Bilfast

Bilastine INN 20 mg

COMPOSITION

Each film coated tablet contains Bilastine INN 20 mg.

PHARMACOLOGY

Bilastine is a non-sedating, long-acting histamine antagonist with selective peripheral H_1 receptor antagonist affinity and no affinity for muscarinic receptors. Bilastine inhibits histamine-induced wheal and flare skin reactions for 24 hours following single doses.

INDICATION

Bilastine is indicated for symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria.

DOSAGE & ADMINISTRATION

The tablet should be swallowed with water one hour before or two hours after intake of food or fruit juice.

Adults and adolescents (12 years of age and over): 20 mg Bilastine (1 tablet) once daily for the relief of symptoms of allergic rhinoconjunctivitis and urticaria.

CONTRAINDICATIONS

Bilastine is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients of the tablet.

WARNING AND PRECAUTION

Co-administration of Bilastine and P-glycoprotein inhibitors (e.g. Ketoconazole, Erythromycin, Cyclosporine, Ritonavir or Diltiazem) should be avoided in patients with moderate or severe renal impairment.

SIDE EFFECTS

The most commonly reported side effects in clinical trial are headache, dizziness, somnolence and fatigue. These adverse events occurred with a comparable frequency in patients receiving placebo.

DRUG INTERACTION

Concomitant intake of Bilastine and Ketoconazole or Erythromycin or Diltiazem increased C_{max} of Bilastine. The psychomotor performance after concomitant intake of alcohol and Bilastine was similar to that observed after intake of alcohol and placebo. Concomitant intake of Bilastine and Lorazepam 3 mg for 8 days did not potentiate the depressant CNS effects of Lorazepam.

USE IN PREGNANCY & LACTATION

There are no or limited amount of data from the use of Bilastine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity, parturition or postnatal development. As a precautionary measure, it is preferable to avoid the use of Bilastine during pregnancy.

The excretion of Bilastine in milk has not been studied in humans. A decision must be made taking into account the benefit of breast-feeding for the child and the benefit of Bilastine therapy for the mother.

USE IN CHILDREN & ADOLESCENTS

Efficacy and safety of Bilastine in children under 2 years of age have not been established and there is little clinical experience in children aged 2 to 5 years, therefore Bilastine should not be used in these age groups.

OVER DOSAGE

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) 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 below 30°C temperature, protected from light and moisture. Keep out of the reach of children.

PACKAGING

Each box contains 30's tablets in Alu-Alu blister pack.

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Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Comilla, Bangladesh.

NIPRO JMI Pharma