

# Stinba<sup>®</sup>

## Ebastine

### COMPOSITION:

Stinba<sup>®</sup> Tablet: Each film-coated tablet contains Ebastine BP 10 mg.

Stinba<sup>®</sup> Syrup: Each 5 ml contains Ebastine BP 5 mg.

### PHARMACOLOGY:

Stinba<sup>®</sup> is a preparation of Ebastine. Ebastine is a potent, highly selective antagonist of the histamine H1 receptor with prolonged effects and no anticholinergic effects. 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.

### INDICATION:

Stinba<sup>®</sup> is indicated for the symptomatic treatment of:

- Seasonal and perennial allergic rhinitis.
- Idiopathic chronic urticarial.

### DOSE & ADMINISTRATION:

#### 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.

#### 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).

### CONTRA-INDICATION:

Hypersensitivity to the active substance or to any of the excipients of prepared medicine.

### WARNING AND PRECAUTION:

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

### 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.

### USE IN PREGNANCY & LACTATION:

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

### USE IN CHILDREN & ADOLESCENTS:

Use of Ebastine is not recommended in patients less than 2 years of age.

### DRUG INTERACTION:

Ebastine in combination with either ketoconazole or erythromycin increase in plasma level of Ebastine and prolonged QTc interval. Ebastine does not interact with the pharmacokinetics of theophylline, warfarin, cimetidine, diazepam or alcohol. The sedation effect of alcohol and diazepam may be enhanced.

### OVERDOSE:

No clinically meaningful signs or symptoms were observed up to 100 mg given once daily. There is no specific antidote for Ebastine. In case of accidental over dosages, gastric lavage, monitoring of vital functions including ECG, and symptomatic treatment should be carried out.

### STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

### PACKING:

Stinba<sup>®</sup> Tablet: Each box contains 3x10's tablet in Alu-Alu blister pack.

Stinba<sup>®</sup> Syrup: Each bottle contains 50 ml syrup with a 10 ml measuring cup.



Manufactured by

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