Bilan™

Tablet/Orally Disintegrating Tablet/ Oral Solution

Bilastine INN

Composition

Bilan™ 20 mg Tablet: Each tablet contains Bilastine INN 20 mg.
Bilan™ Kids (10 mg Orally Disintegrating Tablet): Each Orally Disintegrating Tablet contains Bilastine INN 10 mg.
Bilan™ 2.5 mg/ml Oral Solution: Each ml Oral Solution contains Bilastine INN 2.5 mg.

Pharmacology

Bilastine is an antihistamine. It's principal effects are mediated via selective inhibition of peripheral H_1- receptors.The antihistaminic activity of Bilastine has been documented in a variety of animal and human models. It shows moderate to high affinity for histamine H_1-receptors and no affinity for muscarinic, serotonergic, dopaminergic and noradrenergic receptors.

Indications

Allergic Rhinitis: Bilan™ is indicated for the symptomatic relief of nasal and non-nasal symptoms of allergic rhinitis.
Allergic Rhinoconjunctivitis: Bilan™ is indicated for the relief of the symptoms associated with allergic rhinoconjunctivitis.
Urticaria: Bilan™ is indicated for the relief of the symptoms associated with urticaria (e.g.pruritus and hives).

Dosage and Administration

Route of administration: Oral
Adults & adolescents (12 years of age and over): 20 mg once daily for symptomatic relief of allergic rhinitis, urticaria and allergic rhinoconjunctivitis. The maximum recommended daily dose is 20 mg Bilan™ once daily and should not be exceeded. If a dose is missed, the next scheduled dose should be taken. An extra dose should not be taken. 20 mg Bilan™ once daily should be swallowed with water on an empty stomach to achieve optimal therapeutic effect.
Children (Between 2 to 11 years): 10 mg once daily (10 mg orally disintegrating tablet: once daily or 2.5 mg/ml oral solution: 4 ml once daily) for the symptomatic relief of allergic rhinoconjunctivitis and urticaria in children aged 2 to 11 years with a body weight of at least 20 kg. Orally disintegrating tablet is for oral use only. It should be placed in the mouth. It will disperse rapidly in saliva without any water and can be easily swallowed. The orally disintegrating tablet should be taken one hour before or two hours after intake of food or fruit juice.

Use in Patients with Impaired Hepatic & Renal Function

There is no clinical experience in patients with hepatic impairment. Since Bilastine is not metabolized and renal clearance is its major elimination route, hepatic impairments not expected to increase systemic exposure above the safety margin. Therefore, no dosage adjustment is required in patients with hepatic impairment. No dosage adjustment is required in patients with renal impairment.

Contraindications

Bilastine is contraindicated in patients with hypersensitivity to Bilastine or to any ingredient of the tablet.

Warnings and Precautions

Bilastine should be taken cautiously in case of moderate to severe renal impairment.

Side Effects

Common Side effects : The most common side effects of Bilastine include headache, dizziness and fatigue.
Rare Side effects : Allergic reactions, fever, chills, body aches and cough.

Use in Pregnancy and Lactation

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Until such data become available, Bilastine should be avoided during pregnancy, unless advised by a physician.
Lactation: It is not known whether Bilastine secreted in the breast-milk or not. So, caution is advised.

Use in Children & Adolescents

The safety and efficacy of Bilastine in children under 2 years of age have not been established.

Use in Geriatrics

No dosage adjustments are necessary in patients over 65 years.

Drug Interactions

With medicine:
Interaction with Ketoconazole and Erythromycin: Concomitant intake of Bilastine and Ketoconazole or Erythromycin 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 substrate for P-gp and not metabolized. Other medicinal products that are substrates or inhibitors of P-gp, such as Cyclosporine, may likewise have the potential to increase plasma concentrations of Bilastine.
Interaction with Diltiazem: Concomitant intake of Bilastine 20 mg and Diltiazem 60 mg increased C_{max} of Bilan by 50%. This effect can be explained by interaction with intestinal efflux transporters and does not appear to affect the safety profile of Bilastine.
Interaction with Lorazepam: Concomitant intake of Bilastine 20 mg and Lorazepam 3 mg for 8 days did not potentiate the depressant CNS effects of Lorazepam.
With food & others: Bilastine tablets should not be taken with food or with grapefruit juice or other fruit juices, as this will decrease the effect of Bilastine.

Overdose

Information regarding acute overdose of Bilastine is retrieved from the experience of clinical trials conducted during the development and the post-marketing surveillance. 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) to healthy volunteers, the frequency of treatment emergent adverse events were two times higher than with placebo. The adverse reactions most frequently reported were dizziness, headache and nausea.

Storage

Store below 30^0 C temperature and dry place, protected from light.
Keep of all medicines out of reach of children.

Packing

Bilan™ 20 mg Tablet: Each box contains 3×10 tablets in Alu-Alu blister strips.
Bilan™ Kids (10 mg Orally Disintegrating Tablet): Each box contains 2×10 tablets in Alu-Alu blister strips.
Bilan™ 2.5 mg/ml Oral Solution: Each amber PET bottle contains 50 ml Oral Solution with a measuring cup.

*** Further information is available on request.**

Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness