

How will I know if the medicines I've been prescribed are outside their licence?

Your Doctor, Pharmacist or Nurse may tell you this. However, in pain management and palliative care practice, the use of medicines outside their licence is very common and so your healthcare team may not refer to this specifically. The healthcare team has a lot of experience using medicines in this way. They will have considered very carefully what is best for you.

It is very important that you receive a clear explanation of the reasons that you are taking any medicines, how you should take your medicines, and what benefits and side effects might be expected.

This is just as important when medicines are used according to their licence as when they are used outside their licence.

As with all medicines, if you believe you experience a side effect from this medicine, you should inform your healthcare team.

If you are still unsure or worried about your medicines after reading this leaflet, please talk to your healthcare team about your concerns. The Doctors, Pharmacists, and Nurses will be able to answer your questions and provide further information as necessary.



Use of medicines beyond licence (off-label)

This leaflet will help you to understand some important aspects of medicine licensing regulations and how these issues might affect you. If you have any questions about any aspect of your medication you should ask your healthcare team.





Birmingham Hospice, like all other Specialist Palliative Care Units, commonly prescribes medicines which are used for conditions or ways that are not specified on the licence.

This is accepted practise and you can be reassured that your medical team will have thought carefully about which medicines are best for you in your situation.

What is the licensing process?

The licence obtained by the drug manufacturers from the Medicines Control Agency describes the way in which the drug can be given, what conditions it can be used to treat, the doses that can be given in, and which patients can be treated. To obtain a licence, the manufacturer must prove that the medicine works in the condition it is to be given, that it does not have too many side effects or risks, and that it has been manufactured to a high standard.

The process of obtaining a licence is very expensive for the manufacturer. The licence is there to restrict the way in which the manufacturer promotes and sells the drug. The licensing process does not restrict the prescribing of any medicine by a Doctor provided they are assured that the medicine is safe and effective for that patient.

Why are medicines sometimes used outside of their licence?

Sometimes a medicine has been licensed for a certain use and later experience or research shows that it works to treat or in relation to other conditions.

There is no legal requirement for the medicine manufacturer to apply to the Medicines Control Agency to try to have the more recent information added to the licence. In some situations it is not economical for the manufacturer to obtain or extend a licence.

There is a legal obligation for the manufacturer to include a Patient Information Leaflet with all medicines. This leaflet must be given to you alongside the prescribed medication, and it must only contain the information from the licence. Therefore some of the uses for the medicine will not appear on the Patient information Leaflet. This can be confusing for patients and their carers.

An example of this is the common use of antidepressant medicines to treat pain.

These medicines have a licence for use in depression, but not in pain – so the information leaflet will talk about depression and not refer to the treatment of pain. This happens purely because the Patient Information Leaflet reflects the licence.

If you are given an antidepressant drug it does not necessarily mean that your Doctor has decided you are depressed.

Examples of other circumstances where medicines may be used outside of their licence include:

- Medicines licensed for use in certain age groups that are used in a different age group.
- Medicines licensed for use at one dose that is used at a different dose.
- Medicines licensed for use by injection that are given as tablets.
- Medicines licensed for intramuscular injection that can be given subcutaneously (e.g. in a syringe driver).
- Medicines that do not have licence for a disease because it is so rare.

Can Doctors prescribe outside their licence?

It is legal for a Doctor to prescribe a medicine outside of its licence.

A Pharmacist can legally dispense and a Nurse can legally administer these medicines. It is common for medicines to be used outside their licence.

For example, in specialist palliative care, up to two thirds of patients receive medicines that are not licensed for that indication. Doctors usually only do this when there is clinical experience or research to support such use and when there is no suitable licensed alternative medicine.

