

The majority of medicines prescribed or purchased over the counter (OTC) have a licence for use, which is obtained by the manufacturer prior to being permitted to produce and sell the medicine in the UK.

This is under the remit of the Medicines Control Agency (MCA), which issues a product licence or marketing authorisation.

The licence describes the way in which the drug is given (route of administration e.g. oral or intravenous), the dose range and which patients it should be used to treat (indications).

The manufacturer has to prove that the drug is effective for the condition for which it is given, does not have too many side effects or risks and that it has been manufactured to a high standard.

The licence is designed to restrict the way in which the manufacturer promotes and sells the drug, but does not restrict the way in which doctors prescribe the medicine. It is entirely legal for doctors to prescribe drugs outside the licence.

In palliative care, for example, up to two thirds of patients receive drugs under these circumstances, usually when there is no suitable licensed alternative.

In the field of pain management, the use of drugs beyond their licence is sufficiently commonplace that it is unlikely doctors will make specific reference to this to patients when they are prescribing these drugs.

Obtaining a licence is a highly expensive undertaking for the manufacturer.

If post-marketing research shows that there is an application for the drug to be used in a different way from the one specified in the licence, it may not be economical for the manufacturer to apply for an extended licence.

There is no legal requirement for the manufacturer to apply to the Medicines Control Agency to add the more recent information to the product licence.

However, there is a legal requirement for the manufacturer to include a Patient Information Leaflet (PIL) with all medicines. This can only contain information from the licence, so off licence use will not be covered. This means, for example, that the PIL for antidepressants will not cover their use for pain relief.

As well as off licence use with regard to indications (what it is being used for), drugs may be used outside their licence at different doses from the one licensed, or via a different route of administration (e.g. injection instead of tablets).

The latter includes the use of epidural steroid injections, which are not licensed for use around the spine, although they are licensed for intramuscular injections and injections into joints.

Common drugs used beyond licence include antidepressants and anticonvulsants for pain relief.

A leaflet about this is available from the Pain Society at [www.painsociety.org](http://www.painsociety.org) or [www.palliative-medicine.org](http://www.palliative-medicine.org)

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## COMMON SIDE EFFECTS

Polypharmacy (the use of a 'cocktail' of drugs) carries a substantial side effect profile, which can adversely impact on quality of life.

The commonest side effects are:

- Sedation: is commonly a problem when commencing treatment, but may subside after 2-3 weeks. This can be a beneficial side effect to aid sleep at night.
- Constipation: a highly common problem, which should never be underestimated. It may exacerbate low back pain and urinary incontinence.

Treatment can be difficult. In the US, opiate-related constipation is treated with methylnaltrexone.

- Dry mouth: caused by various types of medication especially antidepressants.
- Cognitive impairment (fuzzy thinking): a distressing problem that can be hard to pinpoint but can nevertheless cause significant difficulties in daily life.
- Sexual dysfunction: quite a common side effect of most antidepressant drugs. As this may also be a problem due to the condition itself, onset of this symptom can be misdiagnosed: if medication-related, it is curable. Opiates may cause loss of libido.
- Weight change: a gain in weight is commonly experienced, particularly with anticonvulsants and also antidepressants. This can compound difficulties with mobility. Weight loss can also be experienced by some people. Fluid retention due to opiates is one cause of weight gain.
- Rash: anticonvulsants in particular are associated with skin problems.
- Allergy : a significant number of arachnoiditis patients develop allergies to various types of medication, especially antibiotics. Some people develop multiple allergies.
- Gastric upset: NSAIDs are known to cause gastrointestinal problems including ulcers.
- Addiction: this is feared by patients and their families and a focus of concern by medical professionals. There is however ample evidence that when used at appropriate levels strictly for pain relief (not to aid sleep, or reduce symptoms of anxiety) then the risk is minimal. Some degree of tolerance may develop as receptor sites adapt to the new levels of opiates, but many patients do not find they need escalating doses of drug to maintain pain relief.