Allertin

Bilastine INN

Composition

Allertin 20 Tablet: Each tablet contains Bilastine INN 20 mg.
Allertin ODT 10: Each orally disintegrating tablet contains Bilastine INN 10 mg.
Allertin Oral Solution: Each ml oral solution contains Bilastine INN 2.5 mg.

Pharmacology

Bilastine is a non-sedating, long-acting histamine antagonist with selective peripheral H_1 receptor antagonist affinity and no affinity for muscarinic receptors. Bilastine inhibits histamine-induced wheal and flare skin reactions for 24 hours following single doses.

Indication

Seasonal Allergic Rhinitis: Bilastine is indicated for the symptomatic relief of nasal and non-nasal symptoms of seasonal allergic rhinitis (SAR) in patients of 4 years and older.
Chronic Spontaneous Urticaria: Bilastine is indicated for the relief of the symptoms associated with chronic spontaneous urticaria (CSU) (e.g. pruritus and hives), in patients of 4 years of age and older.

Dosage & Administration

Allertin 20 Tablet: Adults and adolescents 12 years of age and above: 20 mg tablet once daily. The tablet should be taken one hour before or two hours after intake of food.
Allertin Oral Solution: 4 ml of oral solution once daily for children 4 to 11 years of age. Recently, it has been approved in Latin America for children from 2 years of age. The oral solution should be taken one hour before or two hours after intake of food or fruit juice.
Allertin ODT 10: The maximum recommended daily dose for children in between 4 to 11 years is 10 mg Bilastine orally disintegrating tablet (1 tablet) and should not be exceed. If a dose is missed, the next scheduled dose should be taken. An extra dose is not necessary **or as directed by the physician**.

Contraindication

Bilastine is contraindicated in patients with hypersensitivity to Bilastine or to any ingredient in the formulation or component of the tablet.

Warnings & Precautions

Bilastine should be avoided in subjects with moderate or severe renal impairment.

Side Effects

Common: Drowsiness, headache.
Rare: Anxiety, Increased appetite, Asthenia, Diarrhoea, Dry mouth, Dyspnea, Fever, Gastritis, Gastrointestinal discomfort, Insomnia etc.

Use in Pregnancy & Lactation

There are no adequate and well-controlled studies on pregnant women. Until such data become available, Bilastine should be avoided during pregnancy, unless advised by a physician.
It is unknown whether Bilastine is excreted in human breast milk. A decision to continue/discontinue breastfeeding or to continue/discontinue therapy with Bilastine should be made taking the benefit of Bilastine therapy to the mother into account.

Use in Children & Adolescents

The safety and efficacy of Bilastine in children & adolescent have not been established.

Drug Interaction

Ketoconazole or Erythromycin
Concomitant administration of Bilastine and Ketoconazole or Erythromycin increases Bilastine AUC 2-fold and C_{max} 2-3-fold.
Diltiazem
Concomitant administration of Bilastine and Diltiazem 60 mg increases C_{max} of Bilastine by 50%.
Lorazepam
Concomitant intake of Bilastine and Lorazepam 3 mg for 8 days does not potentiate the depressant CNS effects of Lorazepam.

Overdose

Information regarding acute overdose is limited. After administration of Bilastine at doses 10 to 11 times the therapeutic dose (220 mg as single dose; or 200 mg/day for 7 days) to healthy volunteers, frequency of treatment emergent adverse events are two times higher than with placebo. The adverse reactions most frequently reported are dizziness, headache and nausea. In the event of overdose, symptomatic supportive treatment is recommended.

Storage

Store below 30^0C, protected from light & in a dry place. Keep all medicines out of the reach of children.

Packing

Allertin 20 Tablet: Each box contains 3X10 tablets in Alu-Alu blister pack and an insert.
Allertin ODT 10: Each box contains 3X10 tablets in Alu-Alu blister pack and an insert.
Allertin Oral Solution: Each box contains a bottle of 60 ml oral solution, a measuring cup and an insert.

Manufactured by:
Navana Pharmaceuticals Ltd.
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