Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Oxazepam tablets are and what they are used for
2. Before you take
3. How to take
4. Possible side effects
5. How to store
6. Further 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.

2. Before you take

Do not take Oxazepam tablets and tell your doctor if you:

- are allergic to benzodiazepines or to any of the other ingredients in your tablets (see section 6).
- have breathlessness or difficulty breathing.
- have a phobia (a fear of a particular object or situation).
- have 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.

Check with 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.

Oxazepam 10mg and 15mg tablets

- Withdrawal - treatment should be gradually withdrawn.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).

Taking other medicines

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

- antidiabetics, antipsychotics (to treat mental problems), sedative antihistamines (to help you sleep), antidepressants (to help relieve symptoms when you stop taking opioids), nabilone (to treat nausea and vomiting), antipsychotics (to help you sleep), alpha blockers or moxonidine, muscle relaxants (eg baclofen, tizanidine), probenecid (used to treat gout).

Taking these medicines with Oxazepam could make you very sleepy.

- some strong painkillers 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 eg hydantions, 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 so well.

Taking 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

You should not take Oxazepam tablets if you are pregnant, planning to become pregnant or are breast feeding. If you take Oxazepam tablets late in your pregnancy or during labour your baby might have a low body temperature, flappiness, and breathing difficulties. If taken 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 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 take this while taking this medicine.

Oxazepam tablets contains lactose
Oxazepam tablets contain lactose (a type of sugar). If you have been told that you have intolerance to some sugars contact your doctor before taking this medicine.

How to take
Always take Oxazepam tablets exactly as your doctor has told you. You should not take Oxazepam tablets for longer than 4 weeks. You should 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.

Doses
• 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; 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 immediately or contact your doctor directly.
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 (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
Do not stop taking your medicine without telling your doctor as they may wish to gradually reduce the number of tablets you take before stopping them completely. If you stop taking Oxazepam tablets suddenly, you may experience unpleasant side effects including headaches, muscle pain or cramps, extreme anxiety, tension, stomach cramps, insomnia, being sick, confusion, ringing in the ears, involuntary movements, ‘pins and needles’ depression or sweating. If you have been taking a high dose, you may occasionally experience confusion, unusual behaviour (depersonalisation feeling the world around you is not real) or depersonalisation (feeling your body is separate from your mind), hypersensitivity to light, noise and physical contact, abnormal acute hearing and painful sensitivity to sound numbness and tingling of the extremities, hallucinations.
• Treatment should be gradually withdrawn otherwise the symptoms you are being treated for may return more intense than before (rebound insomnia and anxiety).

The risk of this happening is greater when you stop taking Oxazepam suddenly. You may also experience mood changes, anxiety, restlessness or changes in sleep patterns.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Possible Side Effects
Like all medicines, Oxazepam tablets can cause side-effects, although not everybody gets them.

Contact your doctor at once 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 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 throat, 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, blurring 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 by using 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.

How to store
Keep out of the reach and sight of children.
Store below 25°C in a dry place protected from light. Do not use Oxazepam tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Liver or kidney problems:
• 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

Further Information

What Oxazepam tablets contain:
• The active substance (the ingredient that makes the tablet work) is Oxazepam. Each tablet contains either 10mg or 15mg of the active ingredient.
• 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 looks like and contents of the pack
Oxazepam tablets are white, uncoated tablets. Pack sizes are 28s.

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