

Epinastine Hydrochloride 0.05%

Composition:

Epinast® Eye Drops: Each ml contains Epinastine Hydrochloride BP 0.5 mg.

Pharmacology:

Epinastine is a topically active antihistamine that antagonizes both histamine H_1 and H_2 receptors. Moreover, it has mast cell stabilizing activity and prevents the release of inflammatory mediators from blood vessel. Epinastine does not penetrate the blood-brain barrier and therefore is not expected to induce side effects of the central nervous system.

Indications:

Epinast[®] Eye Drops is indicated for the treatment of signs and symptoms of allergic conditions of the anterior segment of the eye.

Dosage & administration:

Instill 1 drop in the affected eye(s) twice daily.

Contraindications:

Contraindicated in patients who are hypersensitive to Epinastine or to any of the components of this preparation.

Side effects:

Most frequently reported side effects are mild burning sensation, folliculosis, hyperemia, pruritus, cold symptoms and upper respiratory infections.

Precautions:

- For Ophthalmic use only.
- Patients should be advised not to wear contact lenses if their eye is red.

Use in special group:

Use in pregnancy: There are no adequate and well-controlled studies in pregnant women. Epinastine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in lactation: It is not known whether Epinastine is excreted in human milk. Caution should be exercised when Epinastine is administered to a nursing mother.

Use in children: Safety and effectiveness in children below the age of 3 years have not been established.
Use in elderly patients: No overall differences in safety and effectiveness have been observed between elderly and other adult patients.

Storage:

- Store below 30° C temperature in a dry place, protect from light.
- Do not use longer than 30 days after first opening.
- Keep out of the reach of children.

Packing

Epinast® Eye Drops: Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.



