



Use of unlicensed medicines – information for patients and carers

Why have I been given this leaflet?

This leaflet will provide you with information about unlicensed medicines, which include “specials”, and medicines that are being used differently to their licence (off-label). It should help to answer any questions you may have. Please read it carefully and talk to your prescriber or pharmacist if you have any more questions.

Medicine name: _____

What are licensed, unlicensed, ‘specials’ and medicines used off-label?

Medicines sold in the UK must have marketing authorisation or be “licensed”. This is granted by the medicines regulator after they have checked the quality and safety of the medicine, and how well it works. The licence describes how the medicine should be used including:

- who can take it;
- what illness(es) 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 abroad and imported to the UK, or be made specially (in which case, it is called a ‘special’).

If a medicine with a UK licence is being used differently to what its licence describes, this is called “off-label” use, for example:

- treating a different illness;
- treating a different group of patients (e.g., children or during pregnancy);
- using a different dose.

This leaflet uses the term “unlicensed” to describe all unlicensed medicines, including ‘specials’ and medicines used off-label.

Why are unlicensed medicines used?

Usually you will only be prescribed an unlicensed medicine when there is no suitable licensed medicine to treat your condition. The decision to use an unlicensed medicine is a joint one between you and your prescriber. The person treating you will have considered the best choice of medicine, discussed options with you, and will review it regularly to ensure it remains



the best option for you.

Reasons for using an unlicensed medicine include:

- a licensed medicine may not be available yet;
- the medicine may be in the process of getting a licence or may still be undergoing testing in a clinical trial;
- there may be limited information available about treating certain conditions or for certain patient groups;
- the medicine may need to be taken in a form that is not normally available (e.g., liquid), and must be made specially to order;
- there may be a temporary shortage of the licensed medicine;
- the medicine may have a licence but needs to be given in an unlicensed way. For example, crushing tablets to make them easier to swallow.

Are unlicensed medicines commonly used?

Unlicensed medicines have often been widely used and their effects are well known. However, if the medicine comes with a leaflet, it may not say anything about the unlicensed use. This does not mean that it cannot be used safely to treat your condition – it means that the drug company does not have a licence for using it this way and is not allowed to promote or give information about this use.

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

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

Can children be prescribed unlicensed medicines?

Yes. Medicines need to be tested in clinical trials to be granted a licence. It is not always possible to do clinical trials in children, particularly if the medicine is for a rare illness. Therefore, the prescriber may choose an unlicensed medicine to treat your child.

An unlicensed medicine may have advantages over a licensed one, for example:

- it might be in a form your child can take more easily;
- the prescriber may think it will work better for your child's illness;
- the unlicensed medicine may be safer than a licensed one (for example, it could be alcohol free).

As with use of unlicensed medicines in adults, you will have agreed the best option for your child with the prescriber, and the prescription will be reviewed regularly to ensure it remains the best option.



Can I get an unlicensed medicine from a private prescriber?

You may obtain an unlicensed medicine from a private prescriber (for example an optometrist). However, you will need to pay for the medicine. Please speak to the prescriber and your community pharmacist about how much this is likely to cost. You will need to tell your GP surgery, so they can add a note to your medical records.

How can I get more of my unlicensed medicine?

If your medicine is first prescribed at your GP practice and you need more, it is likely that the practice will provide a further prescription. If your medicine is first prescribed in hospital, this may not be the case and you may need to get further supplies from the hospital. If your medicine has been prescribed by a non-medical prescriber, such as a pharmacist or an optometrist, please contact them first. In all cases, please confirm with the prescriber how you will access further supplies.

After speaking with your prescriber and pharmacist, make a note of when you need to order more of your medicine. You should check the expiry date of your medicine as this can affect how frequently you need to order it.

Unlicensed medicines often have short expiry dates. This means it may not be possible to order large quantities to keep in the pharmacy or in your home. If you already take other medicines and have a repeat prescription, you may need to order the unlicensed medicine at a different time.

It may take longer for the pharmacy to get an unlicensed medicine when you need it. Depending on the medicine this could be up to two or more weeks. **You should tell the pharmacy in plenty of time before you run out.**

What if I lose, destroy, or run out of my unlicensed medicine?

If you don't have any of your medicine speak to your pharmacist. They can provide advice about what to do, and whether you can access an emergency supply of the medicine. **Do not take any medicine that may have been compromised (e.g., spilled or damaged).**

What should I do if the pharmacy tells me the supply of my unlicensed medicine is going to be delayed?

If you have enough of the medicine to last until the pharmacy can arrange more supplies, you will not need to do anything. However, if you think that the delay may cause you to run out of your medicine, inform your prescriber as they may need to monitor you until further supplies can be provided. **Please do not take less medicine than advised unless you discuss this with your prescriber first.**



Should I use the medicine past its expiry date if I can't get more supplies in time?

In general, you should not use any medicine past its expiry date. To find out what would be the safest thing for you to do, speak to your pharmacist or prescriber.

My prescriber has decided not to continue the prescription for the unlicensed medicine issued by the hospital, what should I do?

If you have been prescribed an unlicensed medicine through the hospital and a prescriber in your GP surgery does not feel they can take responsibility for writing a prescription for further supplies, please discuss the reasons with them. Another prescriber in the surgery may be willing to take responsibility. If there is no one who can take responsibility, contact the hospital where your medicine was first prescribed and they may be able to arrange further supplies for you.

What if I do not want to receive an unlicensed medicine?

You will only be prescribed an unlicensed medicine if you and your prescriber have agreed it's the best treatment for you. However, if you are not happy, you can discuss your options with your prescribing team or pharmacist.

With some unlicensed medicines you are required to give consent in writing before you start taking them. You can change your mind about this at any time.

How can I find out more?

If you are concerned or have any questions about unlicensed medicines, please speak to your pharmacist or prescriber.

The NHS website also has some information about licensed and unlicensed medicines. Available at: <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/>

You can contact the Welsh Medicines Advice Service. Available at:

<https://www.wmic.wales.nhs.uk/>

Access this leaflet on your phone:

