

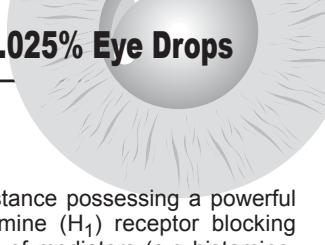
Alarid®

Ketotifen Fumarate BP

Alarid® 0.025% Eye Drops

Ketotifen Fumarate BP

Sterile Solution



Ketotifen is a potent anti-allergic substance possessing a powerful and sustained non-competitive histamine (H₁) 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.

COMPOSITION

Alarid® 0.025% Eye Drops : Each ml contains Ketotifen Fumarate BP equivalent to Ketotifen 0.25 mg.

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®** 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% eye 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 25⁰ C in a cool and dry place protected from light and moisture. Keep out of reach of children. Do not touch the dropper tip to any surface since this may contaminate the solution. Do not use after 30 days of first opening.

HOW SUPPLIED

Alarid® 0.025% Eye Drops: Each plastic dropper bottle contains 5 ml sterile Eye Drops.

Manufactured by :

 **SQUARE**
PHARMACEUTICALS LTD.
BANGLADESH

® Registered Trade Mark.

LFT 0114

Alarid® Tablet & syrup

Ketotifen Fumarate BP

COMPOSITION:

Alarid® Tablet: Each tablet contains Ketotifen Fumarate BP 1.38 mg

equivalent to 1 mg Ketotifen.

Alarid® Syrup: Each 5 ml syrup contains Ketotifen Fumarate BP 1.38 mg

equivalent to 1 mg Ketotifen.

DESCRIPTION:

Alarid® is a preparation of Ketotifen, which has anti-allergic properties and has been used similarly, to sodium chromoglycate in the prophylactic treatment of asthma. It also has the properties of an antihistamine.

USES:

Alarid® (Ketotifen) possesses marked anti-anaphylactic properties and is effective in preventing asthmatic attack.

Alarid® (Ketotifen) exerts as sustained inhibitory effect on histamine reactions, which can be dissociated from its anti-anaphylactic properties.

Experimental investigations in asthmatic subjects have shown that Ketotifen is as effective orally as a selective mast cell stabilizer administered by inhalation.

Antihistamines were ineffective in those tests. The effectiveness of Ketotifen has been studied in long term clinical trials. Asthma attacks were reduced in number, severity and duration and in some cases, the patients were completely freed from attacks. Progressive reduction of corticosteroids and/or bronchodilators was also possible. The prophylactic activity of Ketotifen may take several weeks to become fully established. Ketotifen will not abort established attacks of asthma.

INDICATIONS:

- Prophylactic treatment of bronchial asthma.
- Symptomatic treatment of allergic conditions including rhinitis and conjunctivitis.

DOSAGE AND ADMINISTRATION:

Adults: 1 mg twice daily with food. If necessary the dose may be increased to 2 mg twice daily in severe cases.

Children above 3 years: 1 mg twice daily with food. Patients known to be easily sedated should begin treatment with 0.5 to 1 mg at night for the first few days or as directed by the physician.

Use in elderly: Same as adult dose or as advised by the physician.

CONTRAINDICATIONS:

A reversible fall in the platelet count has been observed in a few patients receiving Ketotifen concomitantly with oral antidiabetic agent and it has been suggested that this combination should therefore be avoided. Although there is no evidence of any teratogenic effect, recommendations for Ketotifen in pregnancy or when breast feeding can not be given.

PRECAUTIONS:

It is important to continue the previous treatment for a minimum of two weeks after starting Ketotifen to avoid the possibility of exacerbation of asthma. This applies specially to systemic corticosteroids and ACTH because of the possible existence of adrenocortical insufficiency in steroid dependent patient. If inter current infection occurs, Ketotifen treatment must be supplemented by specific antimicrobial therapy. During the first day of treatment with Ketotifen, reactions may be impaired and patients should be warned not to take charge of vehicle or machinery until the effect of Ketotifen treatment on the individual is known. Patients should be advised to avoid alcoholic drinks. Ketotifen may potentiate the effects of sedatives, hypnotics, antihistamines and alcohol.

OVERDOSAGE:

The reported features of overdose include confusion, drowsiness, headache, bradycardia, respiratory depression etc. should be watched for. Elimination of the drug with gastric lavage or emesis is recommended. Otherwise general supportive treatment is all that is required shall be instituted.

SIDE EFFECTS:

Drowsiness and in isolated cases, dry mouth and slight dizziness may occur at the beginning of treatment but usually disappear spontaneously after a few days.

STORAGE CONDITION:

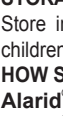
Store in a cool and dry place, protect from light. Keep out of the reach of children.

HOW SUPPLIED:

Alarid® Tablet : Box containing 10x10's tablets in blister pack.

Alarid® Syrup: Each PET bottle 100 ml syrup and a measuring cup.

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