Bilista™

Bilastine INN

COMPOSITION

Bilista™ 20 Tablet: Each tablet contains Bilastine INN 20 mg.
Bilista™ **Kids** Tablet: Each Orodispersible tablet contains Bilastine INN 10 mg.
Bilista™ **Oral Solution**: Each ml solution contains Bilastine INN 2.5 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: Bilastine 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 between 2 to 11 years: 4 ml oral solution once daily or 10 mg orodispersible tablet 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.

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 recommended dose of Bilastine 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 recommended dose 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. Keep out of reach of children.

HOW SUPPLIED

Bilista™ 20 Tablet: Each box contains 20 tablets in blister pack.
Bilista™ **Kids** Tablet: Each box contains 30 tablets in blister pack.
Bilista™ **Oral Solution**: Each bottle contains 50 ml oral solution & a measuring cup.

Manufactured by

SQUARE
PHARMACEUTICALS PLC.
BANGLADESH