

## **PACKAGE LEAFLET**

## Package leaflet: Information for the user

### Oxazepam 10 mg and 15 mg 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. 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 called benzodiazepines. Oxazepam increases the actions of a naturally occurring substance called GABA, in the brain.

Oxazepam is used for the short-term (2 - 4 weeks) treatment of anxiety, which is severe, disabling, distressing and which may be associated with sleeplessness or with other illnesses.

#### 2. What you need to know before you take Oxazepam

##### Do not take Oxazepam

- if you are allergic to oxazepam, other benzodiazepines, or any of the other ingredients of this medicine (listed in section 6)
- if you have severe breathlessness or breathing difficulties
- if you suffer from Myasthenia Gravis (a condition which causes muscles to weaken and tire easily)
- if you have a phobia or obsession, or you are being treated for a mental illness
- if you suffer from sleep apnoea (a condition where you stop breathing when asleep)
- if you have severe problems with your liver
- if you are pregnant, might become pregnant or are breast-feeding

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Oxazepam

- if you have problems with your liver, kidneys or lungs
- if someone close to you has recently died
- If you have a history of alcoholism or drug abuse. The risk of dependence to Oxazepam increases in these patients, and with the dose and length of treatment
- If you have a personality disorder
- if you suffer from depression (with or without anxiety)
- if you have porphyria (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders)

Other considerations when taking Oxazepam are:

- Tolerance – if after a few weeks you notice that the tablets are not working as well as they did when you first started taking them, you should see your doctor, as an adjustment of your dose may be required.
- Dependence – when taking this type of medicine there is a risk of dependence, which increases with dose and length of treatment. There is a greater risk in patients with a history of alcohol or drug abuse.
- Withdrawal – treatment should be gradually withdrawn. Some patients find that their symptoms of difficulty sleeping and anxiety reoccur when stopping treatment. This may be accompanied by other reactions (see section 3 of this leaflet under ‘If you stop taking Oxazepam’).
- Amnesia – Oxazepam can cause memory loss. To reduce the risk you should ensure you are able to have 7-8 hours of uninterrupted sleep.
- Psychiatric and ‘paradoxical’ reactions – Oxazepam can cause restlessness, agitation, irritability, aggressiveness, delusions (false beliefs), rages, nightmares, hallucinations, psychoses, inappropriate behaviour and other behavioural disturbances. If you experience any of these symptoms Oxazepam treatment should be stopped.

Other medicines and Oxazepam

Tell your doctor if you are taking any of the following medicines:

- antidepressants, antipsychotics, sedatives (to calm you down), hypnotics (to help you sleep) codeine, anaesthetics, sedating antihistamines, lofexidine (to help relieve symptoms when you stop taking opioids), nabilone (to treat nausea and vomiting), alpha blockers or moxonidine, muscle relaxants (e.g. baclofen, tizanidine), probenecid (used to treat gout).

These medicines act in the same way as Oxazepam and 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.
- medicines for epilepsy e.g. barbiturates or phenytoin. These can make the side effects of Oxazepam worse.
- 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.
- antivirals such as zidovudine as Oxazepam can cause zidovudine to be removed from the body more slowly, or ritonavir (as this can cause Oxazepam to be removed from the body more slowly).
- medicines to lower high blood pressure as Oxazepam can increase the effect of these medicines.
- levodopa (to treat Parkinson’s disease) as Oxazepam may reduce the effects of levodopa.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

### **Oxazepam with food and, drink and alcohol**

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

### **Pregnancy and breast-feeding**

You **should not** take Oxazepam if you are pregnant, planning to become pregnant or if you are breast-feeding. If you take Oxazepam late in your pregnancy or during labour your baby might have a low body temperature, floppiness, breathing and feeding difficulties. If you take this medicine regularly during late pregnancy, your baby may develop withdrawal symptoms.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Oxazepam may make you feel sleepy, forgetful, affect your concentration or may affect how your muscles work. **Do not** drive or use any tools or machines if you are affected in this way and do not drink alcohol, as this will make these effects worse.

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:
  - o The medicine has been prescribed to treat a medical or dental problem and
  - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - o 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 (a type of sugar).

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

### **3. How to take Oxazepam**

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

The number of tablets you take will depend on what you are taking the tablets for. **You should not take Oxazepam for longer than 4 weeks, including time required for gradual reduction of your dosage.** Oxazepam should be gradually withdrawn as adverse effects such as anxiety, headache, insomnia, tension and sweating have been observed on abrupt withdrawal.

Swallow the tablets whole with a glass of water.

#### **Use in Adults**

If you are taking the tablets for severe anxiety the recommended dose is 15-30 mg three or four times daily.

If you are taking Oxazepam to help you sleep if you have anxiety, the recommended dose is 15 – 25 mg, but some patients may need up to 50 mg. The dose should be taken one hour before bedtime.

If you suffer from liver or kidney problems, you may be prescribed a lower dose.

#### **Use in children**

**Benzodiazepines should not be given to children without careful assessment of the need to do so; the duration of treatment must be kept to a minimum.**

#### **Use in elderly and patients sensitive to benzodiazepines**

The recommended dose for severe anxiety is 10-20 mg three or four times daily.

If you have liver or kidney problems or breathing difficulties you may be given a lower dose.

#### **If you take more Oxazepam than you should**

If you take more Oxazepam than you should contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you. Symptoms of an overdose include drowsiness, confusion, difficulty speaking, rapid eye movements and lack of energy. More serious cases may cause loss of coordination, low muscle strength, low blood pressure, breathing difficulties or coma.

**If you forget to take Oxazepam**

If you forget to take a dose of Oxazepam take it as soon as you remember, unless it is almost time for your next dose, in which case miss out the forgotten dose completely and carry on as normal. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Oxazepam**

Do not stop taking your medicine without telling your doctor. Treatment should be gradually withdrawn as the symptoms that Oxazepam was used to treat will return with more intensity than before (rebound insomnia). Other withdrawal symptoms could include anxiety, restlessness and mood changes; these will however disappear with time.

If you have become physically dependent on Oxazepam, sudden withdrawal of treatment could lead to symptoms such as depression, extreme anxiety, headaches, muscle pain or cramp, nervousness, tension, stomach cramp, insomnia, restlessness, sleeplessness, irritability, sweating or diarrhoea and occasionally confusion, convulsions, unusual behaviour. Other symptoms, such as persistent ringing in the ears, involuntary movements, tingling or numbness, abdominal pain, muscle cramps and vomiting, may also occur. In more severe cases, hypersensitivity to light, noise and physical contact, hallucinations and epileptic seizures have also been reported.

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 serious side effects, tell your doctor immediately. Your doctor will need to gradually stop your treatment:**

- feeling over excited, nervous or irritable
- experiencing rage
- having nightmares and hallucinations (feeling or seeing things that are not there)
- exhibiting inappropriate behaviour
- feeling restless, agitated, aggressive
- suffering from delusions (false beliefs) and psychoses
- feeling depressed with suicidal thoughts
- memory loss
- jaundice (yellowing of the skin and whites of the eyes)

Many of these side effects are more likely to occur in children and the elderly.

**The following side effects happen predominantly at the start of the treatment and usually disappear with repeated administration:**

- drowsiness during the day
- numbed emotions
- reduced alertness
- confusion
- headache
- dizziness, spinning sensation
- fainting
- feeling tired
- double vision
- lack of muscle coordination (ataxia)
- difficulty in controlling movements
- changes in perception
- muscle weakness.

**Other side effects that occur occasionally are:**

- stomach upset, feeling sick
- skin rashes or itching
- changes in sexual drive
- oedema (swollen hands and feet)
- blood problems, including low white blood cells which may cause frequent infections such as fever, severe chills, sore throat or mouth ulcers
- feeling unusually tired
- low blood pressure which may cause dizziness or light headedness
- blurred vision, disorientation, dreams, tremor
- slurred speech or difficulty in speaking, salivation changes
- loss of control of your bladder or difficulty passing urine
- water retention, incontinence
- an increase in liver enzymes (shown in a blood test)

Psychological dependence may occur meaning you think you cannot ever sleep without taking Oxazepam. Use (even at therapeutic doses) may lead to physical dependence, which may result in you suffering withdrawal effects and a recurrence of your problems if you suddenly stop Oxazepam treatment (see section 3 under 'If you stop taking Oxazepam').

**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](http://www.mhra.gov.uk/yellowcard)

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 after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package. Store your medicine in a cool dry place, away from light.

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 contains**

The active substance is oxazepam:

- Each Oxazepam 10 mg tablet contains 10 mg of oxazepam.
- Each Oxazepam 15 mg tablet contains 15 mg of oxazepam.

The other ingredients are:

- Oxazepam 10 mg tablets: lactose monohydrate, maize starch, isopropyl alcohol, povidone K30, magnesium stearate, sodium starch glycollate.
- Oxazepam 15mg tablets: lactose monohydrate, maize starch, magnesium stearate, quinoline yellow, erythrosine.

**What Oxazepam looks like and contents of the pack**

Oxazepam 10 mg tablets: White tablet marked "OM" break line "10" on one side and "G" on the other.

Oxazepam 15mg tablets: Pale yellow tablet marked “OM” break line “15” on one side and “G” on the other

Oxazepam is available in blisters containing 28 tablets and containers containing 100, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

Mylan, Potters Bar, Hertfordshire, EN6 1TL, UK

**Manufacturer**

Generics [UK] Ltd, Potters Bar, Hertfordshire, EN6 1TL, UK

Gerard Laboratories, 35-36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

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