

# Olopatadine HCI USP Anti-allergic Eye Drops

Olopatadine is an inhibitor of the release of histamine from the mast cell and a selective histamine  $H_1$ -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.

## COMPOSITION

Alacot® DS Eye Drops: Each ml contains Olopatadine 2 mg as Olopatadine HCl USP

Alacot® 0.1% Eye Drops: Each ml contains Olopatadine 1 mg as Olopatadine HCI USP.

# INDICATION

**Alacot**® Eye Drops is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

## DOSAGE AND ADMINISTRATION

Alacot® DS Eye Drops: One drop in the affected eye once a day.

**Alacot**® **0.1% Eye Drops:** One drop in each affected eye two times per day at an interval of 6 to 8 hours.

# CONTRAINDICATION

Olopatadine Hydrochloride ophthalmic solution is contraindicated in persons with a known hypersensitivity to Olopatadine Hydrochloride.

# **PRECAUTION**

Olopatadine HCl ophthalmic solution should not be used to treat contact lens related irritation. Patients who wear soft contact lenses should be instructed to wait at least ten minutes after instilling Olopatadine Hydrochloride ophthalmic solution before they insert their contact lenses.

## **USE IN PREGNANCY AND LACTATION**

There are no adequate and well controlled studies in pregnant women. 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 fetus.

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 nursing mother.

## SIDE EFFECT

Headaches have been reported at an incidence of 7% of patients. 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.

## **STORAGE**

Store below 30°C in a cool and dry place. Protect from light. Keep out of reach of children. Do not touch the dropper tip to surfaces since this may contaminate the solution. Do not use after 28 days of first opening.

# **HOW SUPPLIED**

**Alacot® DS & 0.1% Eye Drops:** Each dropper bottle contains 5 ml of Olopatadine HCl USP sterile solution.

