CINNARIZINE TABLETS 25 MG

POM

COMPOSITION:
Each uncoated tablet contains:

Cinnarizine BP	25 mg
Excipients	Q.S.

PHARMACOLOGICAL CLASSIFICATION:
Antihistamine agent

PHARMACOLOGICAL ACTION:
Cinnarizine's action in the treatment of peripheral vascular disease is due to its anti-vasoconstrictor properties, its action on blood hyperviscosity and its anti-ischaemic effect. Anti-vasoconstriction is thought to be through a calcium blocker mechanism and is evident selectively in vascular smooth muscle. Increased peripheral muscle blood flow may be mediated by prevention of calcium entry into ischaemic erythrocytes, thereby preserving flexibility.

Pharmacokinetic:

Absorption: The peak plasma levels of cinnarizine are obtained 1 to 3 hours after intake.
Distribution: The plasma protein binding of cinnarizine is 91%.
Metabolism: Cinnarizine is extensively metabolized mainly via CYP2D6 in the liver.
Elimination: The reported elimination half-life for cinnarizine ranges from 4 to 24 hours. The elimination of *metabolites occurs as follows:* about one third in the urine and two thirds in the faeces. Plasma elimination half life is 3 to 4 hours.

INDICATIONS:
Cinnarizine tablet indicate 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.

CONTRAINDICATIONS:
Cinnarizine Tablets are contra-indicated in patients with known hypersensitivity to cinnarizine.

SPECIAL PRECAUTIONS AND WARNING:
As with other antihistamines, 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.
There have been no specific studies in hepatic or renal dysfunction. 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.
Effects on ability to drive and use machines: Cinnarizine may cause drowsiness, especially at the start of treatment; patients affected in this way should not drive or operate machinery.
Pregnancy: The 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.
Lactation: There are no data on the excretion of Cinnarizine in human breast milk; use of Cinnarizine is not recommended in nursing mothers.

DOSAGE AND DIRECTIONS FOR USE:

Cinnarizine tablet 25 mg should preferably be taken after meals.

Adults and children over the age of 12 years:

Peripheral circulatory disorders: 2-3 tablets (50 mg – 75 mg) two to three times daily.

Disorders of balance: One tablet (25 mg) three times daily.

The maximum recommended dosage should not exceed 225 mg (9 tablets) 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.

ADVERSE EFFECTS:

Immune system disorders: Hypersensitivity.

Nervous system disorders: Somnolence, dyskinesia, extrapyramidal disorder, parkinsonism, tremor.

Gastrointestinal disorders: Gastrointestinal disorder; dry mouth.

Skin and subcutaneous tissue disorders: Lichen planus, subacute cutaneous lupus erythematosus, lichenoid keratosis.

Musculoskeletal and connective tissue disorders: Muscle rigidity.

DRUG INTERACTIONS:

Concurrent use of alcohol, CNS depressants or tricyclic antidepressants may potentiate the sedative effects of either these drugs or of Cinnarizine.

OVERDOSAGE:

Symptoms: 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 of Cinnarizine 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.

PRESENTATION:

Blister pack / Jar pack.

STORAGE INSTRUCTIONS:

Store below 30°C. Protect from light.

DATE OF PUBLICATION:

01.07.2014

Manufactured by :

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E-PI0714