Bilasi®

Bilastine

COMPOSITION:

Bilasi ® 20 Tablet: Each film coated tablet contains Bilastine INN 20 mg.
Bilasi ® Syrup: Each 5 ml syrup contains Bilastine INN 12.5 mg.

PHARMACOLOGY:

Bilastine is an antihistamine. Its principal effects are mediated via selective inhibition of peripheral H1-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 H1-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 Rhinoconjunctivitis: Bilastine is indicated for the relief of the symptoms associated with allergic rhinoconjunctivitis.
Urticaria: Bilastine is indicated for the relief of symptoms associated with Urticaria.
Bilastine is also used to relieve the symptoms of hay fever (sneezing, itchy, runny, blocked-nose and red and watery eyes).

DOSE & ADMINISTRATION:

Adults and adolescents (12 years of age and over): 20 mg (1 tablet) once daily.
Children between 2 to 11 years: 4 ml (Syrup) once daily.
Elderly: No dosage adjustments are required for elderly patients.
The maximum recommended daily dose of Bilastine is 20 mg which should be taken one hour before or two hours after intake of food. If a dose is missed, the next schedule dose should be taken. An extra dose should not be taken.

CONTRA-INDICATION:

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

WARNING AND PRECAUTION:

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

SIDE EFFECTS:

Generally Bilastine is well tolerated. Side effects which may occur are headache, somnolence, dizziness, fatigue, anxiety, vertigo, abdominal pain.

USE IN PREGNANCY & LACTATION:

Pregnancy: 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.
Lactation: It is not known whether Bilastine is excreted in human breast milk. So caution should be exercised if it is administered to a nursing mother.

USE IN CHILDREN & ADOLESCENTS:

The safety and efficacy of Bilastine in children under 12 years of age have not been established.

DRUG INTERACTION:

Concomitant use of Bilastine with Ketoconazole, Erythromycin, Cyclosporine or Diltiazem increases the concentration of Bilastine. But these changes do not appear to affect the safety profile of any of the drugs.
Concomitant intake of Alcohol and Bilastine 20 mg shows same psychomotor performance similar to that of Alcohol and Placebo. 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 QT interval were reported. The information collected in the post-marketing surveillance is consistent with that reported in clinical trials.

STORAGE:

Store in a dry and cool place below 30^0 C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Bilasi ® 20 Tablet: Each box contains 2 x 10's tablets in Alu-PVDC blister pack
Bilasi ® Syrup: Each bottle contains 60 ml syrup and 10 ml measuring cup.

Manufactured by
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