



# Bilbest

Bilastine INN

## Composition

**Bilbest 20 mg Tablet:** Each film coated tablet contains Bilastine INN 20 mg.

**Bilbest 60 ml Syrup:** Each 5 ml syrup contains Bilastine INN 12.5 mg.

## Pharmacology

It 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. It inhibits histamine induced flare skin reactions for 24 hours following single doses.

## Indication

For the symptomatic relief of symptoms of allergic rhinitis, rhino conjunctivitis and urticaria (pruritus and hives).

## Dose and Administration

a) *Route of administration:* Oral

Children between 2 to 11 years: Bilbest Syrup: 4 ml once daily.

Bilbest 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.

## Contra-indication

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

## Warnings & Precaution

Co-administration of this drug 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

a) *Common:* The most common side effects include: headache, dizziness and fatigue.

b) *Rare:* No available data found.

## Drug Interaction

a) *With medicine:* Concomitant intake of Ketoconazole, Erythromycin or Diltiazem increases the concentration of this drug. The psychomotor performance after concomitant intake of alcohol and this drug was similar to that observed after the intake of alcohol and placebo. Concomitant intake of this drug and Lorazepam 3 mg for 8 days did not potentiate the depressant CNS effects of Lorazepam.

b) *With food and others:* Food significantly reduces the oral bioavailability of this drug by 30%. Interaction with grapefruit juice: concomitant intake of this drug and grapefruit juice decreased bioavailability by 30%. This effect may also apply to other fruit juices.

## Overdose

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

## Use in pregnancy and lactation

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

## Use In children & adolescent

*Children (<2 years of age):* The safety and efficacy of this drug in children under 2 years of age have not been established.

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

## Storage

Store below 30°C. Protect from light and moisture. Keep all medicines out of reach of children.

## Packing

**Bilbest 20 mg Tablet:** Each box contains 30 (3x10's) tablets in blister pack.

**Bilbest 60 ml Syrup:** Each box contains an amber color pet bottle containing 60 ml syrup & a measuring cup.



Manufactured by

**ONE PHARMA LTD.**

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