

APO-Oxazepam

Contains the active ingredient, oxazepam

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about oxazepam. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again

What this medicine is used for

The name of your medicine is APO-Oxazepam. It contains the active ingredient, oxazepam.

It is used to treat anxiety, or trembling, confusion or anxiety associated with alcohol withdrawal. Note that anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

Oxazepam belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

In general, benzodiazepines such as oxazepam should be taken for short periods only (2-4 weeks). Continuous long-term use

is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

Use in children

Do not give this medicine to children unless advised by the child's doctor.

There is not enough information to recommend the use of this medicine in children under 16 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have severe lung disease or breathing difficulties**
- **You have sleep apnoea, a condition where you have breathing problems when you sleep.**
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You have had an allergic reaction to oxazepam, any other medicine from the benzodiazepine group of medicines or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the

face, lips, tongue, throat or other parts of the body, itching or hives on the skin.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Do not give this medicine to children under 16 years of age.

The safety and effectiveness of oxazepam in children under 16 years have not been established.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- liver, kidney or lung problems
- blood disorders
- myasthenia gravis (a disease which causes severe muscle weakness)
- low blood pressure

- narrow or acute angle glaucoma (raised pressure in the eye)
- depression or severe mental illness such as psychosis or schizophrenia
- epilepsy (fits or convulsions).

3. You are pregnant.

Oxazepam may affect your developing baby if you take it during pregnancy. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

4. You are breast-feeding.

Oxazepam may pass into human breast milk and cause drowsiness and/or feeding difficulties in the infant. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

5. You drink alcohol regularly.

Alcohol may increase the effects of oxazepam.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and oxazepam may interfere with each other. These include:

- medicines to treat depression, anxiety or mental illness
- sleeping tablets, sedatives or tranquillisers
- strong pain relievers
- muscle relaxants
- antihistamines, for allergies or hay fever
- barbiturates (for sedation or epilepsy)
- anaesthetics
- any other medicines which may make you sleepy
- medicines to control fits

These medicines may be affected by oxazepam or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking oxazepam.

Other interactions not listed above may also occur.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Oxazepam may be taken up to four times a day at evenly spaced intervals. Your doctor will advise you how many times during the day you should take oxazepam.

If you are over 65 years of age, or debilitated in any way, the dose may be smaller.

If you need to break the tablet in half, place it on a hard surface with the score line facing upwards, and press gently on the tablet with your thumb.

Do not stop taking your medicine or change your dosage without first checking with your doctor

How to take it

Swallow the tablet with a glass of water. This medicine can be taken with or without food.

When to take it

Take it at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it for

Do not take this medicine for longer than your doctor says.

Oxazepam is usually used for short periods only (2-4 weeks).

Continuous long-term use is not recommended unless advised by your doctor.

The use of benzodiazepines may lead to dependence on the medicine.

However be sure not to stop taking this medicine suddenly, because you may get unwanted side effects.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of unwanted side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much oxazepam you may feel drowsy, confused, tired, dizzy, have difficulty breathing, feel weak or become unconscious.

While you are taking this medicine

Things you must do

Take oxazepam exactly as your doctor has prescribed.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed

- you are about to have any blood tests
- you are going to have surgery or are going into hospital
- you feel this medicine is not helping your condition
- for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

If you are being treated for anxiety, be sure to discuss with your doctor any problems you may have and how you feel, especially if your anxiety attacks are getting worse or more frequent.

This will help your doctor to decide the best treatment for you.

Always discuss with your doctor any problems or difficulties during or after taking oxazepam.

Go to your doctor regularly for a check-up.

Your doctor needs to check your progress and see whether you need to keep taking oxazepam.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

It is best to avoid drinking alcohol while taking this medicine.

Combining oxazepam with alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest that you avoid

alcohol or reduce the amount of alcohol you drink while you are taking oxazepam.

Things you must not do

Do not:

- **Drive or operate machinery until you know how this medicine affects you.**

It may cause drowsiness or dizziness in some people and therefore may affect alertness. Even if you take this medicine at night, you may still be drowsy or dizzy the next day.

- **Take this medicine for a longer time than your doctor has prescribed.**

It should be taken for short periods only (for example 2 to 4 weeks), unless advised by your doctor.

