Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

OLODIN (Olopatadine Ophthalmic Solution USP 0.1% w/v).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Olopatadine Hydrochloride Uequivalent to Olopatadine ..... 1.0 mg
Benzalkonium Chloride ..... 0.1 mg
(As Preservative)
Sterile Aqueous Vehicle…..... q.s.

3. PHARMACEUTICAL FORM

Ophthalmic solution.

Description

A clear colourless sterile solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

OLODIN Eye Drop is indicated for the treatment of ocular signs and symptoms of seasonal allergic conjunctivitis.

4.2 Posology and Method of Administration

For topical ocular instillation.

Adults and children above 3 years: One drop to be instilled in the conjunctival sac of the affected eye(s) twice daily (8-hour interval). Treatment may be maintained for up to 4 months, if considered necessary.

Paediatric Population

OLODIN Eye Drops may be used in paediatric patients 3 years of age and older at the same dose as in adults; safety and efficacy in children aged less than 3 years has not been established.

Method of Administration

- For ocular use only.
- Not for injection.
- Do not touch tip of the vial to finger or to eye(s)/eyelids or to any other surface since this may contaminate the solution. Keep the bottle tightly closed when not in use.
- If eye irritation occurs, discontinue the use and consult the Physician.
- Contact lenses should be removed before instillation of the eye drops and may be reinserted after 15 minutes.
- If more than one topical ophthalmic medicinal product is being used, the medicinal products should be instilled 5 to 15 minutes apart. Eye ointments should be administered last.
- Discard unused portion of eye drop, if any, after one month of first opening the vial (even though expiry date is longer).
- Follow the directions mentioned on the container label.

4.3 Contraindications

OLODIN Eye Drops is contraindicated in patients with known hypersensitivity to the olopatadine or to any of the excipients listed in section 6.1.

4.4 Special Warnings and Precautions for Use

Olopatadine, although administered topically, is absorbed systemically. If signs of serious reactions or hypersensitivity occur, discontinue the use of this treatment.

Benzalkonium chloride (as a preservative): Benzalkonium chloride may cause eye irritation and has also been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy. Close monitoring is required with frequent or prolonged use in dry eye patients, or in conditions where the cornea is compromised.

From the limited data available, there is no difference in the adverse event profile in children compared to adults. However, eyes in children generally show a stronger reaction for a given stimulus than the adult eye. Irritation may have an effect on treatment adherence in children.

Contact lenses: Benzalkonium is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Patients should be instructed to remove contact lenses prior to administration of the eye drop and wait at least 15 minutes after instillation before re-inserting contact lenses.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

No interaction studies with other medicinal products have been performed.

In vitro studies have shown that olopatadine did not inhibit metabolic reactions which involve cytochrome P-450 isozymes 1A2, 2C8, 2C9, 2C19, 2D6, 2E1 and 3A4. These results indicate that olopatadine is unlikely to result in metabolic interactions with other concomitantly administered active substances.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

There are no or limited amount of data from the use of ophthalmic olopatadine in pregnant women. Studies in animals have shown reproductive toxicity following systemic administration. Olopatadine is not recommended during pregnancy and in women of childbearing potential not using contraception.

Lactation

Available data in animals have shown excretion of olopatadine in milk following oral administration. A risk to the new-born/infants cannot be excluded. Thus, olopatadine eye drops should not be used during breast-feeding.

Fertility

Studies have not been performed to evaluate the effect of topical ocular administration of olopatadine on human fertility.

4.7 Effects on Ability to Drive and Use Machines

Olopatadine eye drops has no or negligible influence on the ability to drive and use machines.

As with any eye drop, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machinery.

4.8 Undesirable Effects

Clinical Trial Experience

In clinical studies involving 1680 patients, olopatadine was administered one to four times daily in both eyes for up to four months as monotherapy or adjunctive therapy to loratadine 10 mg. Approximately 4.5% of patients can be expected to experience adverse reactions associated with the use of olopatadine. No serious ophthalmic or systemic adverse reactions related to olopatadine were reported in clinical studies. The most frequent treatment-related adverse reaction was eye pain, reported at an overall incidence of 0.7%.

