Wales Medicines Strategy Group**. It is an easy read version of ‘**Use of unlicensed “specials” and off-label medicines**’.

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# How to use this document



This is an easy read document. But you may still need support to read it. Ask someone you know to help you.



For more information contact the **All Wales Therapeutics and Toxicology Centre:**

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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.



A medicine sold in the UK usually has a **licence**. The **licence** describes how the medicine should be used.

For example, the **licence** will say:



1. Who can take the medicine.



2. What the medicine can treat.



3. How much should be taken.



4. If it is a tablet, liquid, or something else.



An **unlicensed medicine** is a medicine that does not have a UK licence. It may have a licence in another country.



It may also have been made specially. This is called a **special** medicine.



Sometimes a medicine is used in a different way to what is described in its **licence**. This is called **off-label** use.

For example:



- It is used to treat a different condition to what the **licence** says.



- It is used to treat a different group of people to what the **licence** says.



- The dose is different to what the **licence** says.

Where this document says **unlicensed medicine**, this includes:



- **special** medicine
- **off-label** medicine and
- **unlicensed** medicines.

# Why are unlicensed medicines used?



Often people are prescribed an **unlicensed medicine** when there is nothing else. Other reasons are:



- A **licence** is not in place yet.
- The **licensed medicine** is out of stock.
- The medicine needs to be taken in a different form. For example, a liquid instead of a tablet.
- There is not much information about treating a particular group of people.

## Can children be prescribed unlicensed medicines?



Yes. There may not have been enough studies in children for the medicine to get a **licence**, especially for rare illnesses.

**Unlicensed medicines** can help because:



- They may work better for the child's illness.
- They may be easier to take. For example, a liquid.
- They may be safer.

## How common are unlicensed medicines?



Many have been used a lot and their effects are known.



The person prescribing an **unlicensed medicine** will have thought carefully about if it is right for you, and any risks.



They will check with you how the medicine is working.



You should tell them, or a chemist (also known as a pharmacist) if you have any problems with the medicine.



You can report any issues to the Yellow Card Scheme here: [www.yellowcard.mhra.gov.uk](http://www.yellowcard.mhra.gov.uk)



The Yellow Card Scheme keeps a check on the safety of medicines used in the UK.



Always check the use-by date of your **unlicensed medicine**. They often have a short use-by date.



It can take 1 or 2 weeks to get **unlicensed medicines**. Make sure you give enough time to order them.



**Always** take the dose you have been prescribed.

**Do not** take any medicine that has been damaged.

## Find out more



These websites give more information about **unlicensed** medicines:



NHS Medicines information

[www.nhs.uk/conditions/medicines-information](http://www.nhs.uk/conditions/medicines-information)



Medicines for Children

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



Welsh Medicines Advice Service

[www.wmic.wales.nhs.uk](http://www.wmic.wales.nhs.uk)