ALLNEX 0.1 %

Eye Drops

Composition
Olopatadine hydrochloride 0.1% (1 mg/mL)

Action
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.

Indications
Allnex 0.1 % is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

Contraindications
Contraindicated in persons with a known hypersensitivity to olopatadine hydrochloride or any components.

Warnings
Not for injection
Allnex 0.1% is for topical use only and not for injection or oral use.

Adverse Reactions
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, pruritis, rhinitis, sinusitis, and taste perversion. Some of these events were similar to the underlying disease being studied.

Post Marketing Experience
The following adverse reactions have been reported during clinical studies with Olopatadine solution 0.1% Eye Drops and are classified according to the subsequent convention: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) and very rare (<1/10,000). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Eye disorders
Uncommon (≥ 0.1% to < 1%): punctate keratitis, keratitis, eye pain, dry eye, eyelid oedema, eye pruritus, eye discharge, ocular hyperaemia, eyelid margin crusting, ocular discomfort
Rare (≥ 0.01% to < 0.1%): photophobia, vision blurred, erythema of eyelid

Nervous system disorders
Uncommon (≥ 0.1% to < 1%): headache, dysgeusia
Rare (≥ 0.01% to < 0.1%): dizziness

Respiratory, thoracic and mediastinal disorders
Uncommon (≥ 0.1% to < 1%): nasal dryness

Gastrointestinal disorders:
Rare (≥ 0.01% to < 0.1%): dry mouth

Skin and subcutaneous tissue disorders:
Rare (≥ 0.01% to < 0.1%): dermatitis contact

General disorders and administration site conditions:
Uncommon (≥ 0.1% to < 1%): fatigue
Additional adverse reactions identified from post-marketing surveillance include the following. Frequencies cannot be estimated from the available data.

Eye disorders
Lacrimation increased

Immune system disorders
Hypersensitivity

Gastrointestinal disorders
Nausea

Precautions
Wearing of contact lenses: patients whose eyes are red should not wear contact lenses at all. Patient whose eyes are not red should wait 15 minutes after instilling the drops before inserting soft contact lenses

Pregnancy
Category C
Olopatadine was found not to be teratogenic in rats and rabbits. However, rats treated at 600 mg/kg/day, or 93,750 times the MROHD and rabbits treated at 400 mg/kg/day, or 62,500 times the MROHD, during organogenesis showed a decrease in live fetuses. 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 ophthalmic solution 0.1% is administered to a nursing mother.

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 Interactions
No information provided.

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.

To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas, or other surfaces with the dropper tip of the bottle. Keep the bottle tightly closed when not in use.

In case of concomitant therapy with other topical ocular medicines, an interval of five to ten minutes should be allowed between successive applications.

Presentation

Dropper bottle of 5 ml