



Bilastine INN

COMPOSITION

Bilfast Tablet: Each film coated tablet contains Bilastine INN 20 mg.

Bilfast Kids Tablet: Each orodispersible tablet contains Bilastine INN 10 mg.

Bilfast Oral Solution: Each ml oral solution contains Bilastine INN 2.5 mg.

PHARMACOLOGY

Bilastine is a non-sedating, long-acting histamine antagonist with selective peripheral H₁ 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

It should be taken one hour before or two hours after intake of food or fruit juice.

Adults and Adolescents (≥12 years): 20 mg (1 tablet) once daily.

Children of 6 - 11 years (≥20 kg): 10 mg (1 tablet) or 4 ml once daily.

Children of <6 years (<20 kg): Should not be used in this age group.

CONTRAINDICATIONS

It is contraindicated in patients with hypersensitivity to Bilastine or to any of the excipients of it.

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, nausea, drowsiness and abdominal pain. These side effects 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. There is little clinical experience in children aged 2 to 5 years, therefore Bilastine should not be used in these age groups.

OVERDOSAGE

In the event of overdose symptomatic and supportive treatment is recommended. There is no known specific antidote to Bilastine.

STORAGE

Store below 30°C temperature in a dry place. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Bilfast Tablet: Each box contains 30 tablets in Alu-Alu blister pack.

Bilfast Kids Tablet: Each box contains 30 tablets in Alu-Alu blister pack.

Bilfast Oral Solution: Each Amber PET bottle contains 40 ml oral solution.

Manufactured by:

NIPRO JMI Pharma Ltd.

Chauddagram, Cumilla, Bangladesh.