

W = 100 mm

Rhitin

Tablet

Ebastine BP

Composition

Each film-coated tablet contains Ebastine BP 10 mg.

Pharmacology

Rhitin (Ebastine) is a second generation, non-sedating, longacting histamine antagonist with selective H₁ receptor antagonist activity. After repeated administration, inhibition of peripheral receptors remains at a constant level. Ebastine is rapidly absorbed and undergoes extensive first pass metabolism following oral administration. Ebastine is almost totally converted to the pharmacologically active acid metabolite, carebastine.

Indications

Seasonal and perennial allergic rhinitis such as sneezing, runny nose, itching in the eyes and nose.

Chronic idiopathic urticaria (an allergic skin rash) such as itching, hives (localized skin redness and swelling).

Dosage and Administration

Route of administration: Oral

Allergic Rhinitis: 10 mg (1 tablet) once daily.

Chronic idiopathic urticaria: 10 mg (1 tablet) once daily. Rhitin may be taken with or without food.

OR AS DIRECTED BY THE PHYSICIAN.

Contraindications

The use of Ebastine is contraindicated in patients who have shown hypersensitivity to it.

Warning and Precautions

It is advisable to exercise caution when using Ebastine in patients known to have the following conditions: long QT syndrome, hypokalemia, treatment with any medicine known to produce an increase in QT interval or inhibit CYP4A enzyme systems such as azole antifungals and macrolide antibiotics.

Side Effects

Common side-effects : Headache, dry mouth and drowsiness.

Rare side effects : Pharyngitis, abdominal pain, dyspepsia, asthenia, epistaxis, rhinitis, sinusitis, nausea and insomnia.

Use in Pregnancy and Lactation

Pregnancy : The safety of Ebastine during pregnancy has not been established. So it should be avoided during pregnancy.

Lactation : As a precautionary measure, it is preferable to avoid the use of Ebastine during lactation.

Use in children and adolescents

The experience in children under the age of 12 years is limited.

Geriatrics (>65 years of age)

Care should be taken in dose selection.

Drug Interactions

With medicine: The interaction of Ebastine in combination with either ketoconazole or erythromycin has been evaluated. A significant pharmacokinetic and pharmacodynamic interaction has been observed with these combination; Ebastine does not interact with the kinetics of theophylline, warfarin, cimetidine, diazepam or alcohol.

With food & others : When Ebastine is administered with food, there is a 1.5 to 2.0 fold increase in the plasma levels and the AUC of the main active acid metabolite of Ebastine. This increase does not alter the T_{max}. The administration of Ebastine with food does not cause a modification in its clinical effect.

Overdose

In studies with a high dosage up to 100 mg once daily, no clinically significant symptoms or signs of overdose were seen. A specific antidote for Ebastine is not known. In the event of overdose, monitoring of vital functions, including ECG monitoring with evaluation of the QT interval for at least 24 hours, symptomatic treatment and gastric lavage are indicated.

Storage

Store below 30° C temperature & dry place, protected from light.

Keep out of reach of children.

Packing

Each box contains 3x10 tablets in blister strips.

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



Manufactured by:

The ACME Laboratories Ltd.

Dhamrai, Dhaka, Bangladesh

For Health, Vigour and Happiness

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