For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

Olopatadine Hydrochloride Ophthalmic Solution USP

PATAVUE-BF®

पैटाव्यू-बीएफ

Composition :
Olopatadine Hydrochloride USP
Eq. to Olopatadine.....0.2% w/v
Stabilized Oxychloro Complex.....0.005% w/v
(As preservative)
Sterile aqueous vehicle.....q.s.

Dosage From
Eye Drops - Solution

Pharmacology
Pharmacodynamics
Olopatadine is a potent selective anti-allergic/anti-histaminic agent that exerts its effects through multiple distinct mechanisms of action. It antagonizes histamines (the primary mediator of allergic response in humans) and prevents histamine induced inflammatory cytokine production by human conjunctival mast cells 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.

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 in plasma was approximately eight to 12 hours, and 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 and the N-oxide, were detected at low concentrations in the urine. Since plasma concentrations 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 and symptoms of seasonal allergic conjunctivitis.

Dosage and Administration
The recommended dose of Olopatadine is one drop in affected eye two times per day at an interval of 6-8 hours.

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

Warnings & Precautions
FOR TOPICAL USE ONLY AND NOT FOR INJECTION OR ORAL USE. FOR EXTERNAL USE ONLY.
Use the solution within one month after opening the container.

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 adminisitered active substances.

Use the special populations
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 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 quantites in the human breast milk. Nevertheless, caution should be exercised when Olopatadine Hydrochloride Ophthalmic solution is administered to a lactating women.
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 vial. Keep vial tightly closed when not in use. Patients should be advised not to wear a contact lens if their eye is red. Olaopatadine hydrochloride ophthlmic 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.

Undesirable Effects :
Headaches have been reported at an incidence of 7%. The following undesirable efffects 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.

Overdose :
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.

Storage and handling information :
Store between 4°C & 25°C. Protect from light. Do not freeze.
Keep out of reach of children.

PRESENTATION:
Patavue-BF Eye Drops is available in 5 ml pack.

Manufactured by :
Akums Drugs & Pharmaceuticals Ltd.
2,3,4 & 5, Sector-6B, I.I.E., SIDCUL,
Haridwar - 249 403.

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LAVUE

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