

COMPOSITION

Each ml contains:

Ketotifen	0.5 mg
(added as Ketotifen fumarate)	
Benzalkonium chloride USP	0.05 mg

Clinical Pharmacology

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 is both anti-allergic and anti-anaphylactic and these properties explain its action in conditions characterized by IgE-mediated allergic reactions and abnormalities in histamine release.

INDICATIONS

Ketotifen fumarate ophthalmic solution is indicated for the treatment of allergic conjunctivitis, giant papillary conjunctivitis and atopic conjunctivitis.

CONTRA-INDICATIONS

Hypersensitivity to any component of this product. In patients with hypersensitive skin, eyelid inflammation, eyelid dermatitis and soreness of the cornea.

WARNINGS AND PRECAUTIONS

KETOTIFEN FUMARATE OPHTHALMIC SOLUTION IS MEANT FOR TOPICAL USE ONLY. NOT FOR INJECTION OR ORAL USE.

Patients should not wear contact lens if their eye is red. Ketotifen fumarate ophthalmic solution should not be used to treat contact



ALBALON™
(Ketotifen fumarate ophthalmic solution 0.05%)

lens related irritation. The preservative used in Ketotifen fumarate ophthalmic solution is benzalkonium chloride, which might 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 fumarate ophthalmic solution before they insert their contact lenses.

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.

PREGNANCY & LACTATION

In animal studies high oral doses of Ketotifen fumarate resulted in an increased incidence of postnatal mortality, there was also increased incidence of retarded ossification of the sternal vertebrae.

There are no adequate and well-controlled studies in pregnant women. Ketotifen fumarate ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

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.

SIDE EFFECTS

Conjunctival irritation, headaches and rhinitis have been reported. The occurrence of these side effects is generally mild. Some of these events are similar to the underlying ocular disease being studied.

The following ocular and non-ocular adverse reactions have been reported with a lesser incidence than the former:

Ocular

Allergic reactions, burning or stinging, conjunctivitis, discharge, dry eyes, eyelid disorder, itching, keratitis, lacrimation disorder, mydriasis, photophobia and rash.

Non-Ocular

Flu syndrome, pharyngitis.

OVERDOSAGE

Oral ingestion of the contents of a 5 ml bottle would be equivalent to 1.725 mg of

Ketotifen fumarate. Clinical results have shown no serious signs or symptoms after the ingestion of upto 20 mg of Ketotifen fumarate.

DOSAGE AND ADMINISTRATION

The recommended dose is 1-2 drops in the affected eye(s) every 6 hours.

PRESENTATION

ALBALON™ is available in 5 ml plastic dropper bottles.

NOTE: Store in a cool place.