Only for the use of Medical Professionals

Ebasten

Ebastine

Description

Ebasten is a preparation of Ebastine which is a non-sedative long-acting and selective Hi-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.

Indication

Ebasten is indicated for the symptomatic treatment of:

- Seasonal and perennial allergic rhinitis
- Chronic idiopathic urticaria

Dosage and administration

Ebasten Tablet

Adults & Children over 12 years: 10 mg (one tablet) once daily.

Ebasten® FT (Fast dissolving Tablet)

For adults and adolescents aged 12 years and older: 10 mg once daily. In cases of severe symptoms the dose may be increased to 20 mg (two Ebasten FT) once daily. Method of administration: The Ebasten FT should be placed on the tongue where it will disperse. No water or other fluid is required but if necessary, a glass of water or another beverage may drink after taking the tablet.

Ebasten Syrup

Children (2-5 years): 2.5 ml once daily (up to 5 ml in severe cases such as Perennial Allergic Rhinitis)
Children (6-12 years): 5 ml once daily (up to 10 ml in severe cases such as Perennial Allergic Rhinitis)

Ebasten can be taken with or without food.

Use is pregnancy & lactation

Pregnancy

Ebastine is pregnancy category B. Ebastine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation
It is not known whether Ebastine is excreted in human milk. As a precautionary measure, it is preferable to avoid the use of Ebastine during lactation.

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

Contraindications
Ebastine is contraindicated in patients with known hypersensitivity to Ebastine or to any of the components of this preparation.

Precautions
Caution is advised when used in QTc interval prolongation, hypokalemia, treatment with any medicine known to produce an increase in QTc interval or inhibit CYP3A4 enzyme systems such as azole antifungals, macrolide antibiotics and a type of medicine used to treat tuberculosis (e.g. rifampicin).

Drug interaction
Concomitant use of ketoconazole, itraconazole, clarithromycin or erythromycin may increase plasma levels of Ebastine and cause QTc interval prolongation. The sedation effect of alcohol and diazepam may be enhanced.

Overdose
In studies conducted at a high dosage, 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 overdosages, gastric lavage, monitoring of vital functions including ECG and symptomatic treatment should be carried out.

Pharmaceutical precautions
Ebasten Tablet: Store in a cool (between 15°C to 30°C) & dry place protected from light. Keep away from the reach of children.

Ebasten FT: Store in a cool (below 30°C) & dry place protected from light. Keep away from the reach of children.

Ebasten Syrup: Store in a cool (below 25°C) & dry place protected from light. Keep away from the reach of children.

Presentation

Ebasten Tablet: Each coated tablet contains Ebastine BP 10 mg.

Ebasten FT: Each fast dissolving tablet contains Ebastine BP 10 mg.

Ebasten Syrup: Each 5 ml contains Ebastine BP 5 mg.

Package quantities

Ebasten Tablet: Carton of 50 tablets in blister pack.

Ebasten FT: Carton of 30 tablets in blister pack.

Ebasten Syrup: Bottle of 50 ml.

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