

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

CINNARIZINE TABLETS 25MG / 75MG TAJ PHARMA

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.
- 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 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.

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 belongs to a group of medicines called antihistamines.

Cinnarizine is used to control problems with balance (such as Meniere's disease) which can cause vertigo (a spinning sensation or dizziness), ringing in the ears, nausea (feeling sick), vomiting (being sick) and loss of hearing.

Cinnarizine can also help to control travel sickness.

This medicine is for use in adults and children aged over 5 years.

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).

Warnings and precautions

Talk to your doctor or pharmacist before taking Cinnarizine if you:

- Suffer from Parkinson's disease (Cinnarizine may make your symptoms worse).
- Need a skin allergy test, as Cinnarizine can affect the results. You will need to **stop** taking Cinnarizine 4 days before the test.
- Have a blood problem called porphyria.
- Have problems with your liver or

kidneys.

Other medicines and Cinnarizine Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, especially the following:

- medicines for depression called tricyclic antidepressants (*e.g.* amitriptyline, dosulepin, imipramine)
- Medicines that make you feel drowsy *e.g.* tranquillisers or painkillers.

Cinnarizine with alcohol

You should not drink alcohol during treatment as it may make you drowsier.

Pregnancy and breast-feeding

You **should not** take Cinnarizine if you are pregnant, think you may be pregnant or are trying to become pregnant. If you become pregnant while you are taking Cinnarizine you must stop taking the tablets immediately and tell your doctor. Cinnarizine may reach your baby through the breast milk. Therefore, you should not take Cinnarizine if you are breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine occasionally causes drowsiness, especially at the start of



treatment. If you feel drowsy **do not** drive or use 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 medicine.

3. HOW TO TAKE CINNARIZINE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Problems with balance:

Use in adults, elderly and adolescents over 12 years - Two tablets three times a day.

Use in children 5 – 12 years old - One tablet three times a day.

Travel sickness:

Use in adults, elderly and adolescents over 12 years - Two tablets taken two hours before your journey and if necessary, one tablet taken every eight hours during your journey.

Use in children 5 – 12 years old - One tablet two hours before your journey and if necessary, half a tablet every eight hours during your journey.

Use in children under 5 years - Cinnarizine is **not** recommended for children under the age of 5. These tablets may be sucked,

chewed or swallowed whole with water. Take these tablets after meals.

If you take more Cinnarizine than you should

If you accidentally take too many tablets or if a young child takes this medicine by accident, contact your doctor or nearest hospital emergency department immediately. You may be sick, feel sick or have an upset tummy, be shaking, have uncontrollable muscle spasms, weakness or floppy muscles, become drowsy or lose consciousness. Young children may also experience seizures.

If you forget to take Cinnarizine

Take the next dose as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Cinnarizine

Do not stop taking your treatment without talking to your doctor, even though you may feel better or if you feel the tablets are not working.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them

Stop taking Cinnarizine and seek medical help immediately if you have any of the following: Not known (cannot be estimated

from the available data)

- yellowing of the skin or whites of the eyes, dark urine, pale stools, tiredness, fever, nausea, weakness, drowsiness or abdominal pain. These may indicate you have serious problems with your liver
- red, lumpy, itchy rash which may also have some silvery scales on areas of skin exposed to sunlight
- allergic reactions such as a rash or swelling of the face, lips, tongue or throat, difficulty breathing

Other side effects:

Common (may affect up to 1 in 10 people)

- drowsiness
- feeling sick (nausea), indigestion
- increase in weight

Uncommon (may affect up to 1 in 100 people)

- lack of energy (lethargy), tiredness
- being sick
- pain in the upper stomach area
- excessive sweating
- patches of spots, red or pinkish skin, with a crust

Not known (cannot be estimated from the available data)

- Shaking, uncontrollable twitching or twisting movements, muscle stiffness, restless legs, stiff posture with a slow shuffling walk. You may also feel depressed
- headache



- dry mouth

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.

5. HOW TO STORE CINNARIZINE

Keep this medicine out of the sight and reach of children. This medicine does not require any special storage conditions. Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. 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 CONTAINS

a) Each uncoated modified-release tablet contains:

Cinnarizine	25mg
Excipients	q.s.

b) Each uncoated modified-release tablet contains:

Cinnarizine	75mg
Excipients	q.s.

What Cinnarizine looks like and contents of the pack

PVC/PVDC/Al blisters.

Pack sizes:

Blisters: 7, 14, 28, 30, 50, 90, 100 and 500mg modified-release tablets.

Not all pack sizes may be marketed.

7. MANUFACTURED IN INDIA BY:

TAJ PHARMACEUTICALS LTD.

Mumbai, India
Unit No. 214.Old Bake House,
Maharashtra chambers of Commerce Lane,
Fort, Mumbai - 400001
at:Gujarat, INDIA.

Customer Service and Product Inquiries:
1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00 p.m. EST

E-mail: tajgroup@tajpharma.com