

Oxazepam 10mg and 15mg tablets

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. See section 4.

What is in this leaflet:

- 1 What Oxazepam tablets are and what they are used for**
- 2 What you need to know before you take Oxazepam tablets**
- 3 How to take Oxazepam tablets**
- 4 Possible side effects**
- 5 How to store Oxazepam tablets**
- 6 Contents of the pack and other information**

1 What Oxazepam tablets are and what they are used for

Oxazepam belongs to a group of medicines called benzodiazepines. Oxazepam tablets may be used 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 dependent 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 What you need to know before you take Oxazepam tablets

Do not take Oxazepam tablets if you

- are **allergic** to oxazepam or to other benzodiazepine medicines or to any of the other ingredients of this medicine (listed in section 6)
- are **breathless** or have **difficulty breathing**
- have a **phobia** (a fear of a particular object or situation), **obsessions** or other mental illness
- have **myasthenia gravis** (a condition which causes muscles to weaken and tire easily)
- suffer from **sleep apnoea** (a condition where you stop breathing whilst asleep)
- have **severe liver** disorders.

Warnings and precautions

Talk to your doctor or pharmacist before taking Oxazepam tablets if you

- suffer from **depression** (with or without anxiety)
- have a history of **alcoholism** or **drug abuse**
- have problems with your **lungs, liver** or **kidneys**
- have a **personality disorder**

- have **porphyria** (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders)
- have **glaucoma**.

Other considerations

- **Dependence** - 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 first starting treatment, you should speak to your doctor.
- **Withdrawal** - treatment should be gradually 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:**

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

Other medicines and Oxazepam tablets

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

- antidepressants, antipsychotics (to treat mental problems), sedative antihistamines e.g. 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 (e.g. baclofen, tizanidine), probenecid (used to treat gout). Taking these medicines with Oxazepam could make you very sleepy
- some strong pain killers may give you a heightened sense of well being when taken with Oxazepam, which can increase your desire to continue taking these medicines (dependency) or can make you very sleepy. Concomitant use of Oxazepam 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 Oxazepam 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
- medicines for epilepsy e.g. 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, e.g. 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 so well.

Oxazepam tablets 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.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Oxazepam tablets if you are pregnant, might become pregnant or are 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 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 tablets may affect how your muscles work or may make you feel dizzy or sleepy or forgetful. It may also impair your alertness (especially if you don't have enough uninterrupted sleep). **Do not** drive or use any tools or machines if you are affected in this way.

The medicine can affect your ability to drive as it may make you 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.

Oxazepam tablets contain lactose

If you have been told by your doctor that you have intolerance to some sugars contact your doctor before taking this medicine.

Information on sodium content

The 10mg tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Oxazepam tablets

Always take this medicine exactly as your doctor has told you. **You should not take Oxazepam tablets for longer than 4 weeks.** Check with your doctor or pharmacist if you are not sure.

You should make sure you are able to have 7-8 hours of uninterrupted sleep.

Swallow the tablets whole, **with a glass of water.**

The recommended dose is

- **Anxiety:** 15-30mg three or four times a day.
- **Anxiety associated with sleeplessness:** 15-25mg one hour before going to bed, your doctor may increase this up to a maximum of 50mg.
- **Elderly and patients sensitive to benzodiazepine drugs:** 10-20mg three or four times a day.
- **Liver or kidney problems:** Your dose may be reduced.
- **Children:** Not recommended.

These tablets should be taken as instructed - swallowed with water. This medicine should be taken for as long as your doctor tells you to; it may be dangerous to stop without their advice. Treatment should not usually exceed 2-4 weeks and should be gradually withdrawn as adverse effects, such as anxiety, depression, headache, insomnia, tension and sweating have been observed on abrupt withdrawal.

If you take more Oxazepam tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include loss of coordination, feeling sleepy, confusion, lethargy, rapid eye movements, speech problems. An extreme overdose may lead to low blood pressure, breathing difficulties or coma (unrousable unconsciousness).

If you forget to take Oxazepam tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

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 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, shaking, faster heartbeat or fits.

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible Side Effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

If you get any of the following side effects, tell your doctor immediately.

Your doctor may need to gradually stop your treatment:

- restlessness, agitation, irritability, aggressiveness, delusion, experiencing rages, nightmares, hallucinations (seeing or hearing things that are not there), psychoses (alred 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 any 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, increase 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 perform 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, lack of voluntary control over urination or defecation.

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

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 Oxazepam tablets

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

Store below 25°C in a dry place protected from light.

Do not use this medicine after the expiry date which is stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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 Contents of the pack and other information

What Oxazepam tablets contain

- The active substance is Oxazepam. Each tablet contains either 10mg or 15mg of Oxazepam.
- The other ingredients are colloidal silica, lactose, magnesium stearate, maize starch, microcrystalline cellulose (E460).
- The 10mg tablets also contain sodium lauryl sulfate.

What Oxazepam tablets look like and contents of the pack

Oxazepam tablets 10mg are white, circular, flat bevelled-edge uncoated tablets impressed "C" on one face and the identifying letters "OX" on the reverse.

Oxazepam tablets 15mg are white, circular, flat bevelled-edge uncoated tablets impressed "C" and the identifying letters "OZ" on one face.

Pack sizes are 28 tablets.

Marketing Authorisation Holder and Manufacturer
Accord, Barnstaple, EX32 8NS, UK.

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