Instructions for Use

Fig. 1: Turn right (clockwise) to break the seal and make a dispersing hole on the nozzle.

Fig. 2: Remove the ring and discard.

Fig. 3: Open the cap by turning left (anti-clockwise) and it's ready for use.

Fig. 4: Turn it up side down, squeeze the walls of the bottle gently to deliver sterile drops into the eye.

Fig. 5: Replace the cap, tighten it firmly and keep the bottle closed for subsequent use.

Fig. 6: Do not touch the nozzle.

Fig. 7: Do not touch the nozzle.

Fig. 8: Do not expose to sunlight.

Fig. 9: Do not cut with knife.

Fig. 10: Do not cut with scissors.

Fig. 11: Do not pierce with needle.

Compliance with Good Manufacturing Practice (GMP) as prescribed by the Indian Pharmaceutical Excipients Manufacturers Association (IPEMA).

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

Ketotifen Ophthalmic Solution

Safety precautions:
- Do not remove the cap from the bottle.
- Do not use the bottle after the expiry date.
- Keep out of reach of children.
- Do not share the bottle with others.

Composition:
- Each ml contains:
  - Ketotifen Fumarate BP equivalent to Ketotifen 0.5 mg
  - Benzalkonium Chloride 0.05 mg
  - Purified Water IP q.s.

Clinical Pharmacology:
Ketotifen is a relatively selective, non-competitive histamine antagonist (H1-receptor) and mast cell stabiliser. Ketotifen inhibits the release of mediators from cells involved in histamine release reactions. Decreased chemotaxis and activation of eosinophils has also been demonstrated. Ketotifen is both anti-allergic and anti-inflammatory 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 atop 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 and 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 and 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 ribs.
- 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 lower incidence than the former:
  - Ocular: Allergic reactions including 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 7.725 mg of Ketotifen Fumarate. Clinical results have shown no serious signs or symptoms after the ingestion of up to 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.

Manufactured by: Allergan India Private Limited

Marketed by: Allergan Healthcare Limited

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