Use of unlicensed medicines and ‘off-label’ uses
What is this leaflet about?

Your doctor or pharmacist has given you this leaflet because a medicine that you have been prescribed is not licensed (unlicensed use) or is being used off-label.

Sometimes a medicine is prescribed in a way that is not covered by its UK marketing licence. This does not mean that they are unsafe for this use.

This leaflet tell you what ‘unlicensed’ and ‘off-label’ means and why some medicines are used in this way.

You may want to discuss this further with your doctor or pharmacist.

How are medicines licensed?

To sell a medicine in the UK, the manufacturer must get a licence from a government organisation called the Medicines Healthcare products Regulatory Agency (MHRA).

A separate licence is needed for each product the company sells. The manufacturer must show the MHRA that their medicine works for the illness to be treated, does not have too many side-effects or risks, and has been made to a high standard.
What does a licence cover?

The medication licence will say which illness the medicine can be used for, the ages of the patients it can be used for, how much to give and how to give it.

In some circumstances it may also include information about monitoring that needs to be carried out.

Why are some medicines unlicensed?

Medicines are usually only licensed for conditions that have been investigated in clinical trials. However, many illnesses may not have been studied in this way, but still need to be treated.

In these situations, doctors and pharmacists can use their medical experience and specialist knowledge to recommend use of unlicensed medicines.

They may choose to use medicine that:

• is currently undergoing clinical trials, but does not yet have a licence
• used to be licensed in the UK, but is no longer marketed
• is only licensed abroad and needs to be imported
• needs to be made specially, because it is not readily available from a manufacturer.
Some medicines have no licence at all. These are usually drugs used to treat rare conditions, in which case the manufacturer may consider it too expensive to conduct the clinical trials needed for a licence.

Sometimes the licensed medicine is not available in a suitable form for a particular person. The commonest example of this is when someone has difficulty swallowing, but the medicine is only made in tablet form. In this case, an unlicensed liquid form may be specially prepared.

What is meant by ‘off-label use’?

‘Off-label’ use means that the medicine is being used in a way that is different to that described in the licence.

Some examples of ‘off-label’ uses are:

- Using a medicine for an illness different to that stated in the licence. Doctors may have found that the medicine works very well for this condition, and the use may be supported by expert groups, but the drug manufacturer has not extended the licence.

- Using a medicine in an age group outside the licensed range (i.e. children, or the elderly).

- Using a medicine at a higher dose than stated in the licence. Some people need these higher doses because their body metabolises the drug quickly.
How will I know if my medicine is not licensed or being used ‘off-label’?

Your doctor or pharmacist should tell you.

Also, if you read the manufacturer’s information leaflet you may notice that some of the information does not seem to apply to you (e.g. it may not mention your illness).

If an unlicensed medicine has to be specially prepared or imported, it may be more difficult to obtain. Your pharmacist should tell you this and make sure you know how to get your medicine.

How do I know that an unlicensed medicine or medicine used ‘off-label’ is safe and will work?

Unlicensed medicines are only prescribed after careful consideration of other options.

Your doctor will have read information from medical publications supporting its use, and may have taken advice from other experts.
Where can I get more information about my medicines?

The Choice and Medication website has leaflets about a wide range of individual medicines used in mental health, and this includes some unlicensed medicines and off-label uses:

www.choiceandmedication.org/wlmht

You can also ask your doctor or pharmacist.
Examples

Unlicensed medicines

- Pirenzepine tablets – for increased saliva with clozapine
- Olanzapine short acting injection – for agitation

Off-label use

- Clonazepam – for anxiety
- Sodium Valproate – for mood stabilisation
- Hyoscine hydrobromide tablets - for increased saliva with clozapine
- Most medicines used in children are off-label as they are not licensed for use in the age group.
If you need this information in another format, such as large print, Easy Read or another language, please ask a member of staff.

If you have questions or concerns about any of our services, please contact the patient advice and liaison service (PALS) on 0800 064 3330 or pals@wlmht.nhs.uk.