Bilaxe

Bilastine INN 20 mg

Composition
Bilaxe 20 mg Tablet: Each tablet contains Bilastine INN 20 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
Adults & adolescents (12 years of age and over): 20 mg tablet once daily for symptomatic relief of allergic rhinitis, urticaria and allergic rhino conjunctivitis. The maximum recommended daily dose is 20 mg Bilastine (1 tablet) and should not be exceeded. If a dose is missed, the next scheduled dose should be taken. An extra dose should not be taken. 20 mg Bilastine tablet (1 tablet) once daily should be swallowed with water on an empty stomach to achieve optimal exposure to Bilastine.

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 become available, Bilastine should be avoided during pregnancy, unless advised otherwise by a physician.

Drug Interaction
Interaction with Ketoconazole or Erythromycin: Concomitant intake of Bilastine and Ketoconazole or Erythromycin increased Bilastine AUC 2-fold and Cmax 2-3-fold. These changes can be explained by interaction with intestinal efflux transporters, since Bilastine is substrate for P-gp and not metabolized. These changes do not appear to affect the safety profile of Bilastine and Ketoconazole or Erythromycin, respectively. Other medicinal products that are substrates or inhibitors of P-gp, such as Cyclosporine, may likewise have the potential to increase plasma concentrations of Bilastine.
Interaction with Diltiazem: Concomitant intake of Bilastine 20 mg and Diltiazem 60 mg increased Cmax of Bilastine by 50%. This effect can be explained by interaction with intestinal efflux transporters and does not appear to affect the safety profile of Bilastine.
Interaction with Alcohol: The psychomotor performance after concomitant intake of Alcohol and 20 mg Bilastine was similar to that observed after intake of Alcohol and placebo.
Interaction with Lorazepam: Concomitant intake of Bilastine 20 mg and Lorazepam 3 mg for 8 days did not potentiate the depressant CNS effects of Lorazepam.

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 out of the reach of children.

Packaging
Bilaxe 20 mg Tablet: Each box contains 3 x 10's tablets in Alu-Alu blister pack.

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