

Patient Information Leaflet: Unlicensed and 'Off-label' medicines

What are unlicensed or 'off-label' medicines?

In the UK medicines are given a licence by the government which covers:

- the conditions in which the medicine can be used to treat people,
- the groups of people it can be given to (for example children, adults or the elderly),
- how it can be given (for example as a tablet, liquid, by injection under the skin or through a vein).

We sometimes use medicines to: treat a condition different to the ones it has been licenced to treat; give them to a different group of people, or give them in a different way. This is called using the medicines 'off-label', or using them 'beyond licence'.

The licence is there to control the way in which the manufacturer promotes and sells medicine. It does not stop the prescribing of any medicines by a doctor. Pharmacies can legally dispense and a nurse can legally administer these medicines.

Why are medicines used in this way?

Medicines are used off-label, or beyond license, when research and experience show that:

- they are beneficial in treating a condition that they haven't been licenced for,
- they are beneficial in treating a condition in a group of people they haven't been licenced for, or
- it is more comfortable or easier for the medicine to be given in a different way to the way it has been licenced for.

Sometimes medicines are used off-label because the medicine has been given a licence to be used in a certain way and has later been shown to be beneficial in other ways, but it is too expensive for the manufacturers to extend the terms of the licence. In palliative care, medicines are commonly used for conditions or in ways that are not specified on the licence.

Sometimes medicines are still being tested and they will not yet have a license. Other drugs may have a license in another country, but are not commonly used in the UK.

Which medicines are used off-label?

Some medicines that are successfully used off-label are anti-depressants and anti-epileptic medicines which are also used to relieve some types of pain. Some other medicines used off-label may be given by an injection under the skin instead of into a muscle or vein because this is easier and more comfortable. The manufacturer's patient information leaflet that comes with your medicine reflects the uses the medicine has been licensed for. When a medicine is used beyond its licence, the information in this leaflet may not be relevant to your circumstances. You may also be given a leaflet specially written to give you more information about the medicine.

Is it safe to take medicines off-label?

You will only be prescribed medicines off-label when the benefit of the medicine is likely to be greater than the harm it could cause. The doctor or nurse who prescribes a medicine off-label for you will only do so if there is evidence and experience to support using the medicine this way. They will also explain any possible side effects the medicine could cause. If you have any questions or concerns about taking off-label medicines please speak to your doctor or nurse.

Sources used for the information on this leaflet:

- Palliative Care Formulary 7 palliativedrugs.com 2020
- Sandwell and West Birmingham Hospitals NHS Trust, 'Medicines Management Policy', February 2010
- Medicines and Healthcare products Regulatory Agency, Drug Safety Update: 'Off-label or unlicensed use of medicines: prescribers' responsibilities', April 2009
- The General Medical Council, 'Good practice in prescribing medicines', September 2008
- The British Pain Society, 'The use of drugs beyond licence in palliative care and pain management', November 2005