

# Aljen

Ketotifen BP 0.025%

## Sterile Eye Drops

**Composition:**

Each ml eye drops contains ketotifen fumarate BP equivalent to 0.25 mg ketotifen.

**Description:**

Ketotifen is a relatively selective, non-competitive histamine antagonist (H1-receptor) and mast cell stabilizer. Ketotifen inhibits the release of mediators from cells involved in hypersensitivity reactions. Decreased chemotaxis and activation of eosinophils has also been demonstrated. Ketotifen has been shown to have little systemic exposure following topical ocular administration. A study conducted with 15 healthy volunteers dosed bilaterally with ketotifen fumarate ophthalmic solution twice daily for 14 days demonstrated plasma concentrations generally below the quantitation limit of assay (< 20 pg/mL). In human conjunctival allergen challenge studies, ketotifen was significantly more effective than placebo in preventing ocular itching associated with allergic conjunctivitis. The action of ketotifen occurs rapidly with an effect seen within minutes after administration.

**Indications and usage:**

Ketotifen ophthalmic solution is indicated for the temporary prevention of itching of the eye due to allergic conjunctivitis.

**Dosage and administration:**

The recommended dose is one drop in the affected eye(s) every 8 to 12 hours.

**Contraindications:**

Ketotifen is contraindicated in persons with a known hypersensitivity to any component of this product.

**Precautions:**

To prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep the bottle tightly closed when not in use. Patients should be advised not to wear a contact lens if their eye is red. Ketotifen should not be used to treat contact lens related irritation. The preservative in eye drop, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses and whose eyes are not red, should be instructed to wait at least ten minutes after instilling Ketotifen eye drop before they insert their contact lenses.

**Side-effects:**

In controlled clinical studies, conjunctival injection, headaches, and rhinitis were reported at an incidence of 10 to 25%. The occurrence of these side effects was generally mild. Some of these events were similar to the underlying ocular disease being studied. The following ocular and non-ocular adverse reactions were reported at an incidence of less than 5%. Ocular: Allergic reactions, burning or stinging, conjunctivitis, discharge, dry eyes, eye pain, eyelid disorder, itching, keratitis, lacrimation disorder, mydriasis, photophobia, and rash. Non-Ocular: Flu syndrome, pharyngitis

**Drug Interactions:** No information provided

**Storage :**

Store in a cool & dry place, protected from light, use within one month after the first opening & Keep out of the reach of children.

**Packing :**

Each plastic dropper bottle contains 5 ml sterile Eye Drops.



Manufactured by  
**Apex Pharma Ltd.**  
(Eye Care Division)  
Shahpur, Gazipur