Summary of Pharmaceutics Characteristics

OLOPAT OD
Olopatadine Hydrochloride Ophthalmic Solution USP 0.2% w/v

Composition:

Olopatadine Hydrochloride USP Equivalent to Olopatadine	0.2% w/v
Benzalkonium Chloride USPNF (As preservative)	0.01% w/v
Sterile Aqueous Vehicle	q.s

Pharmaceutical Form:

Eye Drops
Clear, colourless, solution, free from visible particles.

Clinical Particulars

Therapeutic Indications:
Olopat OD solution is indicated for the treatment of ocular itching associated with allergic conjunctivitis.

Posology and Method of administration:

Method of Administration

The recommended dose is one drop in each affected eye once a day.

Pediatric Use
Safety and effectiveness in pediatric patients below the age of 2 years have not been established.

Geriatric Use
No overall differences in safety and effectiveness have been observed between elderly and younger patients.

Contraindications:

Hypersensitivity to the active substance or to any of the excipients.

Special warning and precautions for use:

For topical ocular use only.
Not for injection or oral use.
Contamination of Tip and Solution
As with any eye drop, to prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.
Contact Lens Use

Patients should be advised not to wear a contact lens if their eye is red.
Olopatadine hydrochloride ophthalmic solution 0.2% should not be used to treat contact lens related irritation.
The preservative in Olopat OD solution, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses and whose eyes are not red, should be instructed to wait at least ten minutes after instilling Olopat OD before they insert their contact lenses.

Interactions with other medicinal products and other forms of Interactions :

No Information is available.

Pregnancy and Lactation:

Pregnancy

Teratogenic effects: Pregnancy Category C

Olopatadine was found not to be teratogenic in rats and rabbits. However, rats treated at 600 mg/kg/day, or 150,000 times the MROHD and rabbits treated at 400 mg/kg/day, or approximately 100,000 times the MROHD, during organogenesis showed a decrease in live fetuses. In addition, rats treated with 600 mg/kg/day of Olapatadine during organogenesis showed a decrease in fetal weight. Further, rats treated with 600 mg/kg/day of Olapatadine during late gestation through the lactation period showed a decrease in neonatal survival and body weight. 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 0.2% is administered to a nursing mother.

Effects on ability to drive and use machine:
No Information is available.

Adverse effects:

Symptoms similar to cold syndrome and pharyngitis were reported at an incidence of approximately 10%.
The following adverse experiences have been reported in 5% or less of patients:
Ocular: blurred vision, burning or stinging, conjunctivitis, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, pain and ocular pruritus.
Non-ocular: asthenia, back pain, flu syndrome, headache, increased cough, infection, nausea, rhinitis, sinusitis and taste perversion.

Overdosage:
No Information is available.

Pharmacological properties

Mechanism of Action

Olopatadine is a mast cell stabilizer and a histamine H1 antagonist. Decreased chemotaxis and inhibition of eosinophil activation has also been demonstrated.

Pharmacokinetics Properties:

Systemic bioavailability data upon topical ocular administration of Olopatadine 0.2% solution are not available. Following topical ocular administration of Olopatadine 0.15% ophthalmic solution in man, Olopatadine was shown to have a low systemic exposure.
Two studies in normal volunteers (totalling 24 subjects) dosed bilaterally with Olopatadine 0.15% ophthalmic solution once every 12 hours for 2 weeks demonstrated plasma concentrations to be generally below the quantitation limit of the assay (< 0.5 ng/mL). Samples in which Olopatadine was quantifiable were typically found within 2 hours of dosing and ranged from 0.5 to 1.3 ng/mL. The elimination half-life in plasma following oral dosing was 8 to 12 hours, and elimination was predominantly through renal excretion. Approximately 60 - 70% of the dose was recovered in the urine as parent drug. Two metabolites, the mono-desmethyl and the N-oxide, were detected at low concentrations in the urine.

Preclinical Safety data:

Olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500 mg/kg/day and 200 mg/kg/day, respectively. Based on a 40 µL drop size and a 50 kg person, these doses were approximately 150,000 and 50,000 times higher than the maximum recommended ocular human dose (MROHD). No mutagenic potential was observed when olopatadine was tested in an in vitro bacterial reverse mutation (Ames) test, an in vitro mammalian chromosome aberration assay or an in vivo mouse micronucleus test.
Olopatadine administered to male and female rats at oral doses of approximately 100,000 times MROHD level resulted in a slight decrease in the fertility index and reduced implantation rate; no effects on reproductive function were observed at doses of approximately 15,000 times the MROHD level.

Pharmaceutical particulars

List of Excipients:
Benzalkonium Chloride USPNF, Povidone USP, Disodium Hydrogen Phosphate Dodecahydrate BP, Sodium Dihydrogen Phosphate Dihydrate BP, Sodium Hydroxide BP (Pellets), Sodium Chloride BP, Water for Injection BP/USP.

Incompatibilities: Not known.

Special Precautions for storage: Use the solution within one month after opening the vial.

Storage Condition: Store below 30º C.

Nature and contents of container: 3 mL solution in 5 mL LDPE vial packed in a carton along with pack insert.

Marketing Authorization Holder: Manufacturing Site : Ajanta Pharma Ltd. Mirza - Palashbhari Road, Village Kokhjar, Kamrup (R), Guwahati, Assam – 781128 Registered office: Ajanta House, Charkop, Kandivli (W), Mumbai 400 067 India.
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