

PACKAGE LEAFLET: Information for the patient

CINARIZINE

Tablets – 25 mg or 75 mg

(Cinnarizine)

Read 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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 Cinarizine is and what it is used for
2. Before you take Cinarizine
3. How to take Cinarizine
4. Possible side effects
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1. WHAT CINARIZINE IS AND WHAT IT IS USED FOR

Cinnarizine is a H₁-receptor antagonist and a calcium-channel blocker. Cinnarizine inhibits the transmission of calcium ions in the smooth muscle cells of arteries and causes vasodilatation. Cinnarizine is an effective therapeutic agent for the treatment of labyrinth disorders. It has anti-vasoconstrictor activity and therefore it is used to improve symptoms caused by poor cerebral and peripheral perfusion. Cinnarizine does not affect blood pressure and heart rate.

Cinarizine tablets are indicated in:

- cerebral atherosclerosis symptoms (dizziness, tinnitus, vascular headaches, memory disorders);
- consequences of head trauma;
- consequences of cerebrovascular accidents;
- migraine;
- peripheral vascular disorders (arteritis obliterans, Buerger's disease, Raynaud's disease, diabetes, acrocyanosis, frostbite);
- treatment of nausea and vertigo caused by Meniere's disease and other disorders of the labyrinth;
- prevention of motion sickness (travel by motor vehicle, boat, airplane).

2. BEFORE YOU TAKE CINARIZINE

Do not take Cinarizine if:

- you are sensitive (allergic) to cinnarizine or to any of the other ingredients of Cinarizine;
- you suffer from Parkinson's disease;
- you have extrapyramidal motor system disorders;
- you have acute myocardial infarction;
- you suffer from porphyria.

Take special care with Cinarizine

Ask your doctor before you take Cinarizine if:

- you are pregnant or are planning to become pregnant, because it should not be used during pregnancy, especially during the first trimester;
- you have glaucoma;
- you have prostatic hypertrophy, pyloroduodenal obstruction, urinary retention;
- you suffer from liver disease;
- you have renal impairment;
- you suffer from epilepsy (high doses may induce seizures in epileptic patients);
- you suffer from hypotension because Cinarizine is not recommended in these cases;

- it will be used in children because, in such cases, it is recommended to be used only for short periods.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Cinarizine.

Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Cinarizine if you take any other medicine during treatment.

It is especially important that your doctor be aware of the fact that you are using or are being treated with:

- CNS sedatives, tricyclic antidepressants, opioid analgesics (cinnarizine can increase their sedative effect);
- vasodilators and other antihypertensives (because cinnarizine acts synergistically when combined with them);
- antiemetics, domperidone (cinnarizine also acts synergistically with it).

Because of its antihistaminic effects, cinnarizine may hide a positive reaction to dermal indicators. As such, cinnarizine should be stopped several days before skin testing.

Taking Cinarizine with food and drinks

Cinnarizine strengthens the sedative effect of alcohol and for this reason Cinarizine tablets should not be taken simultaneously with alcohol.

Pregnancy and breastfeeding

Ask for the advice of a pharmacist or doctor before taking this drug.

It is recommended to avoid the use of cinnarizine during pregnancy. Cinarizine should not be used during pregnancy, especially during the first trimester, so always consult your doctor before using Cinarizine during pregnancy.

Use of cinnarizine during breastfeeding is not recommended.

Driving and using machines

You should be careful while driving or using machinery until you see how Cinarizine affects

you. Cinarizine may reduce your ability to drive or use machinery due to side effects caused from its administration, such as blurred vision and drowsiness.

Important information about some of the ingredients of Cinarizine

Cinarizine tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking them.

3. HOW TO TAKE CINARIZINE

Always take Cinarizine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you notice that Cinarizine effects are too strong or too weak, talk to your doctor or pharmacist.

The tablets should be swallowed with at least half glass of water.

The dosage of Cinarizine is individual. Below is presented a practical overview for its dosage.

Vestibular disorders: 75 mg, 1 – 2 times daily.

In ocular circulatory disorders, 75 mg, 2 – 3 times daily.

Peripheral vascular disorders: 75 mg, 2 – 3 times daily.

In motion sickness prevention:

Adults and children over 12 years: 25 mg, 2 hours before travelling.

Children 5 - 12 years: half of the dose used for adults.

The maximum daily dose is 225 mg. However, the dose may need to be increased or reduced.

Your doctor will advise you accordingly.

If you take more Cinarizine

If you take more Cinarizine than you should, or if the children have taken it accidentally, please contact your doctor, the hospital, or any medical care site to seek advice on the risk and the appropriate measures.

If you forget to take Cinarizine

If you forget to take one dose (or more than one dose), take the next dose in its usual time. Do not take a double dose (or higher) to make up a forgotten dose(s).

If you have further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cinarizine can cause side effects, although not everybody gets them.

Sometimes they are serious, sometimes not. Do not get alarmed by this list of possible side effects. You may not get any of them.

Some of the side effects that may occur are:

- at the beginning of treatment with cinnarizine drowsiness may appear;
- gastrointestinal disturbances (nausea, vomiting, dry mouth, diarrhoea and epigastric pain), anorexia;
- headache, weight gain;
- blurred vision, urinary retention;
- allergic reactions;
- confusion, convulsions, depression, dizziness, extrapyramidal effects, sleep disturbances, tremor, sweating, hypotension;
- symptoms of incitement (paradoxal excitement);
- arrhythmias; blood disorders;
- long-term treatment can cause parkinsonism (in such cases treatment should be discontinued).

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.

5. HOW TO STORE CINARIZINE

Keep out of the sight and reach of children!

Do not use Cinarizine after the expiry date which is stated on the package.

Do not store above 25°C!

Keep in the original package to protect it from light and humidity.

6. FURTHER INFORMATION

What Cinarizine 25 mg Tablets contain

The active substance is cinnarizine.

Each tablet contains 25 mg cinnarizine.

The other ingredients: lactose, microcrystalline cellulose, talc, magnesium stearate and sodium starch glycolate.

Content of the pack: Box with 30 tablets.

What Cinarizine 75 mg Tablets contain

The active substance is cinnarizine.

Each tablet contains 75 mg cinnarizine.

The other ingredients: starch, lactose, microcrystalline cellulose, magnesium stearate, povidone, talc and sodium starch glycolate.

Content of the pack: Box with 50 tablets.

Marketing authorisation holder (MAH) and manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania

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This leaflet was last revised in August 2023.