

Composition : Mylastin Tablet : Each Film Coated Tablet Contains Bilastine INN 20mg.

Description : 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.

Indications : 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 with urticaria (e.g. pruritus and hives).

Dosage and administration : Adults & adolescents (12 years of age and over): 20mg bilastine (1 tablet) once daily for the relief of symptoms of allergic rhinoconjunctivitis and urticaria. The maximum recommended daily dose is 20mg (1 tablet) and should not be exceeded. If a dose is missed, the next scheduled dose should be taken. An extra dose should not be taken. 20mg tablet once daily should be swallowed with water on an empty stomach to achieve optimal exposure to Bilastine. Or, as directed by the registered physician.

Contraindication : It is contraindicated in patients with hypersensitivity to Bilastine or any other components in this medicine.

Precautions : Caution should be exercised when using this medicine in patients with moderate or severe renal impairment, co-administration of bilastine with P-gp inhibitors eg, ketoconazole, erythromycin, cyclosporine, ritonavir etc.

Side effects : Bilastine rarely causes serious side effects. These include : Feeling sleepy & headache.

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Use in Pregnancy and lactation : Pregnancy category C. There are no adequate & well controlled studies in pregnant women. It should be avoided by pregnant women. It is not known whether this medicine is excreted in human breast milk.

Use in Child : The safety & Effectiveness of this medicine in pediatric patients under 12 years of age have not been established.

Drug Interactions : Bilastine should not be administered together with other food, grapefruit juice, ketoconazole or erythromycin, diltiazem, alcohol, lorazepam.

Overdose : In clinical trials, after administration of Bilastine at doses 10 to 11 times the therapeutic dose (220mg as single dose; or 200mg/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 : Store below 30°C in a dry place.

Packing : Mylastin Tablet : Each box contains 2 x 14's tablet in blister pack.