
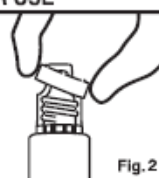
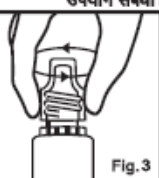
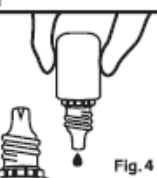
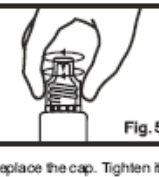
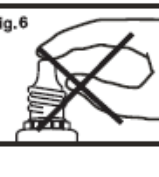
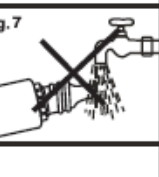
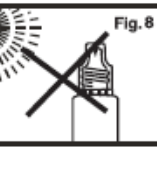

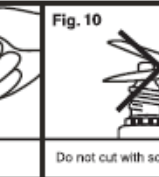
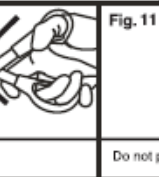


INSTRUCTIONS FOR USE		उपयोग संबंधी निर्देश	
			
Turn tight (clockwise) to break the seal and make a dispensing hole on the nozzle	Remove the ring and discard	Open the cap by turning left (anti-clockwise) and it is ready for use.	Turn it upside down. Squeeze the walls of the bottle gently to deliver sterile drop into the eye.
सिल तोड़ने के लिए घड़ी की दिशा में घुमाएं और छेद बनाने के लिए बल प्रयोग करें।	खरों को हटाएं और फेंक दें।	घड़कन को खोलने के लिए बाईं तरफ घुमाएं। अब बेलन उपयोग के लिए तैयार है।	अब बेलन को उल्टा करें, बेलन की भित्ति को हल्के तौर पर और आंखों में दवा डालें।
			
Replace the cap. Tighten it firmly and keep the bottle closed for subsequent use.	Do not touch the nozzle.	Do not rinse the nozzle.	Do not expose to Sunlight.
पूरा उपयोग के बाद घड़कन को बंद करके बेलन बंद कर दें।	बेलन को नोजल को छूना न चाहिए।	नोजल को धोना न चाहिए।	बेलन को सूर्य में न रखें।
			
Do not cut with knife	Do not cut with scissor	Do not pierce with needle	
कट्टी से न काटे।	कैंची से न काटे।	सुई से छेद न करें।	
State of the art technology From Allergan India Private Limited	अत्याधुनिक तरीके से तैयार किया हुआ अलबालन द्रव्यिया प्राइवेट लिमिटेड द्वारा		

A33/d

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

KETOTIFEN OPHTHALMIC SOLUTION

ALBALON™  
LIQUIFILM™
 ALLERGAN

## COMPOSITION

Each mL contains:

Ketotifen Fumarate BP equivalent to	
Ketotifen	0.5 mg
Benzalkonium Chloride IP/USNF	0.05 mg
Purified Water IP	q.s.

## CLINICAL PHARMACOLOGY

Ketotifen is a relatively selective, non-competitive histamine antagonist (H<sub>1</sub>-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.

## WARNING AND PRECAUTIONS

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

Patient should not wear contact lens if their eye is red. Ketotifen Fumarate ophthalmic solution should not be used to treat contact lens related irritation. The preservative used in Ketotifen Fumarate ophthalmic solution is benzalkonium chloride, which might be absorbed by soft contact lenses. Patient 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 &amp; 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 fetus.

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) twice daily, every 8-12 hours.

## PRESENTATION

ALBALON™ is available in 5 ml sterile plastic dropper bottles.

NOTE: Store in a cool place.

Marketed by: Allergan India Private Limited

Manufactured in India by:  
Piramal Healthcare Limited  
Plot No. 67-70, Sector 2, Pithampur 454 775,  
Dist. Dhar, Madhya Pradesh

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