CIN 25
Cinnarizine Tablets 25 mg

QUALITATIVE AND QUANTITATIVE COMPOSITION:
Label claim:
Each uncoated tablet contains:
Cinnarizine BP 25 mg
Excipients q.s.
Colour: Indigo Carmine

List of excipients:
Lactose BP
Microcrystalline Cellulose BP
Maize Starch BP
Purified Talc BP
Magnesium Stearate BP
Sodium Starch Glycolate BP
Colloidal Anhydrous Silica BP
Indigo Carmine

INDICATION:
CIN 25 is indicated in peripheral vascular disease when such symptoms as intermittent claudication and cold extremities exist and in vasospastic disorders.

PHARMACEUTICAL FORM:
Light blue coloured, round shaped, biconvex, uncoated tablet plain on both sides.

DOSAGE AND ADMINISTRATION:
Route of Administration: Oral
Peripheral Vascular Disease:
The usual dose is 50 to 75 mg (2-3 tablets) two to three times daily.
CIN 25 should preferably be taken after meals. These doses should not be exceeded.
Peripheral arterial disease is slow to improve with any form of drug treatment. Maximum benefits with CIN 25 will not be seen until after several weeks of continuous treatment although significant improvement in blood flow has frequently been demonstrated after 1 week.

CONTRAINDICATION:
CIN 25 Tablets are contra-indicated in patients with known hypersensitivity to cinnarizine.

SPECIAL WARNING AND PRECAUTION FOR USE:
As with other antihistamines, CIN 25 may cause epigastric discomfort; taking it after meals may diminish gastric irritation.
CIN 25 has not been found to reduce blood pressure significantly. However, the drug should be used with reasonable caution in hypotensive patients.
In patients with Parkinson's disease CIN 25 should only be given if the advantages outweigh the possible risk of aggravating this disease.
CIN 25 may cause somnolence, especially at the start of treatment. Therefore, caution should be taken when alcohol or CNS depressants or tricyclic antidepressants are used concomitantly.
Diagnostic Interference:
Because of its antihistamine effect, CIN 25 may prevent an otherwise positive reaction to dermal reactivity indicators if used within 4 days prior to testing.
Use of cinnarizine should be avoided in porphyria.
There have been no specific studies in hepatic or renal dysfunction. CIN 25 should be used with care in patients with hepatic or renal insufficiency.
Patients with rare hereditary problems of fructose or galactose intolerance, LAPP lactase deficiency, glucose-galactose malabsorption or sucrase-isomaltase insufficiency, should not take this medicine because it contains lactose and sucrose.

ADVERSE REACTION:
The following ADRs have been observed from clinical trials and post-marketing experiences reported with the use of CIN 25. Frequencies displayed use the following convention:
Very common (1/10); common (1/100 to < 1/10); uncommon (1/1,000 to < 1/100); rare (1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

System Organ Class	Adverse Drug Reactions		
	Frequency Category		
	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1000 to < 1/100)	Not Known
Nervous System Disorders	Somnolence	Hypersomnia; Lethargy	Dyskinesia; Extrapyramidal disorder; Parkinsonism; Tremor
Gastrointestinal Disorders	Nausea	Stomach discomfort; Vomiting; Abdominal pain upper; Dyspepsia	
Skin and Subcutaneous Tissue Disorders		Hyperhydrosis; Lichenoid keratosis	Lichens planus; Subacute cutaneous lupus erythematosus
Musculoskeletal and connective Tissue Disorders			Muscle rigidity
General Disorders and Administration Site Conditions		Fatigue	
Investigations	Weight increased		

INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:
Concurrent use of alcohol, CNS depressants or tricyclic antidepressants may potentiate the sedative effects of either these drugs or of CIN 25.
Diagnostic Interference:
Because of its antihistamine effect, CIN 25 may prevent an otherwise positive reaction to dermal reactivity indicators if used within 4 days prior to testing.

PREGNANCY AND LACTATION:
Pregnancy:
The safety of CIN 25 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 CIN 25 in pregnancy.
lactation:
There are no data on the excretion of CIN 25 in human breast milk; use of CIN 25is not recommended in nursing mothers.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
CIN 25 may cause drowsiness, especially at the start of treatment; patients affected in this way should not drive or operate machinery.

OVERDOSE:
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.

PHARMACOLOGICAL PROPERTIES:
PHARMACOKINETICS:
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 metabolised mainly via CYP2D6 in the liver.
Excretion
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.

PHARMACODYNAMICS:
Pharmacotherapeutic group: Antivertigo preparations
ATC code: N07CA02
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.

PACKAGING:
10 tablets are packed in an Alu-Alu blister and such 10 blisters are packed in a printed carton along with pack insert.

STORAGE CONDITION:
Store in dry place below 30°C. Keep out of reach of children.

SHELF LIFE:
36 Months

MANUFACTURED BY:
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