

CINNARIZINE
15 mg TABLETS

PACKAGE LEAFLET:
INFORMATION FOR THE USER

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

This medicine is available without prescription. However, you still need to take Cinnarizine carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- These tablets are only for you. Never give them to anyone else.
- You must contact a doctor if your symptoms worsen or do not improve after 2-3 days.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

IN THIS LEAFLET

1. What Cinnarizine is and what it is used for
2. Before you take Cinnarizine
3. How to take Cinnarizine
4. Possible side effects
5. How to store Cinnarizine
6. Further information

1 WHAT CINNARIZINE IS AND WHAT IT IS USED FOR

- Cinnarizine tablets belong to a group of drugs known as antihistamines.
- Cinnarizine is used to:
 - control travel sickness
 - treat symptoms seen in Ménière's disease which include vertigo (a spinning feeling), tinnitus (a ringing in your ears) and feeling or being sick.

2 BEFORE YOU TAKE CINNARIZINE

Do NOT take Cinnarizine if you:

- are allergic (hypersensitive) to Cinnarizine or any of the other ingredients of this medicine
- have a hereditary metabolic disorder called porphyria (a deficiency of specific enzymes within the body, causing an increase in substances called porphyrins).

Take special care with Cinnarizine
Talk to your doctor or pharmacist before you start to take Cinnarizine Tablets if you:

- suffer from Parkinson's disease.

Taking other medicines

Talk to your doctor if you are taking any of the following:

- tricyclic antidepressant medication, or any other form of sedative.

If you need to have a skin test for allergies, tell your doctor that you are taking Cinnarizine tablets as these may affect the result. You should stop taking your tablets at least 4 days before you have the test.

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

If you see another doctor or visit a hospital, remember to tell them what medicines you are taking.

Taking Cinnarizine with food and drink

Do NOT drink alcohol while you are taking Cinnarizine tablets.

Pregnancy and breast-feeding

Cinnarizine is not recommended if you are pregnant, planning to become pregnant or breast-feeding. Ask your doctor for advice before taking this medicine.

Driving and using machines

Cinnarizine may cause dizziness and drowsiness. If affected do not drive or operate machinery.

Important information about some of the ingredients of Cinnarizine

Patients who are intolerant to **lactose** should note that Cinnarizine tablets contain a small amount of lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 HOW TO TAKE CINNARIZINE

If your doctor or pharmacist has prescribed this medicine, you should always take Cinnarizine exactly as they have told you. Otherwise, follow the instructions below. If you are not sure how to take this medicine, talk to your doctor or pharmacist. If your symptoms persist after taking this medicine, consult your doctor.

The tablets should be swallowed preferably with a drink of water. Cinnarizine tablets can cause indigestion or stomach upsets. Taking your tablets after food may help to reduce this.

The usual dose is:

Ménière's disease

- **Adults including the elderly and children over 12 years old**

Two tablets three times a day unless otherwise directed by your doctor.

- **Children aged 5 to 12 years**

Children aged 5 to 12 can take half the adult dose (one tablet, three times a day) unless otherwise directed by your doctor.

Travel sickness

- **Adults (including the elderly) and children over 12 years old**

When Cinnarizine tablets are used to treat travel sickness, the dose is two tablets two hours before you travel then one tablet every eight hours during the journey if necessary, unless otherwise directed by your doctor.

- **Children aged 5 to 12 years**

Children aged 5 to 12 can take half the adult dose (one tablet two hours before they travel then half a tablet every eight hours during the journey if necessary, unless otherwise directed by your doctor).

Children under five years of age should not take Cinnarizine tablets.

If you take more Cinnarizine than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause vomiting, drowsiness, coma, (unconsciousness) tremor (shaking) or hypotonia (floppy, relaxed state of muscles). Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Cinnarizine

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

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

4 POSSIBLE SIDE EFFECTS

Like all medicines, Cinnarizine can cause side effects, although not everybody gets them. If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

If the following rare side effect happens, tell your doctor at once:

- uncontrollable movements and tremors (extrapyramidal symptoms) may start or become worse, particularly if you are elderly and have been taking Cinnarizine tablets for a long time.

The following side effects have been reported at the approximate frequencies shown.

Common:

- drowsiness or stomach upsets. These side effects may disappear as your treatment continues.

Rarely:

- headaches, dry mouth, you may put on weight or sweat more than usual.

Very rarely:

- an extremely itchy skin condition known as lichen planus
- a condition which causes inflammation of the skin known as lupus, which may also affect your internal organs
- you may become jaundiced (where your skin and the white of your eyes go slightly yellow).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

5 HOW TO STORE CINNARIZINE

Keep out of the reach and sight of children.

Store in a cool dry place, in the original package. Do not use Cinnarizine after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

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.

6 FURTHER INFORMATION

What Cinnarizine tablets contain:

- The active ingredient is cinnarizine 15 mg
- The other ingredients are lactose, starch, povidone, isopropyl alcohol, magnesium stearate, pregelatinised starch and colloidal anhydrous silica (inactive ingredients).

What Cinnarizine tablets look like and contents of the pack:

- Cinnarizine Tablets are white with "CNZ 15" and a breakline on one side and a twin triangle logo on the reverse.
 - Cinnarizine Tablets come in a polypropylene tubular container with an open end equipped to accept a polyethylene closure with a tamper evident tear strip containing 7, 10, 14, 22, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 250, or 1000 tablets.
 - PVDC coated PVC/Aluminium blisters containing 7, 14, 21, 30, 50, 56, 60, 84, 90, 100, 112 or 120 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder is TEVA UK Limited, Eastbourne, BN22 9AG. Company responsible for manufacture: Teva Pharmaceutical Works Private Limited Company, 4042 Debrecen, Pallagi út 13, Hungary.

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APPROVALS

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