

CARINTM

Loratadine Tablet 10mg

PRODUCT DESCRIPTION

Carin Tablet 10mg is a white to off-white, oval-shaped tablet, with a break line on one side and plain on the other side.

COMPOSITION

Each Carin Tablet 10mg contains 10 mg of Loratadine.
Excipients: Microcrystalline Cellulose, Magnesium Stearate, Lactose, Silicon Dioxide and Croscarmellose Sodium.

PHARMACODYNAMICS

Loratadine is a non-sedative histamine H₁ receptor antagonist with anti-allergic properties. It binds selectively to peripheral histamine H₁ receptors with a lower affinity to brain H₁ receptors. It is a long-acting antihistamine with little anti-muscarinic activity.

PHARMACOKINETICS

Loratadine is rapidly and almost completely absorbed after oral administration. Loratadine is about 98% bound to plasma proteins. It crosses the placental barrier and is detected in the human breast milk. Loratadine is extensively and rapidly metabolized in the liver to form a major metabolite, descarboethoxyloratadine. Descarboethoxyloratadine has potent histamine H₁ blocking activity. Loratadine and its metabolites are excreted in the urine and faeces.

INDICATIONS

Loratadine is indicated for the relief of symptoms with allergic rhinitis e.g. sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching and burning. It is also indicated for the relief of signs and symptoms of chronic urticaria and other allergic dermatological disorders.

SIDE EFFECTS/ADVERSE REACTIONS

Adverse effects reported are fatigue, dizziness, dry mouth, headache, sedation, nausea and pruritus. Somnolence, alopecia, anaphylaxis and abnormal hepatic function have been reported rarely.

PRECAUTIONS/WARNINGS

Patients with severe liver impairment should be given a lower initial dose because they may have reduced clearance of Loratadine.

Pregnancy and Lactation: The safe use of Loratadine during pregnancy has not been established. Therefore, Loratadine should only be given if the potential benefit justifies the potential risk to the fetus.

Breast Feeding: Loratadine is excreted in the breast milk, so nursing mothers are advised not to take the drug.

CONTRAINDICATIONS

Carin Tablet 10mg is contraindicated in patients who have shown hypersensitivity or idiosyncrasy to any of its components.

DRUG INTERACTIONS

When administered concomitantly with alcohol, Loratadine has no potentiating effects as measured by psychomotor performance studies. Co-administration with drugs that inhibit or are metabolized by hepatic cytochromes P450 3A4 and 2D6 may elevate the plasma concentrations of either drug. Increased plasma concentrations of Loratadine has been reported when used concomitantly with ketoconazole, erythromycin and cimetidine.

RECOMMENDED DOSAGE

Adults and Children ≥ 12 years:

1 tablet (10 mg) once daily.

Children 6 - 12 years: 1 tablet (10 mg) once daily.

Children 2 - 5 years: half tablet (5 mg) once daily.

Not recommended for children under 2 years of age.

Patients with severe liver impairment:

An initial dose of 5mg once daily or 10 mg every other day is recommended.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE AND ANTIDOTE(S)

Nausea, vomiting, drowsiness, hypotension, tachycardia and ataxia have been reported in overdosage. Treatment of overdosage should be supportive and symptomatic. This may include induction of emesis, gastric lavage to decrease absorption and the use of saline cathartics to enhance elimination.

Storage conditions

Store below 30°C in a cool dry place.

Protect from excessive moisture.

Keep medicines out of reach of children.

Jauhi ubat-ubatan daripada kanak-kanak.

Route Of administration : Oral

Shelf Life

Please refer to outer package

Availability

Blister packs of 100's and 500's.

Not all pack size is marketed locally.

Product Registration Holder :

DUOPHARMA MANUFACTURING (BANGI) SDN. BHD.

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