

Ketofall™

KETOTIFEN

Symptomatic treatment of
seasonal allergic conjunctivitis¹

DUAL MODE OF ACTION²



PRESERVATIVE FREE^{1,2}



FAST & LONG-TERM RELIEF³



Treats the active reaction mechanism

Ketotifen is a histamine
H1-receptor antagonist^{1,4}

A preventative long-term solution

Ketotifen stabilises mast
cells and inhibits infiltration,
activation and degranulation
of eosinophils^{1,4}

Ketofall™ Summary

MOLECULE	0.25mg Ketotifen (as hydrogen fumarate).
PHARMACEUTICAL FORM	Eye drops, solution in single dose container.
THERAPEUTIC INDICATIONS	Symptomatic treatment of seasonal allergic conjunctivitis.
POSODOLOGY	One drop per eye, twice daily.
CONTRAINDICATIONS	Hypersensitivity to the active substance or to any of the following excipients: Glycerol (E422), Sodium hydroxide (E524) (for pH-adjustment) or Water for injections.
SPECIAL WARNINGS AND PRECAUTIONS FOR USE	None.
MODE OF ACTION	Preservative free, Antihistamine & Mast Cell Stabiliser.
SHELF LIFE	<ul style="list-style-type: none"> • In unopened aluminium pouch: 2 years. • In opened aluminium pouch: 28 days (4 weeks). • After opening, the contents of a single-dose container, contents should be used immediately.



Prescribing Information:

Please refer to the Summary of Product Characteristics (SmPC) for full details of the prescribing information.

Presentation: Ketofall 0.25 mg/ml eye drops, solution in single-dose container. Ketofall One ml solution contains 0.25 mg ketotifen (as hydrogen fumarate). Each single-dose container of 0.4 ml solution contains 0.1 mg ketotifen (as hydrogen fumarate). Each drop contains approximately 6.95 microgram ketotifen (as hydrogen fumarate). **Indications:** Symptomatic treatment of seasonal allergic conjunctivitis. **Posology and method of administration, Posology:** Adults, elderly and children (age 3 and older): one drop of Ketofall into the conjunctival sac twice a day. The contents of a single-dose container are sufficient for one administration into both eyes. The contents remain sterile until the original closure is broken. To avoid contamination do not touch the eye or any other surface with the tip of the container. **Paediatric population:** The safety and efficacy of Ketofall in children below the age of 3 years has not been established. **Method of administration:** Topical ocular use. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Interactions:** If Ketofall is used concomitantly with other eye medications there must be an interval of at least 5 minutes between the medications. The use of oral dosage forms of ketotifen may potentiate the effects of CNS depressants, antihistamines and alcohol. Although this has not been observed with ketotifen eye drops, the possibility of such effects cannot be excluded. **Fertility, pregnancy and lactation: Pregnancy:** There are no adequate data from the use of ketotifen eye drops in pregnant women. Animal studies using maternally toxic oral doses showed increased pre- and postnatal mortality, but no teratogenicity. Systemic levels after ocular administration are much lower than after oral use. Caution should be exercised when prescribing to pregnant women. **Breastfeeding:** Although animal data following oral administration show excretion into breast milk, topical administration in humans is unlikely to produce detectable quantities in breast milk. Ketofall can be used during lactation. **Fertility:** There are no data available on the effect of ketotifen hydrogen fumarate on fertility in humans. **Effects on ability to drive and use machines:** Any patient who experiences blurred vision or somnolence should not drive or operate machines. **Adverse reactions:** Adverse reactions from clinical trials as follows: *Uncommon* ($\geq 1/1,000$ to $<1/100$): hypersensitivity, headache, blurred vision (during instillation), eyelid disorders, conjunctivitis, photophobia, conjunctival haemorrhage, rash, eczema, urticaria and somnolence. *Common* ($\geq 1/100$ to $<1/10$): Eye irritation, eye pain, punctate keratitis, punctate corneal epithelial erosion. The following post marketing events have also been observed with ketotifen eye drops (frequency not known): hypersensitivity reactions including local allergic reaction (mostly contact dermatitis, eye swelling, eyelid pruritus and oedema), systemic allergic reactions including facial swelling/oedema (in some cases associated with contact dermatitis) and exacerbation of pre-existing allergic conditions such as asthma and eczema. **Overdose:** No case of overdose has been reported. Oral ingestion of the contents of a single-dose container would be equivalent to 0.1 mg of ketotifen which is 5% of a recommended oral daily dose for a 3 year old child. Clinical results have shown no serious signs or symptoms of overdose after oral ingestion of up to 20 mg of ketotifen. **Legal Category:** prescription only medication. **Price:** €6.95 **Marketing Authorisation number:** PL 20905/0002. **Marketing Authorisation Holder:** Pharma Stulln GmbH, Werksstrasse 3, 92551 Stulln, Germany. **UK and Ireland Distribution:** Scope Ophthalmics, Suite 5, Westland House, Westland Park, Willow Road, Dublin 12. Telephone: 1800 816 005. Date of preparation: March 2018.

Adverse events should be reported. Reporting forms and information can be found on www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Pharma Stulln GmbH (Tel: +49 9435 30080). Pharma Stulln GmbH can also be contacted through the licensed UK provider, Scope Ophthalmics (Tel: 0800 270 0253).

References:

1. Ketofall Summary of Product Characteristics. 2. B. Mortemousque et al. Comparison of preservative-free ketotifen fumarate and preserved olopatadine hydrochloride eye drops in the treatment of moderate to severe seasonal allergic conjunctivitis, Journal français d'ophtalmologie 2014 Jan; 37(1):1-8. 3. Horak F et al. Onset and duration of action of ketotifen 0.025% and emedastine 0.05% in seasonal allergic conjunctivitis: efficacy after repeated pollen challenges in the vienna challenge chamber, Clin Drug Investig 2003; 23(5):329-37. 4. S.J. Sarker et al. Comparison of the therapeutic efficacy of 0.1% olopatadine hydrochloride and 0.025% ketotifen fumarate in allergic conjunctivitis. 2011 Future Medicine Ltd, Therapy 2011; 8(5):545-553.

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Full Summary of Product Characteristics available upon request.



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