1. Name of the medicinal Product

Cinnarizine Tablets 75 mg

1.1 Strength

75 mg/tablet

1.2 Pharmaceutical Form

Oral Tablets

2. Qualitative and Quantitative Composition

2.1 Qualitative declaration

Cinnarizine BP

2.2 Quantitative declaration

Sr. No	Ingredients Chemical Name	Specification	Quantity (mg/tablet)	Reason for Inclusion
1	Cinnarizine (A)	BP	75.00	Antihistaminic agent
2	Mannitol	BP	78.00	Diluent
3	Microrystalline cellulose (PH 102) (C)	BP	100.00	Disintegrant
4	Croscarmellose Sodium	USP-NF	15.00	Disintegrant
5	Ess. Pineapple Powder	In-house	7.000	Flavoring agent
6	Aspartame	BP	15.00	Sweetening Agent
7	Colloidal Anhydrous silica (Aerosil)	BP	5.000	Glidant
8	Magnesium Stearate	BP	5.000	Lubricant

3. Pharmaceutical Form

Oral Tablets

A White to off-white coloured, round shaped, flat, uncoated tablet, break line on one side and plain on other side.

4. Clinical Particulars

4.1 Therapeutic Indications

Cinnarizine tablet indicate for control of vesti bul ar 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.

4.2 Posology

Cinnarizine tablet should preferably be taken after meals.

Adults and children over the age of l2 years:

Peripheral circulatory disorders: 75 mg, two to three times daily.

Disorders of balance: 25 mg three times daily or 75mg 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.

4.3 Method of Administration

Oral Route

4.4 Contraindications

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

4.5 Special Warnings and Special Precautions for Use

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.

4.6 Paediatric Population

Children:

Children 8 to 12 years: Half a tablet (12.5 mg) three times daily when necessary.

4.7 Interaction with other medicinal products and other forms of interaction

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

4.8 Additional information on special populations

No specific Information

4.9 Paediatric Population

No specific Information

4.10 Pregnancy and Lactation

4.10.1 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.

4.10.2 Lactation

There are no data on the excretion of Cinnarizine in human breast milk; use of Cinnarizine is not recommended in nursing mothers.

4.11 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.

4.12 Undesirable 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.

4.13 Overdose

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.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Cinnarizine's action in the treatment of peripheral vascular disease is due to its antivasoconstrictor properties, its action on blood hyperv iscosity 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.

5.2 Pharmacokinetic Properties

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 CYP20 6 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.

5.3 Preclinical Safety Data

Not Applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

Mannitol

Microrystalline cellulose (PH 102) (C)

Croscarmellose Sodium

Ess. Pineapple Powder

Aspartame

Colloidal Anhydrous silica (Aerosil)

Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

Store below 30°C. Protect from light.

6.5 Nature and Contents of Container

10 tablets are packed in Alu-PVC blister pack. Such 10 Alu-PVC blisters pack are packed in a printed carton along with package insert.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses

7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com;
Web site: www.lincolnpharma.com

7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com;
Web site: www.lincolnpharma.com

8. Marketing Authorization Number

Rwanda FDA-HMP-MA-0324

9. Date of First <Registration> / Renewal of The <Registration>

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10. Date of Revision of the Text

May,2023

11. Dosimetry (If Applicable)

Not Applicable

12. Instructions for preparation of radiopharmaceuticals

Not Applicable