

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Olopatadine Ophthalmic Solution IP 0.1% w/v

Vylopt™
Eye Drops

Composition:

Olopatadine Hydrochloride	IP	
Equivalent to Olopatadine		0.1% w/v
Benzalkonium Chloride Solution	IP	0.02% w/v
(As Preservative)		
Sterile Aqueous Base		q.s.

Dosage Form :

Eye Drops-Solution

Pharmacology :

Pharmacodynamics

Olopatadine is a potent selective antiallergic/antihistaminic agent that exerts its effect through multiple distinct mechanisms of action. It antagonizes histamine (the primary mediator of allergic response in humans) and prevents histamine induced inflammatory cytokine production by human conjunctival epithelial cells. Data from in vitro studies suggest that it may act on human conjunctival mast cell to inhibit the release of pro-inflammatory mediators. In patients with patent nasolacrimal ducts, topical ocular administration of Olopatadine was suggested to reduce the nasal signs and symptoms that frequently accompany seasonal allergic conjunctivitis. It does not produce a clinically significant change in pupil diameter.

Keep bottle tightly closed when not in use. Patients should be advised not to wear a contact lens if their eyes are red. Olopatadine hydrochloride ophthalmic solution should not be used to treat contact lens related irritation. Patients who wear soft contact lenses and whose eyes are not red should be instructed to wait at least ten minutes after instilling olopatadine hydrochloride ophthalmic solution before they insert their contact lenses.

Stabilized oxychloro complex is a gentle Preservative & makes VYLOPT more compatible with tear film components as well maintains corneal cells' integrity on long term use.

Undesirable Effects

Headaches have been reported at an incidence of 7%. The following undesirable effects 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, pruritis, rhinitis, sinusitis and taste perversion. Some of these events were similar to the underlying disease being studied.

Overdosage

In the case of overdose, appropriate monitoring and management of the patient should be implemented. A topical overdose may be flushed from the eye(s) with warm tap water.

Incompatibility **Shelf Life :**
Not applicable 24 months

Packaging Information:
VYLOPT Eye Drops : Available in bottle of 5ml.

Storage and handling information :

Protect the solutions from light

Pharmacokinetics

Olopatadine is absorbed systemically, as are other topically administered medicinal products. However, systemic absorption of topically applied olopatadine is minimal with plasma concentrations ranging from below the assay quantitation limit (<0.5 ng/ml) up to 1.3 ng/ml. These concentrations are 50 to 200 fold lower than those following well-tolerated oral doses. From oral pharmacokinetic studies, the half-life of olopatadine on plasma was approximately eight to 12 hours & elimination was predominantly through renal excretion. Approximately 60-70% of the dose was recovered in the urine as active substance. Two metabolites, the mono-desmethyl & the N-oxide were detected at low concentrations in the urine. Since plasma concentration following topical ocular dosing of olopatadine are 50 to 200 fold lower than after well-tolerated oral doses, dose adjustment is not expected to be necessary in the elderly or in the renally impaired population.

Liver metabolism is a minor route of elimination. Dose adjustment is not expected to be necessary with hepatic impairment.

Indications

Olopatadine hydrochloride ophthalmic solution is indicated for the treatment of the signs & symptoms of allergic conjunctivitis.

Dosage & Administration

The recommended dose of olopatadine 0.1% is one drop in affected eye/s once a day.

Contraindications

Olopatadine hydrochloride ophthalmic solution is contraindicated in persons with a known hypersensitivity to olopatadine hydrochloride or any components of the formulation.

Warnings and Precautions

Only for topical use and not for injection or oral use.

Drug Interactions

In vitro studies have shown that olopatadine did not inhibit metabolic reactions, which involve cytochrome P-450 isozymes 1A2, 2C8, 2C9, 2C19, 2D6, 2E1 and 3A4. These results indicate that olopatadine is unlikely to result in metabolic interactions with other concomitantly administered active substances.

Use in special populations Pregnancy : Pregnancy Category C.

There are, no adequate and well-controlled studies in pregnant women. Olopatadine should be used in pregnant women only if the potential benefit to the mother justifies the potential benefit risk to the embryo or fetus.

Lactating Women

It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Nevertheless, caution should be exercised when olopatadine hydrochloride ophthalmic solution is administered to a lactating woman.

Pediatric Use :

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

Geriatric Use :

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Information for Patients :

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.



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