

Stiba[®]

Ebastine BP Film Coated Tablet and Syrup

DESCRIPTION

Stiba[®] is a preparation of Ebastine. Ebastine is a long-acting and selective H₁-histamine receptor antagonist. 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.

Stiba[®] tablet is formulated with Micronized Ebastine following Hydrophilization process which improves its dissolution rate upto 250% compared to non-micronized and non-hydrophilized active.

INDICATIONS

- Seasonal and perennial allergic rhinitis
- Idiopathic chronic urticaria

DOSAGE AND ADMINISTRATION

Tablet: Adults and Childrens Older than 12 years

- **Allergic rhinitis:** 10 mg (one tablet) once a day
- **Idiopathic chronic urticaria:** 10 mg (one tablet) once a day

Syrup:

- **Children (2 to 5 years old):** 2.5 ml (half teaspoon) once daily (up to 5 ml in severe cases)
- **Children (6 to 11 years old):** 5 ml (one teaspoon) once daily (up to 10 ml in severe cases)
- **Children more than 11 years old:** 1 tablet (10 mg) or 10 ml once daily

Ebastine may be taken with or without food

CONTRAINDICATIONS

Patients with a known hypersensitivity to Ebastine.

WARNINGS AND 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 AND LACTATION

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

SIDE-EFFECTS

The most common side-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.

SPECIAL PRECAUTIONS

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.

Ebastine lacks significant sedative effects. Patients should, however, be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants.

PHARMACEUTICAL PRECAUTION

Store in a dry place and away from light. Keep out of reach of children.

PACKAGING

Stiba® tablet: Box containing 3 strips of 10 tablets each. Each film coated tablet contains Ebastine BP 10 mg (Micronized).

Stiba® syrup: Bottle containing 30 ml of syrup. Each 5 ml contains Ebastine BP 5 mg.

SK+F

Manufactured by

ESKAYEF BANGLADESH LIMITED

GAZIPUR, BANGLADESH

® REGD. TRADEMARK

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