

Composition:

Alacot ® 0.1% Eye Drops: Each ml contains Olopatadine 1 mg as Olopatadine Hydrochloride INN.

Pharmacology:

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.

Indications:

Alacot ® 0.1% Eye Drops is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

Dosage and administration:

One drop in each affected eye two times per day at an interval of 6 to 8 hours.

Contraindications:

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

Precautions:

Olopatadine Hydrochloride 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 effects:

Headaches have been reported at an incidence of 7%. 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 condition:

Store in a cool and dry place, protect from light. Keep out of reach of children.

How supplied:

Alacot ® 0.1% Eye Drops: 5 ml sterile solution in plastic dropper bottle.