

BETASIL

BEPOTASTINE INN

Compositions:

Betasil eye drops: Each ml sterile eye drops (ophthalmic solution) contains Bepotastine Besilate INN 15 mg.

Pharmacology:

Bepotastine is a topically active, direct H₁-receptor antagonist and an inhibitor of the release of histamine from mast cells. It also suppresses the migration of eosinophils into inflamed tissues and IL - 5 production.

Indications:

Bepotastine Besilate 1.5% is indicated in itching associated with sign and symptoms of allergic conjunctivitis.

Dosage And Administration:

Instill one (1) drop into the affected eye(s) twice a day.

Contraindications:

Bepotastine Besilate is contraindicated in patients with a history of hypersensitivity to Bepotastine Besilate or any ingredient of the preparation.

Warning And Precaution:

Patients should be advised not to wear a contact lens if their eye is red. Bepotastine should not be used to treat contact lens-related irritation. Bepotastine should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of Bepotastine. Lenses may be reinserted after 10 minutes following administration of Bepotastine.

Side Effects:

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

Use in Pregnancy and Lactation:

Pregnancy: Pregnancy category C. There are no adequate and well controlled studies of Bepotastine Besilate in pregnant woman. Bepotastine Besilate 1.5% ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk of the fetus. Nursing mothers: It is not known if Bepotastine Besilate is excreted in human milk. Caution should be exercised when Bepotastine

Drug Interaction:

None known to date.

Overdosage:

If you use more Bepotastine Besilate eye drops than you should, rinse your eye with warm water. Do not put in any more drops until it is time for your next regular dose. Pharmaceutical Precautions

Storage:

Store in a cool, dry place and protected from light. Keep out of reach of children. Discard the container 4 weeks after opening.

Packing:

Betasil eye drops: Each plastic dropper bottle contains 5 ml sterile eye drops.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.