1. Name of the medicinal product

Olopatadine Hydrochloride Ophthalmic Solution USP 0.1% w/v.

2. Qualitative and Quantitative

CompositionQualitative declaration

Olopatadine Hydrochloride USP

Quantitative declaration

For full list of Excipients, see section 6.1.

Excipients with known effects: This product contains Benzalkonium Chloride Solution.

3. Pharmaceutical Form

Ophthalmic Solution

Distribution category POM

A clear colourless solution, free from any visible particulate.

4. Therapeutic Indications

It is used in treatment of ocular signs and symptoms of seasonal allergic conjunctivitis.

4.1. Posology and Method of Administration

For topical ocular use only.

Recommended dose for Olopatadine Hydrochloride Ophthalmic Solution USP 0.1% w/v is onedrop in each affected eye two times per day at an interval of 6 to 8 hours.

4.2. Contraindications

In patient with known hypersensitivity to Olopatadine or to any of excipients.

4.3. Special Warnings and Special Precautions for Use

Not for injection or oral use, only for topical use.

Caution for use: This product contains Benzalkonium Chloride Solution.

Patients should be advised not to wear a contact lens if their eye is red.

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

Pregnancy: Not recommended during pregnancy. Use during pregnancy only if potential benefit to mother justifies potential risk to the embryo or foetus.
Lactation: caution should be exercised when olopatadine hydrochloride ophthalmic solution0.1% is administered to a nursing mother.

4.4. Interaction with other medicinal products and other forms of interaction

No metabolic interactions of olopatadine with other drug as it does not inhibit metabolic reactions involving cytochrome P-450 isozymes 1A2, 2C8, 2C9, 2C19, 2D6, 2E1 and 3A1.

4.5. Fertility, Pregnancy and Lactation

Pregnancy: Not recommended during pregnancy. Use during pregnancy only if potential benefit to mother justifies potential risk to the embryo or fetus.
Lactation: caution should be exercised when olopatadine hydrochloride ophthalmic solution0.1% is administered to a nursing mother.

4.6. Effects on ability to Drive and use Machines

Not applicable

4.7. Undesirable Effects

Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.
Infections and infestations: uncommon: rhinitis. Immune system disorders: not known: hypersensitivity, swelling face. Nervous system disorders; common; headache, dysgeusia; uncommon; dizziness, hypoaesthesia; not known; somnolence. Eye disorders; common; eye pain, eye irritation, dry eye, abnormal sensation in eyes; uncommon ; corneal erosion, corneal epithelium defect, corneal epithelium disorder, punctate keratitis, keratitis, corneal staining, eye discharge, photophobia, vision blurred, visual acuity reduced, blepharospasm, ocular discomfort, eye pruritus, conjunctival follicles, conjunctival disorder, foreign body sensation in eyes, lacrimation increased, erythema of eyelid, eyelid oedema, eyelid disorder, ocular hyperaemia ;Not known; corneal oedema, eye oedema, eye swelling, conjunctivitis, mydriasis, visual disturbance, eyelid margin crusting. Respiratory, thoracic, and mediastinal disorders; common; nasal dryness; not known; dyspnoea, sinusitis. Gastrointestinal disorders; not known; nausea, vomiting, Skin and subcutaneous tissue disorders; uncommon; dermatitis contact, skin

burning sensation, dry skin; not known; dermatitis, erythema. General disorders and administration site conditions; common; fatigue; not known; asthenia, malaise.

4.8. Overdose

No data are available regarding overdose by accidental or deliberate ingestion. It has a low order of acute toxicity in nonclinical. A topical overdosage of Olopatadine eye drops may be flushed from the eye(s) with warm tap water. Accidental ingestion of the entire contents of a bottle would deliver a maximum systemic exposure of would result in a final dose of 0.5 mg/kg in a 10 kg infant, assuming 100% absorption. Prolongation of the QTc interval was observed only at exposures considered sufficiently in excess of the maximum human exposure indicatinglittle relevance to clinical use.

A 5 mg oral dose was administered twice-daily for 2.5 days to some young and elderly healthy human with no significant prolongation of QTc interval compared to placebo. The range of peak steady-state Olopatadine plasma concentrations (35 to 127 ng/ml) seen, it represents at least a 70-fold safety margin for topical Olopatadine with respect to effects on cardiac repolarisation. In the case of overdose, appropriate monitoring and management of the patient should be implemented.

5. Pharmacological Properties

5.1. Pharmacodynamics Properties

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 (Ki values for Histamine H1, H2 and H3 receptors were 32 nM, 100 (M and 79 (M, respectively) 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.

5.2. Pharmacokinetic Properties

Following topical ocular administration, olopatadine was shown to have low systemic exposure.

Absorption: Systemic absorption of topically applied olopatadine is minimal with plasma concentrations ranging from 0.5 to 1.3 ng/ml. These concentrations are 50-to 200-fold lower than those following well tolerated oral doses.

Distribution: The mean apparent volume of distribution at (orally in human) was 133.83 L. Plasma protein binding is about 55%,

Excretion: Following ocular administration, the elimination half-life of olopatadine was 3.4 ± 1.2 hours. In oral, the elimination half-life was reported to be 8 to 12 hours. It has been detectedin breast milk after oral use at in preclinical. The elimination is predominantly through renal excretion with 60% to 70% unchanged dose recovered in urine. About 17% is excreted in the faeces.

Metabolism: Olopatadine is not extensively metabolized. It undergoes hepatic metabolism in a non-extensive manner. Following topical ocular application of olopatadine, olopatadine N-oxide is formed by metabolism catalyzed by flavin-containing monooxygenase 1 and 3 and was detected in the plasma after 4 hours post-dosing in less than 10% of the total plasma in half of the patients. Two metabolites, mono-desmethyl and N-oxide, are detected at low concentrations in urine. Dose adjustment is not expected to be necessary with hepatic impairment.

5.3 Preclinical Safety Data

Not Applicable.

1. Pharmaceutical Particulars

2. List of Excipients

Anhydrous Disodium Hydrogen
PhosphateDisodium Edetate
Sodium Chloride
Benzalkonium Chloride Solution
Hydrochloric acid
Water for Injections

3. Incompatibilities

Not applicable.

4. Shelf Life

24 months

Use the solution within 28 days after first opening the container

5. Special Precautions for Storage

Do not store above 30°C. Protect from light.

6. Nature and Contents of Container

5 ml plastic dropper bottle. Such 1 bottle is packed in printed carton with packing insert.

7. Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses

7.1. Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com;
Web site: www.lincolnpharma.com

7.2. Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com;
Web site: www.lincolnpharma.com

8. Marketing Authorization Number

TAN 22 HM 0302

9. **Date of First Registration**
08/04/2022

10. **Date of Revision of the Text**