Alertadin™

Desloratadine

COMPOSITION

Alertadin : Each film-coated tablet contains Desloratadine INN 5 mg.

PHARMACOLOGICAL INFORMATION

Pharmacological action

Alertadin (Desloratadine)is an active metabolite of loratadine. It is long acting tricyclic histamine antagonist. Alertadin (Desloratadine) inhibits histamine release from human mast cells. Alertadin (Desloratadine)does not readily enter the brain from the blood and, therefore, causes less drowsiness. It is a member of a small family of non-sedating antihistamines.

Mechanism of Action

Alertadin (Desloratadine)is an oral, long-acting antihistamine. It is used to treat the symptoms caused by histamine. Histamine is a chemical, that is responsible for many of the signs and symptoms of allergic reactions. For example, swelling the lining of the nose, sneezing, and itchy eyes. Histamine is released from histamine-storing cells (mast cells) and then attaches to other cells that have receptors for histamine. The attachment of the histamine to the receptors causes the cell to be "activated" releasing other chemicals which produce the effects that we associate with allergy. Alertadin (Desloratadine)blocks one type of receptor for histamine (the H_1 receptor) and thus prevents activation of H_1 receptor-containing cells by histamine.

PHARMACOKINETICS

Absorption: Oral administration of Alertadin (Desloratadine)5 mg once daily for 10 days to normal healthy persons, the mean time to maximum plasma concentrations (T_{max}) occurred at approximately 3 hours and mean steady state peak plasma concentrations (C_{max}) and area under the concentration-time curve (AUC) of 4 ng/mL and 56.9 ng·hr/mL were observed, respectively. Neither food nor grapefruit juice had an effect on the bioavailability (C_{max} and AUC) of Desloratadine (Alertadin). Water has no effect on the bioavailability (AUC and C_{max}) of Alertadin (Desloratadine)tablets.

Distribution: Alertadin (Desloratadine)and 3-hydroxydesloratadine are approximately 82% to 87% and 85% to 89%, bound to plasma proteins respectively. Protein binding of Alertadin (Desloratadine)and 3-hydroxydesloratadine was unaltered in subjects with impaired renal function.

Metabolism: Desloratadine (a major metabolite of loratadine) is extensively metabolized to 3-hydroxydesloratadine, an active metabolite, which is subsequently glucuronidated. The enzyme(s) responsible for the formation of 3-hydroxydesloratadine have not been identified.

Elimination: The mean elimination half-life of Desloratadine is 27 hours. Cmax and AUC values increased in a dose proportional manner following single oral doses between 5 and 20 mg. The degree of accumulation after 14 days of dosing was consistent with the half-life and dosing frequency. A human mass balance study documented a recovery of approximately 87% of the 14 C-desloratadine dose, which was equally distributed in urine and feces as metabolic products.

CLINICAL INFORMATION

Therapeutic Indications

Seasonal Allergic Rhinitis: Alertadin (Desloratadine)is indicated for the relief of the nasal and non-nasal symptoms of seasonal allergic rhinitis in patients with 2 years of age and older.

Perennial Allergic Rhinitis: Alertadin (Desloratadine)is indicated for the relief of the nasal and non-nasal symptoms of perennial allergic rhinitis in patients with 6 months of age and older.

Chronic Idiopathic Urticaria: Alertadin (Desloratadine)is indicated for the symptomatic relief of pruritus, reduction in the number of hives, and size of hives, in patients with chronic idiopathic urticaria

6 months of age and older.

Dosage and Administration
Adults and children 12 years of age and over: The recommended dose of Alertadin (Desloratadine)tablet is once daily.
Children 6 to 11 years of age: Alertadin (Desloratadine)tablet is recommended 2.5 mg once daily.

Use in pregnancy and lactation
There is no experience of the use of Alertadin (Desloratadine)during pregnancy. Alertadin (Desloratadine)is excreted in human milk. The amount of Alertadin (Desloratadine)antihistamine presents in milk although not known as harmful.

Side-effects
Most common side-effects are fatigue, drowsiness, dry mouth, headache, and gastrointestinal disturbances.

Contraindications
Alertadin (Desloratadine)5 mg is contraindicated in patients who are hypersensitive to this medication or to any of its ingredients, or to loratadine.

Precautions
Antihistamine should be used with caution in hepatic diseases and dose reduction may be necessary in renal impairment. Caution may be required in epilepsy. Children and the elderly are more susceptible to side effects.

Drug Interaction
No clinically important drug interactions have been reported.

Overdose and treatment
In the event of overdose, consider standard measures to remove any unabsorbed drug. Symptomatic and supportive treatment is recommended.

PHARMACEUTICAL INFORMATION
Storage condition
Store in a cool and dry place away from light. Keep out of reach of children.

Presentation & Packaging
Alertadin : Each commercial box contain 100 tablets in Alu-PVC blister pack.

Manufactured By
BEACON®
Pharmaceuticals PLC
Bhaluka, Mymensingh, Bangladesh

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