

Billerg-20

Bilastine Syrup

Quantitative composition : Billerg Syrup : Each ml contains Bilastine 2.5mg

Billerg tablet : Each uncoated tablet contains Bilastine 20mg

Pharmacology: Pharmacotherapeutic group: Antihistamines for systemic use, other antihistamines for systemic use. ATC code R06AX29. Bilastine is a non-sedating second generation H₁-antihistamine, 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 dose.

Pharmacokinetics:

Absorption: Bilastine is rapidly absorbed after oral administration with a time to maximum plasma concentration of around 1.3 hours. No accumulation is observed. The mean value of bilastine oral bioavailability is 61%.

Distribution: At therapeutic doses bilastine is 84-90% bound to plasma proteins.

Metabolism: Bilastine is not significantly metabolized in humans and is largely eliminated unchanged both in urine and feces.

Excretion: Bilastine is largely eliminated unchanged both in urine and feces – a third and two thirds of the administered dose, respectively. Ninety six percent of the administered dose is eliminated within 24 hours.

Renal impairment: Pharmacokinetic changes are not expected to have a clinically relevant influence on the safety of bilastine, since bilastine plasma levels in patients with renal impairment are within safety range of bilastine.

Hepatic impairment: Bilastine is not metabolized in human. Changes in liver function are not expected to have a clinically relevant influence on bilastine pharmacokinetics.

Indications: Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. Indicated in children aged 2 to 11 years with a body weight of at least 15kg.

Posology and method of administration:

Method of administration: Oral use

Paediatric population: Children 2 to 11 years of age with a body weight of at least 15 kg: 10 mg Bilastine (4 ml of oral solution) once daily for the relief of symptoms of allergic rhinoconjunctivitis (seasonal allergic rhinitis and perennial allergic rhinitis) and urticaria

Adults and 12 years of age and above: Bilastine 20mg (One tablet) once daily

Duration of treatment: For allergic rhino-conjunctivitis 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.

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

Special population: Elderly: No dosage adjustments are required in elderly patients.

Renal impairment: No dosage adjustments are required.

Hepatic impairment: No dosage adjustment is required in patients with hepatic impairment.

Children under 2 years of age and under 15 kg: Not recommended.

Contraindications: Hypersensitivity to the active substance or to any of the excipient

Special warnings and precautions for use: Paediatric population: Bilastine should not be used in children under 2 years of age or with a body weight below 15 kg. Co-administration of Bilastine and P-glycoprotein inhibitors (Ketoconazole, Erythromycin, Cyclosporine, Ritonavir or Diltiazem) should be avoided in patients with moderate or severe renal impairment. Caution should be exercised when administering Bilastine to patients who are at increased risk of experiencing QT/QTc-prolongation. This includes patients with a history of cardiac arrhythmias, Patients with hypokalemia, Hypomagnesaemia, Hypocalcemia, Patients with known prolongation of the QT interval or significant bradycardia, Patients with concomitant use of other medicinal products associated with QT/QTc-prolongation.

Interaction with other medicinal products and other forms of interaction: Interaction with food: Food significantly reduces the oral bioavailability of bilastine 20 mg tablets by 30% and that of bilastine 2.5 mg/ml oral solution by 20%.

Interaction with grapefruit juice: Concomitant intake of Bilastine 20 mg and grapefruit juice decreased Bilastine bioavailability by 30%. This effect may also apply to other fruit juices

Interaction with Ketoconazole or Erythromycin: Concomitant intake of bilastine 20 mg O.D and ketoconazole 400 mg O.D or erythromycin 500 mg t.i.d. increased bilastine AUC 2-fold and C_{max} 2-3-fold. These changes can be explained by interaction with intestinal efflux transporters, since bilastine is a substrate for P-gp and not metabolised.

Interaction with Diltiazem: Concomitant intake of bilastine 20 mg o.d. and diltiazem 60 mg O.D. increased C_{max} of bilastine by 50%. This effect can be explained by interaction with intestinal efflux transporters and does not appear to affect the safety profile of Bilastine.

Fertility, pregnancy and lactation: As a precautionary measure, it is preferable to avoid the use of Bilastine during pregnancy. Pharmacokinetic data have shown excretion of Bilastine in milk. A decision on whether to continue/discontinue breast-feeding or to discontinue/abstain from Bilastine therapy must be made taking into account, the benefit of breast-feeding for the child and the benefit of Bilastine therapy for the mother. A study in rats did not indicate any negative effect on fertility.

Effects on ability to drive and use machines: Individual response to the medicinal product may vary and patients should be advised not to drive or use machines until they have established their own response to Bilastine.

Adverse reactions: Headache, Somnolence and allergic conjunctivitis are common side effects. Dizziness, Tinnitus, Vertigo, Oral herpes, Increased appetite, Anxiety, Insomnia, Right bundle branch block, Sinus arrhythmia, Electrocardiogram QT prolonged, Other ECG abnormalities, Dyspnoea, Nasal discomfort, Nasal dryness, Upper abdominal pain, Abdominal pain, Nausea, Stomach discomfort, Diarrhoea, Dry mouth, Dyspepsia, Gastritis, Pruritus, Fatigue, Thirst, Improved pre-existing condition, Pyrexia, Asthenia, Increased gamma -glutamyltransferase, Alanine aminotransferase increased, Aspartate aminotransferase increased, Blood creatinine increased, Blood triglycerides increased and Increased weight are uncommon adverse effects.

Overdose and Treatment: The adverse reactions most frequently reported were dizziness, headache and nausea. No serious adverse events and no significant prolongation in the QTc interval. In the event of overdose, symptomatic and supportive treatment is recommended and there is no known specific antidote to Bilastine.

Presentation: Billerg 20mg uncoated tablets: ALU-ALU blister pack of 3x10's, packed in printed unit carton along with literature insert.

Billerg syrup: A well labeled amber coloured PET bottle, in a unit box along with literature insert.

Shelf life: 2 years from the date of manufacture.

Storage: Do not store above 30°C. Protect from direct sunlight. Keep all medicines out of reach of children.

Distribution category: Prescription only medicine (POM).



Manufactured for: Dawa Limited Plot No. 7879/8, Baba Dogo Road, Ruaraka. P. O. Box 16633-00620, Nairobi, Kenya.
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