

YOUR HEALTH

USING MEDICINES OUTSIDE THEIR LICENCE



Before medicines can be used, they have to be licensed for use by the Medicines and Healthcare product Regulatory Agency (MHRA).

Medicines prescribed by a doctor, and those you can buy over the counter at a pharmacy, are licensed in this way. The licence shows the conditions that a medicine can be used to treat, what type of patients it can be given to, and the doses that should be used. This information is in the Patient Information Leaflet (PIL), which is included with every medicine.

What is meant by the use of a medicine outside the licence?

This is also known as off-label use.

It means that a medicine is being used:

- in doses outside the range stated in the licence
- for a different patient group e.g. children rather than adults
- as a generic medicine (medicines not having a trademark or brand name) for conditions not included in the licence
- for conditions for which there are no other treatments
- administered in a different way, such as giving an injection orally or crushing a tablet before the patient takes it.

Is it common for medicines to be used outside their licence?

It is very common in some areas such as palliative care, pain management and paediatrics for medicines to be used outside of their licence.

What is an unlicensed medicine?

An unlicensed medicine is one, which does not have a licence within the UK.

This applies to:

- a mixture of two or more medicines in a syringe pump or mixing medicines before they are injected given in an injection
- a medicine manufactured specifically for your use by a pharmacist
- medicines that have a licence in another country but not in the UK
- a medicine bought from a 'specials' medicines' manufacturer (specials are products which have been specially manufactured or imported for the treatment of an individual patient)
- new drugs undergoing clinical trials
- medicines where the licence has been suspended or not renewed

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Prescribing off-label or unlicensed medicines

In this country, doctors may legally prescribe medicines outside their licence.

Other health professionals with a prescribing qualification, such as pharmacists or nurses may also prescribe off-label or unlicensed medicines as long as it is within their area of expertise.

As with all prescribers, they are responsible for the consequences. Specialist services recommending the use of such medicines to other doctors involved in your treatment should explain why this is necessary, but they can decline to prescribe them.

How will I know if medicines are being prescribed outside their licence?

You can tell if a medicine has been prescribed outside of the license if you read the PIL and it does not contain information on your condition. Your clinical team may discuss this with you.

Getting consent for the use of medicines outside their licence

The medical team at the hospice will ask for your permission to treat you with a medicine outside its licence only if, it is not normal practice to use that medicine.

We would only do this after considering all the options and when there is no suitable alternative available. The medical team will provide you with enough information about the expected benefits and risks to allow you to make an informed choice.

What if I have questions?

If you have any concerns about the information in this leaflet or whether any of the medicines you are receiving are being used off licence, please do not hesitate to raise your concerns with a member of the hospice team, who will be pleased to help.

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