

# Bilosen

## Bilastine INN

### COMPOSITION:

**Bilosen 20 Tablet:** Each film coated tablet contains Bilastine INN 20 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 dose.

### INDICATIONS:

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

### DOSAGE AND ADMINISTRATION:

**Adults & adolescents (12 years of age and above):** For the symptomatic relief of allergic rhinitis, allergic rhinoconjunctivitis, and urticaria, Bilastine 20 mg Tablet once daily.

**Solution: Children Between 2 to 11 years:** 4 ml once daily

To achieve optimum exposure to Bilosen, once daily dose should be taken on an empty stomach.

### CONTRAINDICATIONS:

Bilosen is contraindicated in patients with known hypersensitivity to Bilastine and/or any other ingredients of the formulation.

### WARNINGS AND PRECAUTIONS:

Co-administration of Bilosen and P-glycoprotein inhibitors (e.g. Ketoconazole, Erythromycin, Cyclosporine, Ritonavir, Diltiazem) should be avoided in patients with moderate to severe renal impairment.

### SIDE-EFFECTS:

The most common side-effects of Bilastine like headache, dizziness, and fatigue have been reported.

### DRUG INTERACTIONS:

Concomitant intake of Bilastine and Ketoconazole, Erythromycin or Diltiazem increases the C<sub>max</sub> of Bilastine. The psychomotor performance after concomitant intake of alcohol and Bilastine is similar to the intake of alcohol and placebo. Concomitant intake of Bilastine and Lorazepam does not potentiate the depressant CNS effects of Lorazepam.

### USE IN SPECIFIC POPULATION:

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

**Geriatrics (>65 years of age):** No dosage adjustment is required 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 over dosage. However, in the event of overdosage, symptomatic and supportive treatment is recommended.

### STORAGE:

Store below 30°C temperature in a dry place. Keep away from light. Keep out of the reach of children.

### PACKING:

**Bilosen 20 Tablet:** Each box contains 30 tablets in Alu-Alu blister strip.

Manufactured by:

**Novatek Pharmaceuticals Ltd.**

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**NOVATEK**