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

Allerpat™-OD

Eye Drops

(Olopatadine Hydrochloride Ophthalmic Solution IP 0.2% w/v)

COMPOSITION:

Olopatadine Hydrochloride IP Equivalent to Olopatadine …..... 0.2 % w/v
Benzalkonium Chloride Solution IP ..... 0.02 % v/v
(As Preservative)
Water for Injections IP ..... q.s

Pharmacological Action

Olopatadine is a potent selective antiallergic/antihistaminic agent that exerts its effects 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 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 mg/ml) up to I .3 mg/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 ocular symptoms of allergic conditions, such as inflammation, itching and watering.

Dosage and Administration

The recommended dose of Allerpat-OD

Adults : (Age Group : above 17 years) : One drop in each affected eye, once a day or as directed by the Physician.

Children : (Age Group : 3-17 years) : One drop in each affected eye, once a day for 6 weeks or as directed by the Physician

Contraindications

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

Warnings

For topical use only and not for injection or oral use.

Precautions

General: If irritation persists or increases, discontinue the use and consult the Physician. 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 should not be used to treat contact lens related irritation. The preservative in this formulation, benzalkonium chloride, 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 olopatadine hydrochloride ophthalmic solution before they insert their contact lenses

Drug Interactions:

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 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.

Adverse Reactions

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, 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 under the care of a Physician. A topical overdose may be flushed from the eye(s) with warm tap water.

Storage Instructions

KEEP IN A COOL PLACE

PROTECT FROM LIGHT.

KEEP OUT OF REACH OF CHILDREN.

FOR EXTERNAL USE ONLY

Presentation

Allerpat OD is a sterile solution supplied in an opaque plastic bottle with a cap containing 3ml of solution.

Directions for use:

Turn the tamper proof cap anti-clockwise to break the seal.

Remove the cap, dispense drops with gentle pressure.

Replace the cap immediately after every use.

Manufactured in INDIA by :

Senses Pharmaceuticals Pvt. Ltd.,

No.77, 3rd Road, Bommasandra Industrial Area,
Bommasandra 4th Phase, Bengaluru - 560 099.

AODP-02

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