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- **Suddenly stop taking this medicine if you suffer from epilepsy.**
- **Stop taking your medicine, or change the dosage, without first checking with your doctor.**

Stopping this medicine suddenly may cause some unwanted effects such as disturbed sleep. Also, if you suffer from

epilepsy, stopping this medicine suddenly may make your epilepsy worse.

Your doctor may slowly reduce your dose of oxazepam before you can stop taking it completely.

Things to be careful of

Be careful while driving or operating machinery until you know how oxazepam affects you.

This medicine may cause dizziness and tiredness in some people. If you have any of these symptoms, do not drive, or operate machinery or do anything else that is dangerous.

Even if you take oxazepam at night, you may still be drowsy or dizzy the next day.

Be careful when drinking alcohol while taking oxazepam.

Combining oxazepam and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking this medicine.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness, unsteadiness and/ or a drop in blood pressure which may increase the risk of a fall.

Some people may also become depressed or have problems breathing.

Sometimes people may also have problems remembering things.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking oxazepam or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following and they worry you.

This list includes the more common side effects. Mostly, these are mild:

- mild drowsiness, especially when you first start taking oxazepam. It generally becomes less noticeable as you continue to take the tablets. If it does not, then your doctor may lower your dose of oxazepam
- feeling exhausted or having no energy
- muscle weakness
- feeling sick, dizzy, giddy or light-headed
- stomach pain

- memory loss
- feeling confused or disoriented
- headache
- problems speaking, or feeling wobbly on your feet, possibly leading to falls
- trembling or shaking
- blurred vision
- skin rash, which may be itchy, or may look like a measles rash
- increased or decreased libido (sex drive).

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- sudden aggression, excitation or rage
- fainting
- depression
- hallucinations (seeing, feeling or hearing things that are not there) or delusions
- severe sleep disturbances or unpleasant dreams

- yellowing of the skin or eyes, and/or pale stools, dark urine (jaundice)
- fever
- numbness and tingling
- swelling of the hands, ankles or feet or other parts of the body
- low blood pressure
- frequent infections such as fever, severe chills, sore throat or mouth ulcers

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation

- occasionally the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide.

Make sure that you or anyone close to you or caring for you watch for these symptoms and tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences.

Unwanted side effects can occur with or without alcohol intake. Taking alcohol will increase the risk of side effects.

They can also occur at the dosage prescribed by your doctor. However, there is an increased risk of side effects if you take more tablets than the recommended dose.

These medicines should, in most cases, be used only for short periods of time. If your anxiety problems continue, consult your doctor.

Some medicines can cause dependence, especially when they are used regularly for longer than a few weeks. People who have been dependent on alcohol or other drugs in the past may have a higher chance of becoming addicted to benzodiazepines such as oxazepam. If you have been addicted to alcohol or drugs in the past, it is important to tell your doctor before starting oxazepam.

Withdrawal Symptoms

Sometimes when medicines are stopped suddenly, after being used for a long time, withdrawal symptoms may occur.

Symptoms of withdrawal may include muscle pain, sweating, vomiting, stomach or muscle cramps, sensitivity to light, touch or sound, headache, anxiety, tension, restlessness, confusion, giddiness, memory loss, strange thoughts or feelings, numbness, tingling, palpitations, panic attacks, mood changes, irritability or feeling not part of your body.

Speak to your doctor if any of the above occurs.

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell when you are taking, or soon after you have finished taking this medicine.

Allergic reactions

If you think you are having an allergic reaction to oxazepam, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing.
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What APO-Oxazepam looks like

APO-Oxazepam 30 mg Tablets

White, round tablets with one side convex and embossed "30", and the other side flat with an Ezi-split breakline.

Ingredients

Each tablet contains 30 mg of oxazepam as the active ingredient.

It also contains the following inactive ingredients:

- magnesium stearate
- methylcellulose
- polacrillin potassium
- lactose

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Oxazepam 30 mg Tablets

Blister packs containing 25 tablets:

AUST R 163213

Distributor

Apotex Pty Ltd

66 Waterloo Road

North Ryde, NSW 2113

Australia

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This leaflet was revised in:

June 2010