

# Ketotifen Fumarate BP 0.025% Sterile Solution

#### COMPOSITION

 $\textbf{Alarid}^{\otimes}$  0.025% Eye Drops : Each ml contains Ketotifen Fumarate BP equivalent to Ketotifen 0.25 mg.

#### **PHARMACOLOGY**

Ketotifen is a potent anti-allergic substance possessing a powerful and sustained non-competitive histamine (H<sub>1</sub>) receptor blocking property. Ketotifen inhibits the release of mediators (e.g histamine, leukotrienes and prostaglandins) from cells responsible for type-(I) allergic reactions. Ketotifen also stabilizes mast cells, decreases chemotaxis, activation of degranulation of eosinophils.

## INDICATION

**Alarid**® 0.025% eye drop is indicated for the treatment of signs & symptoms (itchy, watery, red & swollen eyes and eyelids) of allergic conjunctivitis including vernal kerato-conjunctivitis, vernal-keratitis, blepharitis, blepharo-conjunctivitis, and giant papillary conjunctivitis.

#### DOSAGE AND ADMINISTRATION

Adults and children 3 years and older:1 drop in the affected eye(s) twice daily, every 8-12 hours, not more than twice per day.

Children under 3 years of age: Consult with a doctor.

## CONTRAINDICATION

Hypersensitivity to Ketotifen or any of the components.

#### **PRECAUTION**

The formulation of **Alarid**® 0.025% eye drops contains benzalkonium chloride as a preservative, which may be deposited in soft contact lenses; therefore **Alarid**® 0.025% eye drops should not be instilled while the patient is wearing lenses. The lenses should be removed before application of the drops and not reinserted earlier than 15 minutes after use.

## SIDE EFFECT

Between 1% and 2%: Burning/stinging, punctate corneal epithelial erosion. <1%: Blurring of vision upon drug instillation, dry eyes, eyelid disorder, conjunctivitis, eye pain, photophobia, subconjunctival haemorrhage.

#### DRUG INTERACTION

If **Alarid**<sup>®</sup> 0.025% eye drops is used concomitantly with other eye medications there must be an interval of at least 5 minutes between the two medications.

#### USE IN PREGNANCY AND LACTATION

There are no adequate data from the use of ketotifen eye drops in pregnant women. Systemic levels after ocular administration are much lower than after oral use. Caution should be exercised when prescribing to pregnant women.

Although animal data following oral administration show excretion into breast milk, topical administration to humans is unlikely to produce detectable quantities in breast milk. **Alarid**® 0.25% eve drops can be used during lactation.

## **OVERDOSAGE**

No case of overdose has been reported. Oral ingestion of the contents of a 5 ml bottle would be equivalent to 1.25 mg of Ketotifen which is 60% of a recommended oral daily dose for a 3 years old child. Clinical results have shown no serious signs or symptoms after oral ingestion of up to 20 mg of Ketotifen.

## STORAGE

Store below 25°C. Protect from light. Keep out of children's reach.

# **HOW SUPPLIED**

Alarid® 0.025% Eye Drops: Dropper bottle containing 5 ml / 10 ml / 15 ml sterile solution

