

TebastTM

Ebastine BP

Composition

TebastTM Tablet: Each film-coated tablet contains Ebastine BP 10 mg.

TebastTM Syrup: Each 5 ml syrup contains Ebastine BP 5 mg.

Pharmacology

Ebastine is a long-acting and selective H₁-histamine receptor antagonist.

Ebastine is almost totally converted to the pharmacologically active acid metabolite, Carebastine. Peak plasma levels of Carebastine occur at 2.6 to 4 hours and achieve levels of 80 to 100 ng/ml. The half-life of Carebastine is between 15 and 19 hours.

Indication

Ebastine is indicated for the symptomatic treatment of:

- Seasonal and Perennial Allergic Rhinitis
- Chronic Idiopathic Urticaria

Dosage & Administration

Syrup: Children (2-5 years of age): 2.5 ml once daily (upto 5 ml in severe cases such as Perennial Allergic Rhinitis).

Children (6-12 years of age): 5 ml once daily (upto 10 ml in severe cases such as Perennial Allergic Rhinitis).

Tablet: Adults (more than 12 years of age): 10 mg (one tablet) once daily.

Children (6-12 years of age): 5 mg (half tablet) once daily.

Ebastine may be taken with or without food.

Side Effect

The most common side-effects are headache, dry mouth and drowsiness. Less commonly reported side effects include abdominal pain, dyspepsia, nausea and insomnia.

Contraindication

Patients with a known hypersensitivity to Ebastine or any of its ingredients.

Overdose

In studies conducted at a high dosage, no clinically meaningful signs or symptoms were observed up to 100 mg given once daily. There is not specific antidote for Ebastine. In case of accidental overdose, gastric lavage, monitoring of vital functions including ECG, and symptomatic treatment should be carried out.

Special Precaution

Caution is advised when used in hepatic impairment, renal insufficiency, QTc interval prolongation.

Pregnancy and lactation

The safety of Ebastine during pregnancy and lactation has not been established.

Drug Interaction

Concomitant use of Ketoconazole, Itraconazole, Clarithromycin or Erythromycin may increase plasma levels of Ebastine and cause QTc interval prolongation.

Storage

Store below 30° C at a cool and dry place, away from light. Keep out of rich of children.

How Supplied

TebastTM Tablet: Each box contains 30 tablets.

TebastTM Syrup: Each bottle contains 50 ml syrup.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH