

Bilargo

Bilastine INN



Composition

Bilargo 20 Tablet: Each tablet contains Bilastine INN 20 mg.
Bilargo 10 ODT: Each orally dispersible tablet contains Bilastine INN 10 mg.
Bilargo OS: Each ml oral solution contains Bilastine INN 2.5 mg.

Description

Bilastine is a non-sedating, long-acting H1 receptor selective antagonist. Its effects are mediated via selective inhibition of peripheral H1-receptors. It shows moderate to high affinity for histamine H1-receptors and no affinity for muscarinic, serotonergic, dopaminergic and noradrenergic receptors. Bilastine inhibits histamine induced flare skin reactions for 24 hours following single doses.

Indications

Bilastine is indicated for the symptomatic relief of symptoms of allergic rhinitis, rhinoconjunctivitis and urticaria (pruritus and hives).

Dosage and Administration

Children between 2 to 11 years:

For the symptomatic relief of allergic rhinitis, allergic rhinoconjunctivitis and urticaria,
• Bilargo OS: 4 ml oral solution once daily.
• Bilargo 10 ODT: 10 mg orally dispersible tablet once daily.

Adults & adolescents (12 years of age and over):

For the symptomatic relief of allergic rhinitis, allergic rhinoconjunctivitis and urticaria,
• Bilargo 20 Tablet: 20 mg Tablet once daily.
To achieve optimal exposure to Bilastine, once daily dose should be taken with water on an empty stomach.

Contraindications

Bilastine is contraindicated in patients with hypersensitivity to Bilastine or to any ingredient in the formulation or component.

Warnings and Precautions

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 common side effects of Bilastine include: headache, dizziness and fatigue.

Drug Interactions

Concomitant intake of Bilastine and Ketoconazole, Erythromycin or Diltiazem increased C_{max} of Bilastine. The psychomotor performance after concomitant intake of alcohol and Bilastine was similar to that observed after the 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 Specific Population

Use in pregnancy and lactation: There are no adequate and well-controlled studies in pregnant women. Until such data becomes available, Bilastine should be avoided during pregnancy, unless advised otherwise by a physician.

Geriatrics (>65 years of age): No dosage adjustments are necessary in patients over 65 years.

Pediatrics (<2 years of age): The safety and efficacy of Bilastine in children under 2 years of age have not been established.

Overdosage

No serious adverse events have been reported in case of overdosage. However, in the event of overdosage, symptomatic and supportive treatment have been reported.

Storage

Do not store above 30°C. Store in a dry place & protect from light. Keep out of reach of children.

Packaging

Bilargo 20 Tablet: Each box contains 3x10's tablets in blister pack.
Bilargo 10 ODT: Each box contains 3x10's tablets in blister pack.
Bilargo OS: Each box contains a bottle of 50 ml oral solution.

Manufactured by



Ziska Pharmaceuticals Ltd.

Kaliakoir, Gazipur, Bangladesh