

Oxazepam 10mg and 15mg Tablets

Oxazepam

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side-effects, talk to your doctor or pharmacist. This includes any possible side-effects not listed in this leaflet.

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2. Before you take Oxazepam Tablets
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4. Possible side-effects
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1. WHAT OXAZEPAM TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Oxazepam Tablets. Oxazepam is a member of a group of medicines called 'benzodiazepines'. Oxazepam is prescribed for the short term (maximum of 2-4 weeks) treatment of anxiety, which is disabling or distressing and may be associated with sleeplessness or other illnesses.

This medicine should be used for as short a time as possible and should not be used for more than four weeks. If used for too long without a break, there is a risk of becoming dependant or of having problems when you stop taking it.

When taking this medicine there is a risk of dependence (a need to keep taking the medicine). The risk increases with the dose and length of treatment period. The risk is greater if you have ever had a history of alcohol or drug abuse.

2. BEFORE YOU TAKE OXAZEPAM TABLETS

Do not take Oxazepam Tablets and tell your doctor:

- if you are allergic (hypersensitive) to Oxazepam or to other benzodiazepine medicines or any of the ingredients in your tablets (see section 6)
- have a phobia (a fear of a particular object or situation), obsessions or other mental illness
- if you have severe breathing or chest problems
- if you suffer from sleep apnoea (breathing problems when you are asleep)
- if you have myasthenia gravis (very weak or tired muscles)
- if you have serious liver problems

Talk to your doctor or pharmacist:

- if you are pregnant, or trying to become pregnant (see below)
- if you abuse or have in the past abused drugs or alcohol
- if you have any lung, kidney or liver problems
- if you are suffering from depression, since oxazepam may increase any suicidal feelings which you may have
- if you have suffered from depression before, since it could recur during treatment with oxazepam
- if you have a personality disorder
- if you suffer from breathing problems
- if you are suffering from an eye problem called glaucoma.

Oxazepam may cause muscle relaxation and caution is advised as you may be at a greater risk of falling (see section 4).

Taking Oxazepam with alcohol

Do not drink alcohol while you are taking Oxazepam tablets. Alcohol may increase the sedative effects of Oxazepam tablets and make you very sleepy.

Other considerations

- **Dependance** – when taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse.
- **Tolerance** – if, after a few weeks, you notice that the tablets are not working as well as they did when you first started treatment, you should speak to your doctor.
- **Withdrawal** – treatment should gradually be withdrawn. Withdrawal symptoms occur with Oxazepam tablets even when normal doses are given for short periods of time. See Section 3, 'If you stop taking Oxazepam tablets'.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- Antidepressants, antipsychotics (to treat mental problems), sedative antihistamines eg chlorphenamine (to treat allergies), anaesthetics, lofexidine (to help relieve symptoms when you stop taking opioids), nabilone (to treat nausea and vomiting), hypnotics (to help you sleep), alpha blockers or moxonidine, muscle relaxants (eg baclofen, tizanidine), probenecid (used to treat gout) or medicines containing alcohol. Taking these medicines with Oxazepam could make you very sleepy.
- Some strong pain killers may give you a heightened sense of wellbeing when taken with Oxazepam, which can increase your desire to continue taking these medicines (dependency) or can make you very sleepy.
- Medicines for epilepsy eg hydantoins, in particular phenytoin, or barbiturates (Oxazepam may make side effects more likely).
- Oestrogen-containing contraceptives, as these can cause Oxazepam to be less effective.
- Rifampicin (an antibiotic) as this can cause Oxazepam to be removed from the body more quickly than usual.
- Antiviral medication, eg Zidovudine (this may remain in the body longer than usual when used with Oxazepam) and Ritonavir (this can cause Oxazepam to remain in the body longer than usual)
- Medicines to lower high blood pressure (increased effect)
- Medicines used to inhibit liver enzymes (increases effects of Oxazepam)
- Levodopa (to treat Parkinson's Disease) as Oxazepam may cause levodopa to not work as well).

Concomitant use of this product and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe this product together with opioids the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant, might become pregnant or breast-feeding.

If you and your doctor decide that you should take this medicine towards the end of your pregnancy (or during labour) this may harm your baby. The baby may have a low body temperature, be listless, have breathing problems or difficulty in feeding. Also, if you take this medicine regularly during your pregnancy, your baby may get withdrawal symptoms.

Driving and using machines

Oxazepam may make you feel dizzy or sleepy during the day, or may affect your concentration. This may affect your performance at skilled tasks such as driving and operating machinery.

The medicine can affect your ability to drive as it may make you feel sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and

- It was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Important information about some of the ingredients of Oxazepam Tablets

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE OXAZEPAM TABLETS

Always take Oxazepam Tablets exactly as your doctor has told you. You should not take Oxazepam Tablets for longer than 4 weeks. The label on your medicine should also tell you. You should check with your doctor or pharmacist if you are not sure. Oxazepam Tablets should be swallowed with water. Where possible, you should aim to have 7-8 hours of undisturbed sleep after taking your tablets.

