

Ocutifen

Ketotifen

Sterile Eye Drops

Presentation

Ocutifen: Each ml sterile eye drops contains Ketotifen 0.25 mg (as Ketotifen Fumarate BP).

Preservative: Benzalkonium Chloride 0.01%

Pharmacological Action

Ketotifen is a relatively selective, non-competitive histamine antagonist (H₁-receptor) and mast cell stabilizer. Ketotifen inhibits the release of mediators (e.g. histamine, leukotrienes, prostaglandin etc.) from cells involved in hypersensitivity reactions (mast cell, eosinophils, basophils and neutrophils). Ketotifen also reduces the chemotaxis, activation and degranulation of eosinophils.

Indications

Ketotifen is indicated for the treatment of signs & symptoms (itchy, watery, red & swollen eyes and/or eyelids) of allergic conjunctivitis including vernal keratoconjunctivitis, vernal keratitis, blepharitis, blepharoconjunctivitis, and giant papillary conjunctivitis.

Dosage and Application

Adult and Children 3 years and older: The usual dose of Ketotifen eye drops is 1 drop in the affected eye(s) twice a day (in the morning and evening).

Children under 3 years of age: Consult with doctor.

Contraindications

It is contraindicated in person with a known hypersensitivity to any component of this product

Side Effects

Rarely (<2%): change in visual acuity, dry eyes, headache, fatigue, skin rash.

Isolated cases: burning/stinging, conjunctivitis, subconjunctival hemorrhage, sensitivity to light, allergic reaction, dry mouth & eczema.

Precautions

Patients should be advised not to wear contact lenses during treatment with Ketotifen ophthalmic solution. The treatment should also be discontinued in the presence of an allergic reaction.

Drug Interactions

Not known. If several medicines are to be administered to the eye, there should be an interval of at least 5 minutes between each application.

Use in Pregnancy and Lactation

The safety of this medicine in pregnancy has not been established. It should therefore be used with caution during pregnancy, and only if the benefits to the mother outweigh any risks to the fetus. This medicine is unlikely to be excreted into the breast milk after application to the eye, and this medicine may therefore be used by breast feeding mothers.

Over Dose

No case of overdose has been reported. Oral ingestion of the contents of a 5 ml bottle would be equivalent to 1.25 mg of Ketotifen which is 60% of a recommended oral daily dose for a 3 years old child. Clinical results have shown no serious signs or symptoms after oral ingestion of up to 20 mg of Ketotifen.

Storage Conditions

Store in a cool and dry place away from light. Keep out of reach of children. Do not touch the dropper tip to surfaces since this may contaminate the solution. After one month of the opening do not use the medicine of dropper.

Commercial Pack

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

Manufactured by :

 **GENERAL**
Pharmaceuticals Ltd.
Unit-2, Gazipur, Bangladesh

