

APO-LORAZEPAM TABLET

Lorazepam (1mg)

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What Apo-Lorazepam is used for

Apo-Lorazepam is useful for the short-term relief of manifestations of excessive anxiety in people with anxiety disorder.

How Apo-Lorazepam works

Apo-Lorazepam contains the active ingredient lorazepam. Apo-Lorazepam belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

Before you use Apo-Lorazepam

- When you must not use it

You must not use this medication, if you have any allergies to lorazepam, any other benzodiazepines, or any other ingredients in this medication. (See section **Product description**).

Do not take Apo-Lorazepam (lorazepam) if you have myasthenia gravis (weakness and rapid fatigue of muscles) or acute narrow angle glaucoma (increased pressure in the eye).

- Before you start to use it

Before you start to use this medication, your doctor should know if you have or have had any of the following conditions:

- any past drug abuse/ dependency history
- depression, psychosis (loss of contact with reality) or other mental illness
- suicidal attempts or thoughts
- liver or kidney problems
- elderly

This medication is not recommended for children and adolescent under the age of 18. Anaphylaxis (severe allergic reaction) and angioedema (severe facial swelling) might occur as early as the first time the product is taken.

Pregnancy and lactation

Do not take Apo-Lorazepam if you are pregnant, trying to get pregnant or think you may be pregnant. Do not take Apo-Lorazepam if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Taking other medicines

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

You should not take medications such as:

- other benzodiazepines
- barbiturates (medicines used to treat anxiety, sleeplessness, or seizures)
- medications that works on your central nervous system (CNS)

This is because some medication could cause complications when taken together with Apo-Lorazepam.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use Apo-Lorazepam

- How much to use

Generalised Anxiety Disorder: The recommended initial adult daily oral dosage is 2mg in divided doses of 0.5, 0.5 and 1.0mg, or of 1mg and 1mg. The daily dosage should be carefully increased or decreased by 0.5mg depending upon tolerance and response.

Usually, a daily dosage of 6mg should not be exceeded.

If you are elderly or debilitated, or if you are having liver or kidney problems, a lowered initial dose may be given, and to be gradually increased if needed and as tolerated.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Apo-Lorazepam should be taken for short periods only.

Initial course of treatment should not last longer than one week without reassessment by the doctor.

Continue taking Apo-Lorazepam for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

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Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think 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 lorazepam overdose may include drowsiness, confusion, lethargy and ataxia (loss of control of the body movement), hypotonia (low muscle tone), low blood pressure, hypnosis, coma, and, very rarely, death.

While you are using it

- Things you must do

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Lorazepam.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Your doctor will explain how you should slowly reduce your dose of Apo-Lorazepam before you can stop taking it completely.

Do not take any new medicines without consulting your doctor.

Do not give Apo-Lorazepam to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

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

This medication might also cause complex sleep-related behaviors which may include sleep driving, making phone calls, preparing and eating food (while asleep).

Side effects

Like all medicines, Apo-Lorazepam can cause side effects, although not everybody gets them.

Tell your doctor if you notice any of the following side effect and they worry you: drowsiness, dizziness, weakness, fatigue, lethargic, nausea, vomiting.

Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:

- symptoms of an allergic reaction e.g. rash or itching on the skin,

shortness of breath, wheezing or difficulty breathing, and swelling of hands, ankles or feet

- headache
- feeling irritated or excited
- hypotension
- mental confusion
- slurred speech
- abnormal liver and kidney function

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list. Other side effects not listed above may occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Apo-Lorazepam

- Storage

Keep out of the reach and sight of children.

Bottle: Store below 30°C. Protect from moisture.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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Product Description

- What it looks like

White capsule-shaped, flat-faced, beveled edged tablet. Scored and engraved APO 1 on one side, other side plain.

- Ingredients

- Active ingredient

Lorazepam

- Inactive ingredients

Lactose Monohydrate,
Microcrystalline Cellulose,
Croscarmellose Sodium, Magnesium
Stearate

- MAL number:

MAL19984741ARZ

Manufacturer

Apotex Incorporated,
150 Signet Drive,
Ontario, Canada
M9L 1T9

Product Registration Holder

Pharmaforte (M) Sdn Bhd
2, Jalan PJU 3/49
Sunway Damansara
47810 Petaling Jaya
Selangor

Date of revision

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