

CINNARIZINE 15 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 2-3 days.

What is in this leaflet

1. What Cinnarizine is and what it is used for
2. What you need to know before you take Cinnarizine
3. How to take Cinnarizine
4. Possible side effects
5. How to store Cinnarizine
6. Contents of the pack and other 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 What you need to know before you take Cinnarizine

Do not take Cinnarizine:

- if you are allergic to Cinnarizine or any of the other ingredients of this medicine (listed in section 6).
- if you have a hereditary metabolic disorder called porphyria (a deficiency of specific enzymes within the body, causing an increase in substances called porphyrins).

Warnings and precautions

Talk to your doctor or pharmacist before taking Cinnarizine Tablets

- if you suffer from Parkinson's disease.

Other medicines and Cinnarizine

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.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

Cinnarizine contains 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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. 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 recommended 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, this medicine 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: may affect up to 1 in 10 people

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

Rare: may affect up to 1 in 1,000 people

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

Very rare: may affect up to 1 in 10,000 people

- 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Cinnarizine

Keep this medicine out of the sight and reach of children.

Store below 25°C.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other 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.

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: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer: Teva Pharmaceutical Works Private Limited Company, 4042 Debrecen, Pallagi street 13, Hungary.

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