Bilista™

Bilastine

COMPOSITION
Bilista™ 20 Tablet: Each tablet contains Bilastine INN 20 mg.

PHARMACOLOGY
Bilastine is a potent, effective, non-sedating, long-acting histamine antagonist with selective & high affinity to H_1 receptor (3 times higher than Cetirizine and 5 times higher than Fexofenadine). Even at a high concentration, Bilastine does not show affinity for the 30 other receptors including muscarinic, serotonergic, dopaminergic and noradrenergic receptors, nor for the other histamine receptor subtypes (H_2, H_3 and H_4). It shows excellent safety profile and very favorable pharmacokinetic characteristics.
Bilastine doesn't undergo any metabolism to be active. Bilastine is excreted by feces (non systemic) & urine (systemic) approximately 66.35% & 28.31% respectively.

INDICATION
Bilista™ is indicated for the symptomatic treatment of
- Allergic rhino-conjunctivitis (seasonal and perennial) and
- Urticaria.

Bilastine is also used to relieve the symptoms of hay fever (sneezing, itchy, runny, blocked-nose and red and watery eyes).

DOSAGE & ADMINISTRATION
- Adults and adolescents (12 years of age and over): 20 mg (1 tablet) once daily.
- Children under 12 years: The safety and efficacy in children under 12 years have not been established yet.
- 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.

USE IN PREGNANCY & LACTATION
Fertility: Limited data available. Study in rats did not indicate any negative effect.
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. Animal studies do not indicate major direct or indirect harmful effects with respect to reproductive toxicity, parturition or postnatal development.
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.

CONTRAINDICATION
Hypersensitivity to the active substance of Bilastine or to any of the excipients.

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

PRECAUTION
Treatment with Bilastine 20 mg does not affect the driving performance. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.
In clinical trials elderly patients (≥ 65 years) showed no difference in efficacy or safety with respect to younger patients.
The maximum plasma concentration of Bilastine after administration of 20 mg in patients with severe renal impairment is below the safety threshold of most common adverse effects and cardiac or CNS safety. No dosage adjustment is necessary in patients with renal impairment.
Bilastine is not metabolized in human. Since renal elimination is the major excretion, biliary excretion is expected to be only marginally involved in the elimination of Bilastine. Changes in liver function are not expected to have a clinically relevant influence.

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. Intake of alcohol and 20 mg Bilastine 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.

STORAGE CONDITION
Store below 30^0 C, protected from light & moisture. Keep out of reach of children.

HOW SUPPLIED
Bilista™ 20 Tablet: Each box contains 20 tablets in blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH