

Olopan® Eye Drops

(Olopatadine INN 0.1%)

Description: 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 human, olopatadine was shown to have low systemic exposure.

Indications: For the treatment of the signs and symptoms of allergic conjunctivitis.

Dosage and Administration: The recommended dose is one drop in each affected eye two times per day at an interval of 6 to 8 hours. Side Effect: Headaches, 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.

Contraindication: In persons with a known hypersensitivity to olopatadine hydrochloride or any components of the drug.

Warning: For topical ophthalmic use only. Not for injection or oral use.

Precaution: 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. Patients who wear soft contact lenses and whose eyes are not red should be instructed to wait at least ten minutes after instilling olopatadine before they insert their contact lenses.

High Risk Group: Pregnancy Category C: Because animal studies are not always predictive of human responses, this drug should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the embryo or fetus. 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.

Drug Interaction: No information available.

Pharmaceutical Precaution: Store in a cool and dry place, away from light. Keep out of reach of children.

Commercial Pack: Olopan® 0.1% Eye Drops: Dropper bottle containing 5 ml of sterile solution. Each ml contains Olopatadine Hydrochloride INN equivalent to Olopatadine INN 1 mg.

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH

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