Apex™ Pharma

Bilaxe

Bilastine

Composition

Bilaxe Kids 10 Tablet: Each tablet contains Bilastine INN 10 mg.
Bilaxe 20 Tablet: Each tablet contains Bilastine INN 20 mg.
Bilaxe 60 ml Oral Solution: Each 5 ml oral solution contains Bilastine INN 12.5 mg.

Pharmacology

Bilastine is an antihistamine. Its principal effects are mediated via selective inhibition of peripheral H_1 receptors. The antihistaminic activity of Bilastine has been documented in a variety of animal and human models. It shows moderate to high affinity for histamine H_1-receptors and no affinity for muscarinic, serotonergic, dopaminergic and noradrenergic receptors.

Indication

Allergic Rhinitis: Bilastine is indicated for the symptomatic relief of nasal and non-nasal symptoms of allergic rhinitis. *Allergic Rhino-conjunctivitis:* Bilastine is indicated for the relief of the symptoms associated with allergic rhino conjunctivitis. *Urticaria:* Bilastine is indicated for the relief of the symptoms associated with urticaria (e.g. pruritus and hives).

Dosage & Administration

Route of administration: Oral. Bilaxe Oral Solution: *Children between 2 to 11 years:* 4 ml once daily. **Bilaxe Kids 10 Tablet:** *Children between 6 to 11 years:* 10 mg Tablet once daily. **Bilaxe 20 Tablet:** *Adults & adolescents (12 years of age and over):* 20 mg Tablet once daily. To achieve optimal exposure to Bilastine, once daily dose should be taken with water on an empty stomach.

Contraindication

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

Precaution

Bilastine should be taken cautiously in case of moderate to severe renal impairment.

Side Effect

The most common side effects of Bilastine include: headache, dizziness, and fatigue.

Use in Pregnancy & Lactation

There are no adequate and well-controlled studies in pregnant women. Until such data becomes available, this drug should be avoided during pregnancy, unless advised otherwise by a physician.

Use In children & adolescent

Children (<2 years of age): The safety and efficacy of this drug in children under 2 years of age have not been established.
Adolescents (>65 years of age): No dosage adjustments are necessary in patients over 65 years.

Drug Interaction

a) With medicine: Concomitant intake of Ketoconazole, Erythromycin or Diltiazem increases the concentration of this drug. The psychomotor performance after concomitant intake of alcohol and this drug was similar to that observed after the intake of alcohol and placebo. Concomitant intake of this drug and Lorazepam 3 mg for 8 days did not potentiate the depressant CNS effects of Lorazepam.
b) With food and others: Food significantly reduces the oral bioavailability of this drug by 30%. Interaction with grapefruit juice: concomitant intake of this drug and grapefruit juice decreased bioavailability by 30%. This effect may also apply to other fruit juices.

Overdose

Information regarding acute overdose of Bilastine is retrieved from the experience of clinical trials conducted during the development and the post-marketing surveillance. In clinical trials, 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, the frequency of treatment emergent adverse events was two times higher than with placebo. The adverse reactions most frequently reported were dizziness, headache and nausea. No serious adverse events and no significant prolongation in the QTc interval were reported.

Storage

Keep away from light & moisture and store below 30° C. Keep all medicine out of the reach of children.

Packaging

Bilaxe Kids 10 Tablet: Each box contains 3 x 10's tablets in blister pack.
Bilaxe 20 Tablet: Each box contains 3 x 10's tablets in blister pack.
Bilaxe 60 ml Oral Solution: Each box contains a pet bottle containing 60 ml oral solution & a measuring cup.

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Manufactured by: **Apex Pharma Limited**; Shafipur, Kaliakair, Gazipur, Bangladesh