

Olopatadine Hydrochloride USP Sterile Ophthalmic Solution

DESCRIPTION

Aladay® & Aladay® DS are preparations of Olopatadine. Olopatadine is an anti-allergic compound which has been demonstrated to stabilize human conjunctival tissue mast cells, preventing the release of histamine and other inflammatory mediators. Olopatadine is a selective histamine H1-antagonist that inhibits Type I immediate hypersensitivity reactions. It has been shown to inhibit the release of pro-inflammatory mediators from human conjunctival mast and epithelial cells. Olopatadine has no significant effects on alpha-adrenergic, dopamine and muscarinic Type 1 and 2 receptors.

INDICATIONS

Aladay® & Aladay® DS ophthalmic solution are indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

DOSAGE & ADMINISTRATION

Aladay®: Instill one drop in the affected eye(s) twice daily. **Aladay**® **DS**: Instill one drop in the affected eye(s) once daily.

CONTRAINDICATIONS

Hypersensitivity to any component of the product.

SIDE EFFECTS

The frequently reported adverse experiences have been burning and stinging upon instillation. Others include; asthenia, blurred vision, cold syndrome, dry eye, foreign body sensation, hyperaemia, keratitis, lid oedema, nausea, pharyngitis, pruritus, rhinitis, sinusitis and taste perversion.

PRECAUTION & WARNING

Not for injection or oral ingestion. For ophthalmic use only.

USE IN PREGNANCY & LACTATION

No adequate and well controlled studies in pregnant women have been performed; it should be carefully considered whether the potential benefit to the mother justifies the potential risk to the embryo or foetus.

It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities of Olopatadine/metabolites in human breast milk. Olopatadine ophthalmic solution should be used with caution in breastfeeding woman.

PHARMACEUTICAL PRECAUTION

Store in a cool (4-25 °C), dry place and away from light. Keep out of reach of children. Store in an upright position. To prevent contamination of the dropper tip and solution, care should be taken. Don't touch the eyelids, surrounding areas, finger or other surfaces with the dropper tip of the bottle. The bottle should be tightly closed when not in use. Do not use after 4 weeks of first opening.

PACKAGING

Aladay® Ophthalmic Solution: Plastic dropper bottle containing 5 mL sterile ophthalmic solution. Each mL contains Olopatadine Hydrochloride USP equivalent to Olopatadine 1 mg.

Aladay® DS Ophthalmic Solution: Plastic dropper bottle containing 5 mL sterile ophthalmic solution. Each mL contains Olopatadine Hydrochloride USP equivalent to Olopatadine 2 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH ® REGD. TRADEMARK PM03025 V03