SUMMARY OF PRODUCT CHARACTERISTICS
OLOPAT (Olopatadine Hydrochloride Ophthalmic Solution USP 0.1% w/v)

1. NAME OF THE MEDICINAL PRODUCT

OLOPAT (Olopatadine Hydrochloride Ophthalmic Solution USP 0.1% w/v)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of solution contains olopatadine hydrochloride USP equivalent to olopatadine 1 mg (0.1% w/v).

Excipient with known effect:
Benzalkonium chloride 0.1 mg/mL (0.01% w/v).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.

A clear, colourless to pale yellow, sterile isotonic aqueous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

OLOPAT is indicated for the treatment of the signs and symptoms of allergic conjunctivitis in adults and children.

4.2 Posology and method of administration

One to two drops in each affected eye twice daily (morning and evening). Treatment should be continued for as long as required to relieve signs and symptoms.

Contact lenses
OLOPAT contains benzalkonium chloride (BAK) as a preservative, which may be absorbed by soft contact lenses and discolour them. Patients who wear soft contact lenses whose eyes are not red should be instructed to wait at least 10 minutes after instilling OLOPAT before inserting their contact lenses. OLOPAT should not be used to treat contact lens-related irritation.

Special populations
No dose adjustment is required for elderly patients or patients with renal or hepatic impairment.

Method of administration
Topical ocular use only — not for injection or oral use.

4.3 Contraindications

- Hypersensitivity to olopatadine hydrochloride or to any of the excipients listed in section 6.1, including benzalkonium chloride.

4.4 Special warnings and precautions for use

For topical ocular use only
OLOPAT is for topical use only and not for injection or oral use.

Contact lenses
See section 4.2 regarding benzalkonium chloride absorption and soft contact lenses.

Benzalkonium chloride
Benzalkonium chloride may cause eye irritation or eye surface disease, especially with prolonged use or pre-existing corneal disease. Monitor patients using this product for prolonged periods.

4.5 Interaction with other medicinal products and other forms of interaction

In vitro studies have shown that olopatadine did not inhibit metabolic reactions involving CYP450 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. No formal ocular drug interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies: olopatadine was not teratogenic in rats or rabbits at therapeutic doses. Rats treated at 93,750 times the maximum recommended ophthalmic human dose (MROHD) and rabbits at 62,500 times the MROHD during organogenesis showed a decrease in live foetuses. No adequate and well-controlled studies in pregnant women are available. OLOPAT should be used during pregnancy only if the expected benefit justifies the potential risk to the foetus.

Breast-feeding

Olopatadine has been identified in the milk of nursing rats following oral administration. It is not known whether topical ocular administration could result in detectable quantities in human breast milk. Caution should be exercised when administering OLOPAT to breast-feeding women.

Fertility

Animal studies with oral olopatadine at 62,500 times the MROHD showed a slight decrease in the fertility index and reduced implantation rate. No effects on reproductive function were observed at doses up to 7,800 times the MROHD.

4.7 Effects on ability to drive and use machines

Olopatadine has no or negligible influence on the ability to drive and use machines. Transient blurring of vision may occur after instillation; patients should not drive or operate machines until vision is clear.

4.8 Undesirable effects

Ocular: Common — transient ocular stinging/burning or discomfort on instillation, blurred vision, keratitis, dry eye, eye pain, eyelid oedema. Uncommon — corneal staining, abnormal sensation in the eye. Systemic (due to topical absorption): headache, bitter taste, rhinitis, sinusitis. Benzalkonium chloride may cause eye irritation with prolonged use. In case of systemic absorption, anti-histamine-related effects (somnolence) may occasionally occur.

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 Regulatory Authority.

4.9 Overdose

Accidental ingestion of the entire contents of a bottle would result in a systemic exposure of approximately 5 mg olopatadine. At this dose level, no specific toxicological concern is expected. In case of overdose, institute appropriate monitoring and management.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals; anti-allergic preparations. ATC code: S01GX09.

Olopatadine is a dual-acting anti-allergic agent that acts as a selective histamine H1-receptor antagonist and inhibits the release of histamine from mast cells. It inhibits in vivo and in vitro type 1 immediate hypersensitivity reactions, 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 humans, olopatadine has low systemic exposure. A QTc study in healthy volunteers showed no significant prolongation of the QTc interval at doses providing at least a 70-fold safety margin compared to topical olopatadine exposure.

5.2 Pharmacokinetic properties

Two studies in normal volunteers dosed bilaterally with olopatadine 0.15% ophthalmic solution twice daily for 2 weeks demonstrated plasma concentrations generally below the quantitation limit of the assay (<0.5 ng/mL). When quantifiable, samples ranged from 0.5–1.3 ng/mL at approximately 2 hours post-dosing. Plasma half-life approximately 3 hours. Elimination predominantly through renal excretion; approximately 60–70% of the

dose recovered in the urine as parent drug. Two minor metabolites (mono-desmethyl and the N-oxide) were detected at low concentrations in urine.

5.3 Preclinical safety data

Olopatadine administered orally was not carcinogenic in mice or rats. Not mutagenic in standard genotoxicity tests (Ames test, mammalian chromosome aberration assay, mouse micronucleus test). Not teratogenic in rats or rabbits at exposures well above the MROHD. QTc prolongation in dogs observed only at exposures considered sufficiently in excess of maximum human exposure to be of minimal clinical relevance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium Chloride, Disodium Hydrogen Phosphate Dodecahydrate, Sodium Dihydrogen Phosphate Dihydrate, Sodium Chloride, Sodium Hydroxide and Water for Injections.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years (unopened). 1 month after first opening.

6.4 Special precautions for storage

Store below 30°C. Keep out of the reach and sight of children. Discard 1 month after first opening.

6.5 Nature and contents of container

Ophthalmic solution in a plastic dropper bottle.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ajanta Pharma Limited
Ajanta House,
Charkop, Kandivli (West),
Mumbai- 400 067,
India

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2016/CTD4107/941

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

16/02/2017

10. DATE OF REVISION OF THE TEXT

08 Jan 2026