

Rinobas™

Ebastine

Composition:

Rinobas™ Tablet: Each film coated tablet contains Ebastine BP 10 mg.

Rinobas™ Syrup: Each 5 ml Syrup contains Ebastine BP 5 mg.

Description:

Rinobas™ (Ebastine) is a long-acting and selective H₁-histamine receptor antagonist. After repeated administration, inhibition of peripheral receptors remain at a constant level. **Rinobas™** (Ebastine) is rapidly absorbed and undergoes extensive first pass metabolism following oral administration. **Rinobas™** (Ebastine) is almost totally converted to the pharmacologically active acid metabolite, carebastine. After a single 10 mg oral dose, 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 with 66% of the medicine being excreted in the urine mainly as conjugated metabolites. Following repeated administration of 10 mg once daily, steady state is achieved in 3 to 5 days with peak plasma levels ranging from 130 to 160 ng/mL. Both ebastine and carebastine are highly (>95%) protein bound.

Indications:

Rinobas™ (Ebastine) is indicated for the symptomatic treatment of Seasonal and Perennial allergic rhinitis, Chronic idiopathic urticaria.

Dosage & Administration:

Syrup:

Children between 2 and 5 years: 2.5 ml once daily (up to 5 ml in severe cases such as perennial allergic rhinitis),

Children between 6 and 11 years: 5 ml (one teaspoonful) once daily (up to 10 ml in severe cases such as perennial allergic rhinitis),

Adults and children more than 11 years: 1 tablet (10 mg) or 10 ml (two teaspoonfuls) once daily.

Tablet:

Adult: Allergic rhinitis: 10 mg (one tablet) once daily,

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

OR AS DIRECTED BY THE PHYSICIAN.

Side Effects:

The most common adverse-effects are headache, dry mouth and drowsiness. Other less commonly reported side effects include pharyngitis, abdominal pain, dyspepsia, asthenia, epistaxis, rhinitis, sinusitis, nausea and insomnia.

Precautions:

It is advisable to exercise caution when using Ebastine in patients known to have the following conditions: long QT syndrome, hypokalaemia, treatment with any medicine known to produce an increase in QT interval or inhibit CYP3A4 enzyme systems such as azole antifungals and macrolide antibiotics.

Use in Pregnancy & Lactation:

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

Drug Interactions:

The interaction of Ebastine in combination with either ketoconazole or erythromycin (both known to prolong the QT interval) has been evaluated. A significant pharmacokinetic and pharmacodynamic interaction has been observed with these combination; an 18-19 msec (4.7% - 5%) increase in QTc has been reported with either combination. Ebastine does not interact with the kinetics of theophylline, warfarin, cimetidine, diazepam or alcohol.

Contraindications:

Ebastine is contraindicated to patients with hypersensitivity to any component of this product.

Storage Condition:

Store in a cool & dry place below 25°C, protect from light. Keep out of the reach of children.

Presentation:

Rinobas™ Tablet: Each box contains 5x10's tablets in blister pack.

Rinobas™ Syrup: Each bottle contains 50 ml syrup.

Manufactured by:

Julphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.