

# Stiba<sup>®</sup>

Ebastine BP Film Coated Tablet and Syrup

## DESCRIPTION

**Stiba<sup>®</sup>** 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<sup>®</sup>** 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 Children 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 teaspoonful) once daily (up to 5 mL in severe cases).

**Children (6 to 11 years old):** 5 mL (one teaspoonful) 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

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

## PACKAGING

**Stiba<sup>®</sup>** Tablet: Box containing 3 strips of 10 tablets each. Each film coated tablet contains Ebastine BP 10 mg (Micronized).

**Stiba<sup>®</sup>** Syrup: Bottle containing 30 mL of syrup. Each 5 mL contains Ebastine BP 5 mg.

**SK•F**

Manufactured by

**EKAYEF PHARMACEUTICALS LTD.**

TONGI, GAZIPUR, BANGLADESH

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