

Bepotastine Besilate 1.5% Sterile Eye Drops

Description

Bepost Eye Drops is the preparation of Bepotastine Besilate which is a topically active, direct H₁-receptor antagonist and an inhibitor of the release of histamine from mast cells.

Indications

Bepost® Eye Drops is indicated for the treatment of itching associated with allergic conjunctivitis.

Dosage and administration

Adult: Instill one drop of **Bepost®** Eye Drops into the affected eye (s) twice a day.

Children: Safety and effectiveness in children below the age of 2 years have not been established.

Use in pregnancy and lactation

Pregnancy: Bepotastine besilate is pregnancy category C drug. There are no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not known if bepotastine besilate is excreted in human milk. Caution should be exercised when bepotastine besilate is administered to a nursing woman.

Side effects

The most common reported side effect occurring in approximately 25% of subjects was a mild taste following instillation. Other side effects occurring in 2-5% of subjects were eye irritation, headache, and nasopharyngitis.

Contraindications

Bepotastine besilate is contraindicated in patients with known hypersensitivity to bepotastine besilate or any components of this product.

Warnings and precautions

To minimize the risk of contamination, do not touch dropper tip to any surface. It should not be used to treat contact lens related irritation and patients should be advised not to wear contact lens when using this drop.

Drug interactions

There is no adequate information regarding drug interaction of bepotastine besilate. But bepotastine besilate has a low potential for drug interaction via inhibition of CYP3A4, CYP2C9 and CYP2C19.

Overdose

There is no adequate information regarding overdose of bepotastine besilate.

Pharmaceutical precautions

- Store in a cool (15°C 25°C) and dry place protected from light.
- · Do not use after one month once the cap is opened.

Presentation

Bepost® Eye Drops: Each mI contains Bepotastine Besilate INN 15 mg.

Package quantities

Bepost® Eye Drops: Plastic dropper bottle of 5 ml.

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