Biltin™

Bilastine INN tablet

DESCRIPTION

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

INDICATIONS

Biltin™ is used for Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. It is also used to relieve the symptoms of hayfever (sneezing, itchy, runny, blocked-up nose and red and watery eyes) and other forms of allergic rhinitis. It may also be used to treat itchy skin rashes (hives or urticaria).

DOSAGE AND ADMINISTRATION

Adults and adolescents (12 years of age and over): 20 mg (1 tablet) once daily for the relief of symptoms of allergic rhinoconjunctivitis and urticaria. The tablet should be taken by oral route one hour before or two hours after intake of food or fruit juice. It is recommended to take the daily dose in one single intake.

Elderly: No dosage adjustments are required in elderly patients. There is little experience in patients above the age of 65.

Children under 12 years: The safety and efficacy of bilastine in children under 12 years of age have not yet been established.

Duration of treatment: For allergic rhinitis the treatment should be limited to the period of exposure to allergens. For seasonal allergic rhinitis treatment could be discontinued after the symptoms have resolved and reinitiated upon their reappearance. In perennial allergic rhinitis continued treatment may be proposed to the patients during the allergen exposure periods. For urticaria the duration of treatment depends on the type, duration and course of the complaints.

CONTRAINDICATIONS

Hypersensitivity to the active substance bilastine.

SIDE EFFECTS

• Somnolence • Headache

PRECAUTION AND WARNING

Efficacy and safety of bilastine in children under 12 years of age have not been established. In patients with moderate or severe renal impairment coadministration of bilastine with P-glycoprotein inhibitors, such as e.g, ketoconazole, erythromycin, cyclosporine, ritonavir or diltiazem, may increase plasmatic levels of bilastine and therefore increase the risk of adverse effects of bilastine. Therefore, coadministration of bilastine and P-glycoprotein inhibitors should be avoided in patients with moderate or severe renal impairment.

USE IN PREGNANCY AND 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. It is unknown whether bilastine is excreted in human breast milk. The excretion of bilastine in milk has not been studied in human. A decision on whether to continue/discontinue therapy with bilastine should be made taking into account the benefit of breast-feeding to the child and the benefit of bilastine therapy to the mother.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Biltin™ Tablet: Box containing 2 strips of 10 tablets each. Each tablet contains Bilastine INN 20 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

TM TRADEMARK

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