



Use of off-label medicines

Mental health services

Improving lives

oxleas.nhs.uk



This leaflet is for anyone who has been prescribed off-label medicines by a doctor at Oxleas NHS Foundation Trust.

Why have I been given this leaflet?

You have been given this information leaflet by your doctor or pharmacist because the medicine prescribed for you is not licensed either for people of your age or to treat the problem(s) that you have. This is called 'off-label' use.

We want to reassure you that we have thought very carefully about the most appropriate medicine for you. Your doctor can discuss the reasons for choosing this medicine over others, and any other options that are open to you.

Why and how are medicines licensed?

Before a manufacturer can sell a medicine to treat a particular problem in the UK they need to apply for a licence. A group called the Medicines and Healthcare Products Regulatory Agency (MHRA) looks after this.

The manufacturers must show the MHRA that their medicine works for the illnesses to be treated, does not have too many side effects/risks, and that it is made under good conditions.

To make sure that the medicine is safe and that it works, the manufacturer has to test it on a small number of people - called a 'clinical trial'. The information from these clinical trials is looked at by the MHRA who then decide if a licence should be granted.

Why am I being given off-label medicine?

There are several reasons why medicines are used off-label, for example:

- the medicine may have a licence for one illness but not for other illnesses that may be similar
- sometimes new uses are found for medicines

- the medicine may be licensed for use in adults but not in young people or the elderly. This is usually because people from these age groups were not involved in the clinical trials. Some medicines may have more side effects in children or the elderly than in working-age adults. For example antipsychotics are known to be associated with more risks in people with dementia.

What this may mean for you

- There are no licensed medicines currently available to treat the problem(s) that you have.
- Your doctor feels this medicine will suit you better than any licensed medicines.

Patient information leaflets (packed with your medicine) may not mention the problem that your doctor is trying to treat. Do not worry about this.

Your doctor will have thought through the benefits of this medicine very carefully before prescribing it.

Where can I get further information?

- Speak to the person who gave you the leaflet (doctor or pharmacist). They can tell you more about why the medicine has been chosen and why they think it is a good choice for you.
- Call the Oxleas Medicines Line for patients and carers. This line is open from 10am-4pm, Monday to Friday on 01322 621062.

You can find more information at:

- Medicines for children www.medicinesforchildren.org.uk

This document is suitable for parents.

- Royal College of Psychiatrists www.rcpsych.ac.uk
This document gives a detailed account of the issues related to medicines used outside the terms of their licence (off-label).

Contact us

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