

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

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 want 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 is and what it is used for
2. What you need to know before you take Oxazepam
3. How to take Oxazepam
4. Possible side effects
5. How to store Oxazepam
6. Contents of the pack and other information

1 What Oxazepam is and what it is used for

Oxazepam belongs to a group of medicines known as benzodiazepines.

Oxazepam is intended for short term use (approximately 2-4 weeks) to relieve severe anxiety.

2) What you need to know before you take Oxazepam

Do not take Oxazepam if:

- You are allergic (hypersensitive) to Oxazepam, other benzodiazepines or any of the other ingredients of this medicine (listed in section 6)
- You have a phobia (a very strong fear of something), obsessions or other mental disorders
- You suffer from severe liver disorders
- You suffer from breathing difficulties
- You suffer from myasthenia gravis (muscle weakness)
- You suffer from sleep apnoea syndrome (a condition where the throat relaxes during sleep and interrupts normal breathing)

Warnings and precautions

Talk to your doctor before taking Oxazepam if:

- **Taking Oxazepam can lead to a dependency (addiction). See section 3 “If you stop taking Oxazepam”**
- Oxazepam should not be used alone to treat depression or anxiety associated with depression as the use of benzodiazepines may release suicidal tendencies in depressed patients
- You have a history of alcohol or drug dependency
- You have a personality disorder
- You have glaucoma
- You suffer from kidney disorders

Oxazepam may cause muscle relaxation, dizziness or drowsiness. Therefore, caution is advised as you may be at a greater risk of falling (see section 4 “Possible side effects”).

Other medicines and Oxazepam

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

Medicines which may interact with or be affected by Oxazepam:

- Barbiturates, used to treat anxiety and sleep disorders
- Medicines used to treat mental illness (antipsychotics)
- Strong pain relievers (narcotic analgesics, opioids)
- Medicines used to treat depression (antidepressants)

- Medicines to help you sleep (hypnotics)
- Anaesthetics
- Antihistamines, used to treat allergic conditions
- Lofexidine, used for drug and alcohol dependency
- Nabilone, used for feeling (nausea) or being sick (vomiting)
- Muscle relaxants, such as baclofen, tizanidine
- Oestrogen-containing contraceptives ('the pill')
- Antibacterial medicines, such as rifampicin
- Antiviral medicines, such as zidovudine or ritonavir
- Medicines for epilepsy (anticonvulsants), such as phenytoin, hydantoins
- Medicines for high blood pressure (antihypertensives), such as doxazosin (alpha blockers) or moxonidine
- Medicines used to treat Parkinson's disease such as levodopa (dopaminergics)
- Probenecid, used to treat gout

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.

Taking Oxazepam with food and alcohol

Do not drink alcohol when you are taking this medicine. Alcohol may make you feel more sleepy than usual.

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 for advice before taking this medicine.

Pregnancy

- Oxazepam should not be used during pregnancy, especially during the first and last trimesters. Oxazepam may cause foetal damage when administered to pregnant women.
- If you take Oxazepam during late pregnancy, your baby may develop withdrawal symptoms such as a low body temperature, floppy limbs, feeding problems and breathing difficulties.

Breast-feeding

Oxazepam is passed into breast milk and therefore you should not take Oxazepam whilst breastfeeding.

Driving and using machines

Oxazepam may make you feel drowsy, forgetful, dizzy or cause muscular problems. Do not drive or use machinery if affected.

This 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 contains lactose

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

3) How to take Oxazepam

Always take Oxazepam exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- These tablets are to be taken orally.
- The score line is not intended for breaking the tablet.
- You should take Oxazepam for the shortest time possible and treatment should not exceed 4 weeks.
- You should ensure that you will be able to have 7-8 hours of uninterrupted sleep.

Adults

- **Anxiety:** The recommended dose is 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 medicines: 10-20mg three or four times a day.

Patients with liver or kidney problems

Your dose may be reduced.

Use in children

Oxazepam is not recommended for use in children.

If you take more Oxazepam than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of overdose include: drowsiness, confusion, speech difficulties (dysarthria), uncontrollable eye movement (nystagmus) lack of energy (lethargy). In more serious cases, symptoms may include unsteadiness/clumsiness (ataxia), muscle weakness (hypotonia), low blood pressure (hypotension), breathing more slowly or weakly than usual (respiratory depression), coma (rare), death (very rare)

If you forget to take your Oxazepam

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

If you stop taking Oxazepam

It is important that you keep taking Oxazepam for as long as your doctor has told you to.

