

Stafen

Ketotifen BP 0.025%
Sterile Eye Drops

Composition:

Stafen Sterile Eye Drops : Each ml contains Ketotifen Fumarate BP equivalent to Ketotifen 0.25mg.

Preservative: Benzalkonium Chloride Solution BP 0.02%.

Vehicle: Polyvinyl Alcohol USP 1.4%.

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 have also been demonstrated.

Indications:

Stafen is indicated for the temporary prevention of itching of the eye due to allergic conjunctivitis.

Dosage and administration:

1 drop in the affected eye(s) every 8-12 hours.

Contraindications:

Stafen is contraindicated in patients with known hypersensitivity to any component of this product.

Adverse Reactions:

Burning or stinging, discharge, dry eyes, eye pain, eye lid disorder, keratitis, lacrimation, disorder, mydriasis, photophobia, rash, headache, rhinitis may be reported.

Precautions:

Stafen should not be used to treat contact lens related irritation. Stafen should not be administered while wearing contact lenses. Lenses may be inserted 10 minutes following administration of Stafen.

Pregnancy:

Pregnancy category C.

Nursing Mother:

It is not known whether this drug or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **Stafen** is administered to a nursing woman.

Paediatric Use:

Safety and effectiveness in pediatric patients below the age of 3 years have not been established.

Storage:

- Store at 4-25⁰ C temperature.
- Don't use for longer than one month after first opening.
- Keep all the medicine out of the reach of children.

Packing:

Stafen Sterile Eye Drops : Each plastic dropper bottle contains 5 ml /10 ml sterile eye drops.

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Manufactured by:
ARISTOPHARMA LTD.
SHAMPUR-DHAKA-BANGLADESH