

APO-Lorazepam

lorazepam

Consumer Medicine Information

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

What is in this leaflet

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

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

APO-Lorazepam tablets contain the active ingredient lorazepam.

Lorazepam is used to relieve anxiety or used before surgery to help you relax. However, anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines.

Lorazepam belongs to a group of medicines called benzodiazepines, thought to work by their action on brain chemicals.

In general, benzodiazepines such as lorazepam, should be taken for short periods only (e.g. 2 to 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.

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

Your doctor may have prescribed it for another reason.

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

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing lorazepam
- any other medicine from the benzodiazepine group of medicines
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- 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

Do not take this medicine if you have any of the following medical conditions:

- severe and chronic lung disease
- sleep apnoea, a condition where you have breathing problems when you sleep
- depression with or without anxiety problems.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

Lorazepam passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to a child under the age of 16 years.

Safety and effectiveness in children younger than 16 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver, kidney or lung disease

- blood disorders
- fits or convulsions
- severe muscle weakness known as myasthenia gravis
- low blood pressure
- glaucoma (high pressure in the eye)
- depression, psychosis or schizophrenia

Tell your doctor if you drink alcohol regularly.

Alcohol may increase the effects of lorazepam.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

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 get without a prescription from your pharmacy, supermarket or health food shop.

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

- other sleeping tablets, sedatives or tranquillisers
- medicines for depression
- medicines for allergies for example antihistamines or cold tablets
- pain relievers
- muscle relaxants
- medicines to control fits.

These medicines may be affected by lorazepam 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 have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the directions, ask your doctor or pharmacist for help.

How much to take

The dose of lorazepam may be different for each person. Your doctor will decide the right dose for you.

For anxiety, the usual daily dose is 2 to 3 mg administered in divided doses. However, the daily dose can range from 1 to 10 mg.

For sleeping problems (insomnia) due to anxiety, a dose of 1 to 2 mg taken at bedtime is usually prescribed.

If you are taking lorazepam before surgery the usual dose is 2 to 4 mg the night before surgery. Another dose of 2 to 4 mg may also be given 1 to 2 hours before surgery.

Elderly people may need a lower dose.

How to take it

Swallow the tablets with a full glass of water.

When to take it

Take your medicine at about the same time each day.

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

It does not matter if you take this medicine before or after food.

How long to take it

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

Lorazepam is usually used for short periods only (e.g. 2 to 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.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

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 the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have missed more than two doses in a row, speak to your doctor or pharmacist.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

If you are taking this medicine for insomnia due to anxiety and forget to take it before you go to bed, do not take it if you wake up late in the night or early morning.

Taking lorazepam late at night or early in the morning may make it hard for you to wake in the morning.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include feeling drowsy, confused, tired, dizzy, weak, having difficulty breathing, or becoming unconscious.

While you are using this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

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 determine the best treatment for you.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Always discuss with your doctor any problems or difficulties you have during or after taking this medicine.

Tell your doctor if, 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.

Things you must not do

Do not drive or operate machinery until you know how this medicine affects you.

This medicine may cause drowsiness or dizziness in some people and therefore may affect alertness.

Make sure you know how you react to lorazepam before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

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

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

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

Stopping this medicine suddenly may cause some unwanted effects. Your doctor will slowly reduce your dose before you can stop taking it completely.

Do not suddenly stop taking this medicine if you suffer from epilepsy.

Stopping this medicine suddenly may make your epilepsy worse.

Do not take this medicine for a longer time than your doctor has prescribed.

Lorazepam should be taken for short periods only (e.g. 2 to 4 weeks), unless advised otherwise by your doctor.

Things to be careful of

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, symptoms such as dizziness and drowsiness may be worse.

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking lorazepam.

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

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

This medicine helps most people with anxiety, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- drowsiness
- dizziness
- sleepiness
- clumsiness or unsteadiness
- weakness
- loss of memory.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- feeling sick or vomiting
- outbursts of anger and increased excitement
- dry mouth
- excessive salivation
- changes in appetite
- nausea
- headache
- skin rashes
- confusion or depression
- sleep disturbances
- blurred vision
- low blood pressure

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Storage and Disposal

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store this 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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

APO-Lorazepam 0.5 mg

White, round tablets with rounded edges. AUST R 304303.

Available in blister packs of 100 tablets.

APO-Lorazepam 1 mg

White, round, flat, bevelled, scored tablets, with the inscription "1.0" on one side. AUST R 304306.

Available in blister packs of 50 tablets.

APO-Lorazepam 2.5 mg

White, round, flat, bevelled, scored tablets. AUST R 304307.

Available in blister packs of 50 tablets.

*Not all strengths are available.

Ingredients

This medicine contains 0.5, 1 or 2.5 mg of lorazepam as the active ingredient.

This medicine also contains the following:

- maize starch
- microcrystalline cellulose
- sodium starch glycollate (Type A)
- lactose monohydrate
- povidone
- crospovidone
- magnesium stearate
- polacrillin potassium

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Distributor

This medicine is distributed in Australia by:

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

Tel: (02) 8877 8333

Web: www1.apotex.com/au

This leaflet was prepared in June 2018.