

**PATIENT INFORMATION LEAFLET**  
**(VASTEN 25 & 75) CINNARIZINE TABLETS 25 MG & 75 MG**  
**[Cinnarizine BP]**

**Read all of this leaflet carefully before you start using this medicine.**

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others.

It may harm them, even if their symptoms 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 physician, health care provider or pharmacist.

**WHAT IS IN THIS LEAFLET:**

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

**1. WHAT CINNARIZINE TABLETS IS AND WHAT IT IS USED FOR**

It contain active ingredient cinnarizine, medicines known as antihistaminic agent. It is reported to possess smooth muscle relaxant properties and to inhibit vasoconstriction, and is thus used in the management of various vascular disorders. Sedative effects are not marked. Cinnarizine has been shown to be a non-competitive antagonist of the smooth muscle contractions caused by various vasoactive agents including histamine. Cinnarizine also acts on vascular smooth muscle by selectively inhibiting the calcium influx into depolarised cells, thereby reducing the availability of free  $Ca^{++}$  ions for the induction and maintenance of contraction. It is also indicated for control of vestibular symptoms of both peripheral and central origin and of labyrinthine disorders including vertigo, dizziness, tinnitus, nystagmus, nausea and vomiting. It is also used for prophylaxis of motion sickness.

**2. BEFORE YOU USE CINNARIZINE TABLETS**

It is contraindicated in patient history of serious hypersensitivity to cinnarizine or to any of excipients.

**Take special care with Cinnarizine tablets: Warnings and Precautions:** Talk to your physician before taking Cinnarizine tablets. Cinnarizine may cause epigastric discomfort; taking it after meals may diminish gastric irritation. In patients with Parkinson's disease, cinnarizine should only be given if the advantages outweigh the possible risk of aggravating this disease. Use of cinnarizine should be avoided in porphyria. Cinnarizine should be used with care in patients with hepatic or renal insufficiency. Cinnarizine may cause somnolence, especially at the start of treatment. Therefore caution should be taken when alcohol, central nervous system (CNS) depressants or tricyclic antidepressants are used concomitantly. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take cinnarizine. Diagnostic interference: Because of its antihistamine effect, cinnarizine may prevent otherwise positive reactions to dermal reactivity indicators if used up to 4 days prior to skin testing.

**Using other medicines:** Tell your physician if you are taking cinnarizine may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, tricyclic antidepressants, sedatives and tranquillisers. The side-effects of anticholinergic substances such as atropine and tricyclic antidepressants may be enhanced by the concomitant administration of antihistamines. Monoamine-oxidase inhibitors may enhance the antimuscarinic effects of antihistamines. **Using cinnarizine tablets with food and drink:** It should not take with alcohol. **Pregnancy and breast-feeding:** Before taking any medicine for advice consult to direction of **physician. Pregnancy:** Safety of cinnarizine in human pregnancy has not been established although studies in animals have not demonstrated teratogenic effects. As with other drugs, it is not advisable to administer cinnarizine in pregnancy. **Use in breast-feeding:** There are no data on the excretion of cinnarizine in human breast milk; use of Cinnarizine is not recommended in nursing mothers. **Driving and using machines:** It may cause drowsiness, especially at the start of treatment; patients affected in this way should not drive or operate machinery. **Important information about some of the ingredients of cinnarizine tablets contains excipients with known effects:** Mannitol: May have a mild laxative effect. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. Talk to your physician.

### 3. HOW TO USE CINNARIZINE TABLETS

It should be taken as directed by physician. Take your normal dose immediately and continue taking your tablets at the usual time of day, do not take a double dose to make up for the missed dose. Do not change your usual dose without talking to physician. **Method of administration:** *For oral use only.* It should be preferably taken after meals or as directed by physician. It should be swallowed with a glass of water. **The usual recommended doses:** The maximum recommended dosage should not exceed 225 mg daily. **Adults and children over the age of 12 years:** **Peripheral circulatory disorders:** 75 mg, two to three times daily. **Disorders of balance:** 25 mg three times daily or 75 mg once a day. The maximum recommended dosage should not exceed 225 mg daily. If necessary the dosage may be divided over 2 or 3 intakes per day. As the effect of Cinnarizine tablets on vertigo is dose dependent, the dosage should be increased progressively. **Motion Sickness: Adults:** One tablet of 25 mg half an hour before traveling; to be repeated every 6 hours. **Children 8 to 12 years:** Half a tablet (12.5 mg) three times daily when necessary.

**If you more Cinnarizine tablets than you should:** If you accidentally take too many tablets, contact your Physician immediately. Acute cinnarizine overdoses have been reported with doses ranging from 90 to 2,250 mg. The most commonly reported signs and symptoms associated with overdose include: alterations in consciousness ranging from somnolence to stupor and coma, vomiting, extrapyramidal symptoms, and hypotonia. In a small number of young children, seizures developed. Clinical consequences were not severe in most cases, but deaths have been reported after single and polydrug overdoses involving Cinnarizine. Treatment: There is no specific antidote. For any overdose, the treatment is symptomatic and supportive care. Activated charcoal may be given if considered appropriate. **If you forget to Cinnarizine tablets:** If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten tablet. If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

#### 4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. Immune system disorders: Hypersensitivity. Nervous system disorders: Somnolence, dyskinesia, extrapyramidal disorder, parkinsonism, tremor, Gastrointestinal disorder; dry mouth. Skin and subcutaneous tissue disorders: Lichen planus, subacute cutaneous lupus erythematosus, Lichenoid keratosis. Musculoskeletal and connective tissue disorders: Muscle rigidity.

#### 5. HOW TO STORE CINNARIZINE TABLETS

Keep this medicine out of the sight and reach of children. Store below 30°C. Protect from light. 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. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

#### 6. FURTHER INFORMATION

It contain active substances as cinnarizine BP. Each uncoated tablet contains: Cinnarizine USP 25 mg/75 mg. **Excipients:** Mannitol, Microrystalline cellulose (PH 102), Croscarmellose Sodium, Ess. Pineapple Powder, Aspartame, Colloidal Anhydrous silica (Aerosil), Magnesium Stearate. **Pack size:** White coloured, round shaped, flat, uncoated tablets, plain on one side and break line on other side, 10 Tablets are packed in a Alu-PVC blister Pack. Such 10 Alu-PVC blisters are packed in a printed carton along with packing insert.

##### Manufactured by:

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