Clinical Studies and Post-marketing Experience

The following adverse reactions have been reported during clinical studies and post-marketing data and are classified according to the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1000), very rare (<1/10,000) or not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

System Organ Classification	**Frequency**	**Adverse Reactions**
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.

One of the excipient of the OLODIN Eye Drops contains phosphate. 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.

Reporting of Suspected Adverse Reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

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4.9 Overdose
No data are available in humans regarding overdose by accidental or deliberate ingestion. Olopatadine has a low order of acute toxicity in animals. Accidental ingestion of the entire contents of a bottle of olopatadine eye drops would deliver a maximum systemic exposure of 5 mg olopatadine. This exposure would result in a final dose of 0.5 mg/kg in a 10 kg infant, assuming 100% absorption.
Prolongation of the QTc interval in dogs was observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use. A 5 mg oral dose was administered twice-daily for 2.5 days to 102 young and elderly male and female healthy volunteers 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 in this study 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 Pharmacodynamic Properties
Pharmacotherapeutic Group: Ophthalmologicals; decongestant and antiallergics; other antiallergics; **ATC Code:** S01GX09.

Mechanism of Action
Olopatadine is a potent selective antiallergic/antihistaminic agent that exerts its effects through multiple distinct mechanisms of action. It antagonises histamine (the primary mediator of allergic response in humans) and prevents histamine induced inflammatory cytokine production by human conjunctival epithelial cells. Data from *in vitro* studies suggest that it may act on human conjunctival mast cells to inhibit the release of pro-inflammatory mediators.

Pharmacodynamic Effects
In patients with patent nasolacrimal ducts, topical ocular administration of olopatadine was suggested to reduce the nasal signs and symptoms that frequently accompany seasonal allergic conjunctivitis. It does not produce a clinically significant change in pupil diameter.

5.2 Pharmacokinetic Properties

Olopatadine is absorbed systemically, as are other topically administered medicinal products. However, systemic absorption of topically applied olopatadine is minimal with plasma concentrations ranging from below the assay quantitation limit (<0.5 ng/ml) up to 1.3 ng/ml. These concentrations are 50-to 200-fold lower than those following well tolerated oral doses.
From oral pharmacokinetic studies, the half-life of olopatadine in plasma was approximately 8 to 12 hours, and elimination was predominantly through renal excretion. Approximately 60 to 70% of the dose was recovered in the urine as active substance. Two metabolites, the mono-desmethyl and the N-oxide, were detected at low concentrations in the urine.
Since olopatadine is excreted in urine primarily as unchanged active substance, impairment of renal function alters the pharmacokinetics of olopatadine with peak plasma concentrations 2.3-fold greater in patients with severe renal impairment (mean creatinine clearance of 13.0 ml/min) compared to healthy adults.

5.3 Preclinical Safety Data
Non-clinical data reveal no special hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.
Studies in animals have shown reduced growth of nursing pups of dams receiving systemic doses of olopatadine well in excess of the maximum level recommended for human ocular use. Olopatadine has been detected in the milk of nursing rats following oral administration.

6. PHARMACEUTICAL PARTICULARS
6.1 List of Excipients
Dibasic Sodium Phosphate Dodecahydrate, Sodium Chloride, Benzalkonium Chloride, Sodium Hydroxide, Hydrochloric Acid, Water for Injection.

6.2 Incompatibilities
Not available.

6.3 Shelf-life
24 months.

6.4 Special Precautions for Storage
Store at a temperature not exceeding 25°C. Protect from light.

6.5 Nature and Contents of Container
5.0 mL solution filled in 5.0 mL LDPE bottle with insert cap assembly comprising of white colored, HDPE screw cap over a LDPE nozzle with tamper evident LDPE dust cover, sealing the bottle cap.

6.6 Special Precautions for Disposal and Other Handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
Registered Office:
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Phone: 022-26739-273

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8. MARKETING AUTHORISATION NUMBER(S)
Certificate No: 08816/10529/NMR/2023

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Jul 13, 2023

10. DATE OF REVISION OF THE TEXT
September 2023