

Alcek

Olopatadine INN 0.1%

Sterile Eye Drops

Composition:

Each ml contains Olopatadine Hydrochloride INN Equivalent to 1 mg Olopatadine.

Description:

Alcek is a sterile ophthalmic solution containing Olopatadine, a relatively selective H₁-receptor antagonist and inhibitor of histamine release from the mast cell for topical administration to the eyes

Pharmacology:

Olopatadine is an inhibitor of the release of histamine from the mast cell and a relatively selective histamine H₁-antagonist that inhibits the in vivo and in vitro type 1 immediate hypersensitivity reaction including inhibition of histamine induced effects on human conjunctival epithelial cells. Olopatadine is devoid of effects on alpha-adrenergic, dopamine and muscarinic type 1 and 2 receptors. Following topical ocular administration in man, Olopatadine was shown to have low systemic exposure. Two studies in normal volunteers (totaling 24 subjects) dosed bilaterally with olopatadine 0.15% ophthalmic solution once every 12 hours for 2 weeks demonstrated plasma concentrations to be generally below the quantitation limit of the assay (<0.5 ng/mL). Samples in which olopatadine was quantifiable were typically found within 2 hours of dosing and ranged from 0.5 to 1.3 ng/mL. The half-life in plasma was approximately 3 hours, and elimination was predominantly through renal excretion. Approximately 60-70% of the dose was recovered in the urine as parent drug. Two metabolites, the mono-desmethyl and the N-oxide, were detected at low concentrations in the urine. Results from an environmental study demonstrated that olopatadine was effective in the treatment of the signs and symptoms of allergic conjunctivitis when dosed twice daily for up to 6 weeks. Results from conjunctival antigen challenge studies demonstrated that olopatadine, when subjects were challenged with antigen both initially and up to 8 hours after dosing, was significantly more effective than its vehicle in preventing ocular itching associated with allergic conjunctivitis.

Indications and usage:

It is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

Dosage & Administration:

The recommended dose is one drop in each affected eye two times per day at an interval of 6 to 8 hours.

Precautions:

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 bottle tightly closed when not in use. Patients should be advised not to wear a contact lens if their eye is red. Olopatadine hydrochloride ophthalmic solution 0.1% should not be used to treat contact lens related irritation. Benzalkonium chloride, the preservative used in Alcek eye drops may be absorbed by soft contact lenses. Patients who wear soft contact lenses and whose eyes are not red should be instructed to wait at least ten minutes after instilling Alcek (Olopatadine Hydrochloride ophthalmic solution 0.1%) before they insert their contact lenses.

Side-effects:

Headaches have been reported at an incidence of 7%. The following adverse experiences have been reported in less than 5% of patients: asthenia, blurred vision, burning or stinging, cold syndrome, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, nausea, pharyngitis, pruritus, rhinitis, sinusitis, and taste perversion. Some of these events were similar to the underlying disease being studied.

Drug Interactions:

No information provided.

Contraindication:

It is contraindicated in persons with a known hypersensitivity to Olopatadine Hydrochloride or any components of Olopatadine Eye drop.

Overdose :

No information available

Storage :

Store at 4°C to 25°C. Protected from moisture and light. Keep out of the reach of children. Use within one month after the first opening.

Packing :

Each plastic dropper bottle contains 5 ml sterile Eye Drops.



Manufactured by
Apex Pharma Ltd.
(Eye Care Division)
Shafipur, Gazipur