

**Presentation and packaging quantities:**

Plastic dropper bottle of 5 ml. Each ml contains Ketotifen Fumarate BP equivalent to Ketotifen 0.25 mg.

**Description**

It is a sterile ophthalmic solution containing ketotifen for topical administration to the eyes. 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.

**Indications**

Indicated for the temporary prevention of itching of the eye due to allergic conjunctivitis.

**Dosage**

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

**Side Effects**

Transient burning or stinging, punctate corneal epithelial erosion; less commonly dry eye, subconjunctival haemorrhage, photophobia; headache, drowsiness, skin reactions, and dry mouth also reported.

**Contraindications**

Contraindicated in persons with a known hypersensitivity to any component of this product.

**Warning**

For topical ophthalmic use only. Not for injection or oral use.

**Precaution**

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. This drug should not be used to treat contact lens related irritation. The preservative in it, 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 the drug before they insert their contact lenses.

**High risk group**

**Pregnancy Category C. Nursing Mothers:** Ketotifen fumarate has been identified in breast milk in rats following oral administration. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in breast milk. Nevertheless, caution should be exercised when ketotifen fumarate is administered to a nursing mother.

**Pediatric Use:** Safety and effectiveness in pediatric patients below the age of 3 years have not been established.

**Drug Interactions**

No information available.

**Pharmaceutical Precaution**

Store in a cool and dry place, away from light. Keep out of reach of children.

**How Supplied**

Tofen<sup>®</sup> 0.025% Eye Drops: Dropper bottle containing 5 ml of sterile solution.



Manufactured by

**BEXIMCO PHARMACEUTICALS LTD.**

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