

AREST 0.1% Eye Drops

(Olopatadine Hydrochloride Ophthalmic Solution)

DESCRIPTION

AREST (Olopatadine hydrochloride) **0.1% Eye Drops** is a sterile ophthalmic solution containing olopatadine, a relatively selective H₁-receptor antagonist and inhibitor of histamine release from the mast cell, for topical administration to the eyes.

COMPOSITION

Each ml of **AREST** contains:

Olopatadine hydrochloride	1.11 mg
equivalent to Olopatadine	1 mg
Benzalkonium chloride	0.01 % w/v
[as preservative]	
Sterile aqueous vehicle	q.s.

CLINICAL 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. Olopatadine is devoid of effects on alpha-adrenergic, dopamine and muscarinic type-1 and 2 receptors.

Following topical ocular administration in man, Olopatadine was shown to have low systemic exposure. The half-life in plasma was approximately 3 hours, and elimination was predominantly through renal excretion. Approximately 60-70% of the dose was recovered in the urine as parent drug. Two metabolites, the monodesmethyl and the N-oxide, were detected at low concentrations in the urine.

Results from an environmental study demonstrated that Olopatadine was effective in the treatment of the signs and symptoms of allergic conjunctivitis when dosed twice daily for up to 6 weeks. Results from conjunctival antigen challenge studies demonstrated that when subjects were challenged with antigen both initially and up to 8 hours after dosing, Olopatadine was significantly more effective than its vehicle in preventing ocular itching and in reducing ocular redness associated with allergic conjunctivitis.

INDICATIONS AND USAGE

AREST (Olopatadine hydrochloride) **0.1% Eye Drops** is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

DOSAGE & ADMINISTRATION

The recommended dose is one drop in each affected eye twice daily at an interval of 6 to 8 hours..

CONTRAINDICATIONS

AREST (Olopatadine hydrochloride) **0.1% Eye Drops** is contraindicated in persons with a known hypersensitivity to olopatadine hydrochloride or any component of this product.

WARNINGS

AREST (Olopatadine hydrochloride) **0.1% Eye Drops** is for topical use only and not for injection or oral use.

PRECAUTIONS

Patients should be given the following instructions:

To prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip.

The bottle should be kept tightly closed when not in use.

If the eye is red, contact lens should not be worn.

AREST (Olopatadine hydrochloride) **0.1% Eye Drops** should not be used to treat contact lens related irritation.

The preservative in **AREST 0.1% Eye Drops**, 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 0.1% Eye Drops before they insert their contact lenses.

PREGNANCY

Olopatadine was found not to be teratogenic in rats and rabbits. There are, however, 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 embryo or fetus.

NURSING MOTHERS

Olopatadine has been identified in the milk of nursing rats following oral administration. 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 0.1% Eye Drops is administered to a nursing mother.

PEDIATRIC USE

Safety and effectiveness of **AREST 0.1% Eye Drops** 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

AREST [Olopatadine hydrochloride] **0.1% Eye Drops** is well tolerated. Side effects reported by a minority of patients are: headache, blurred vision, burning or stinging, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, nausea, pharyngitis, pruritis, rhinitis, sinusitis, and taste perversion. Some of these events were similar to the underlying disease being studied.

PRESENTATION

AREST (Olopatadine hydrochloride) **0.1% Eye Drops** is supplied in 5 ml bottles.

STORAGE

Store at 39°F-77°F (4°C-25°C)