Adults

- **Anxiety:** The usual dose is one to two 15mg tablets three or four times daily. Your doctor will tell you how often to take your tablets.
- **Sleeping problems:** 15-25mg one hour before going to bed, your doctor may increase this up to a maximum of 50mg.
- **Adults with liver or kidney problems:** Your dosage may be reduced if you suffer from kidney or liver problems.

Oxazepam Tablets are not recommended for use by children under 18 years of age. Oxazepam is usually prescribed for short courses of treatment, lasting from a few days to 4 weeks including a dose reduction at the end. This reduces the risk of becoming dependent on Oxazepam Tablets, or suffering unpleasant effects when you stop taking them. (See 'If you stop taking Oxazepam Tablets' section).

If you take more Oxazepam Tablets than you should

If anyone has taken an overdose of Oxazepam Tablets (that is more than the doctor has prescribed), seek medical help immediately, either by calling your doctor, or going to the nearest casualty department. Always take the labelled medicine container with you, even if there are no tablets left.

If you forget to take Oxazepam Tablets

Do not take a double dose to make up for a forgotten tablet. If you forget to take a tablet for anxiety, you should take it as soon as you remember if it is less than 3 hours since your usual time. If more than 3 hours has passed from when you usually take your tablet, just take your next tablet when it is due.

If you stop taking Oxazepam Tablets

This medicine should not be stopped suddenly; keep taking it until your doctor tells you how to reduce the dose slowly. If you stop taking the tablets suddenly you may experience the following withdrawal effects:

- depression,
 - nervousness,
 - difficulty in sleeping,
 - irritability,
 - sweating,
 - upset stomach/diarrhoea,
 - or the symptoms you are being treated for can come back worse than before.
- You may also experience mood changes, anxiety, restlessness, headaches, muscle pains, and changes in sleep patterns. These effects may occur even after taking low doses for a short period of time.

If you stop taking these tablets suddenly after being treated with high doses of Oxazepam, you may experience confusion, hallucinations, tinnitus (ringing sounds in your ears), shaking, faster heartbeat or fits.

Withdrawal may also cause unusual behaviour including aggressive outbursts, excitement or depression with suicidal thoughts or actions.

4. POSSIBLE SIDE-EFFECTS

Like all medicines, Oxazepam Tablets can cause side-effects, although not everybody gets them.

Contact your doctor immediately if the following symptoms occur:

- restlessness, agitation, irritability, aggressiveness, delusion, experiencing rages, nightmares, hallucinations (seeing or hearing things that are not there), psychoses (loss of contact with reality), inappropriate behaviour (more likely to occur in children and the elderly), depression with feelings of suicide.

Tell your doctor if you notice any of the following side effects or notice other effects not listed:

- mild drowsiness and light-headedness may occur during the first few days of treatment
- allergic reaction: skin rashes, itching
- dizziness, fainting, loss of co-ordination, 'spinning' sensation or headache with or without drowsiness, tiredness
- becoming less alert, disorientation, dreams, confusion, excitement, numbed emotions, slurred speech or speech disorder, loss of memory, lack of muscle control/co-ordination, difficulty in controlling movements, changes in perception, increased risk of falling
- changes in blood cells, if you notice increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion, or abnormal paleness of the skin, you should tell your doctor who may want to have a blood test, reduction in white blood cells, changes in sex drive, blurred or double vision, low blood pressure, muscle weakness, tremor, fever, tiredness
- stomach upsets or cramps, feeling sick, changes in saliva
- yellowing of the skin or whites of the eyes (jaundice), increased liver enzymes seen in tests, difficulty passing urine, water retention, incontinence.

Withdrawal symptoms: see Section 3, 'If you stop taking Oxazepam tablets'.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side-effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE

Keep this medicine out of the sight and reach of children.

Do not take Oxazepam Tablets after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of the month.

Store below 25°C in a dry place.

Return any unused tablets to your pharmacist. Only keep them if your doctor tells you to. Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Oxazepam Tablets contain:

- The active substance is oxazepam. Each tablet contains either 10mg or 15mg of oxazepam.
- The other ingredients are: lactose, maize starch and magnesium Stearate.

What Oxazepam Tablets look like and the contents of the pack

Oxazepam Tablets are white, round tablets with a flat face and bevelled edges. A breakbar can be seen on one side with the imprint '10' or '15' on the other. They are supplied in blister packs and cartons of 28 tablets.

POM

PL 17225/0014 Oxazepam 10mg Tablets

PL 17225/0015 Oxazepam 15mg Tablets

Marketing Authorisation Holder:

Genus Pharmaceuticals, Linthwaite, Huddersfield, HD7 5QH, UK.

Manufacturer:

Haupt Pharma Münster GmbH, Schleebürgerkamp 15, 48159 Münster, Germany.

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