Do not stop taking your tablets suddenly. Your doctor will tell you how to reduce your dose gradually. This will reduce the risk of withdrawal symptoms.

While your dose is being gradually reduced, you may notice a recurrence of symptoms; mood changes, anxiety, restlessness and have trouble sleeping. You may feel similar to the way you did before you started to take Oxazepam. This is a side effect of reducing your tablets and will pass.

Dependency

There is a possibility that you may become dependent on (addicted to) Oxazepam. This is more likely if you take higher doses and/or are taking Oxazepam long term. The risk of dependency further increases if you have a history of alcoholism, drug dependency or a personality disorder.

Withdrawal

Withdrawal symptoms may last for weeks or months and possible symptoms include: extreme anxiety, shaking (tremor) including involuntary movements, difficulty sleeping (insomnia), depression,

problems with your perception, confusion, fits (convulsions), muscle cramps, headaches, tension, restlessness, irritability, stomach problems, being sick (vomiting) and sweating.

More severe withdrawal symptoms include: a feeling of loss of identity/feeling detached from yourself (depersonalisation or derealisation), sensitivity to light, noise (including tinnitus) and physical contact, numbness or tingling in the hands or feet (paraesthesia), seeing or hearing things that are not real (hallucinations).

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

4 Possible side effects

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

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness
- Swelling of parts of the body (oedema)

If you experience any of the following symptoms, particularly if you are elderly, your treatment may need to be stopped:

- Aggressive outbursts, agitation, irritability, rages
- Seeing or hearing things that are not real (hallucinations), delusions
- Restlessness
- Nightmares/dreams
- Mental health problems (including confusion, excitement), inappropriate behaviour

Side effects (Frequency not known)

- Mild drowsiness. If this side effect becomes troublesome, your dose may need to be reduced
- Disorientation
- Lack of energy (lethargy)
- Skin rashes (with or without itching)
- Feeling sick (nausea)
- Changes in your sex drive
- Fever
- Feeling tired (fatigue)
- Slurred speech or a difficulty in speaking (dysarthria)
- Shakiness (tremor)
- Increased liver enzymes (detected through blood test)
- Jaundice (yellowing of the skin or the whites of the eyes)
- Low blood pressure (hypotension)
- Blood disorders
- Reduction in white blood cells (leucopenia)
- Muscle weakness
- Saliva changes
- Stomach problems
- Difficulty passing urine
- Inability to control the flow of urine (incontinence)
- Loss of memory (see section 2 "Warnings and precautions")
- Blurred or double vision
- Headache
- Feeling of dizziness or "spinning" (vertigo)
- Feeling less alert or numbed emotions
- Dizziness, lightheadedness. If this side effect becomes troublesome, your dose may need to be reduced
- Difficulty in controlling movements (ataxia)
- Fainting (syncope)
- Falls

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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

- Keep this medicine out of the sight and reach of children.
- Do not use Oxazepam after the expiry date, which is stated on the carton/blister after EXP. The expiry date refers to the last day of that month.
- Store in a cool dry place. Store in the original container in order to protect from light.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6) Contents of the pack and other information

What Oxazepam contains:

Each tablet contains 10mg or 15mg of Oxazepam.

The other ingredients are: lactose, maize starch, pregelatinised maize starch and magnesium stearate.

The 15mg tablets also contain colour E104 (quinoline yellow) and E127 (Anstead Dispersed Pink).

What Oxazepam looks like and the contents of the pack:

- Oxazepam 10mg are white round flat tablets with a score line on one side and coded OXA 10 on the other side.
- Oxazepam 15mg are yellow round flat tablets with a score line on one side and coded OXA 15 on the other side.

Oxazepam is available in:

Oxazepam Tablets are available in containers or blister packs of 7, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 250, 500 or 1000 tablets.

Not all pack sizes or pack types may be marketed.

Marketing Authorisation Holder

Tillomed Laboratories Ltd
220 Butterfield
Great Marlings
Luton
LU2 8DL
UK

Manufacturer¹

Tillomed Laboratories Ltd
220 Butterfield
Great Marlings
Luton
LU2 8DL
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Kleva Pharmaceuticals S.A
189 Parnithios Ave
13675 Acharnai-Attiki
Greece

¹ Only actual batch release site listed on printed leaflet

Product Licence Numbers:

- PL 11311/0526: Oxazepam 10mg Tablets
- PL 11311/0527: Oxazepam 15mg Tablets

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