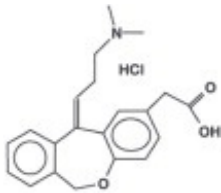


OLOPATADINE- olopatadine hydrochloride solution/ drops Akorn

DESCRIPTION

Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1% is a sterile ophthalmic solution containing Olopatadine, a relatively selective H₁-receptor antagonist and inhibitor of histamine release from the mast cell for topical administration to the eyes. Olopatadine Hydrochloride is a white, crystalline, water-soluble powder with a molecular weight of 373.88. The chemical structure is presented below:



Chemical Name: 11-[(Z)-3-(Dimethylamino)propylidene]-6-11dihydrodibenz[b,e] oxepin-2-acetic acid hydrochloride

Each mL of Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1% contains: Active: 1.11 mg Olopatadine Hydrochloride equivalent to 1 mg Olopatadine. Inactives: Dibasic Sodium Phosphate; Sodium Chloride; Hydrochloric Acid/Sodium Hydroxide (adjust pH); and Water for Injection. Preservative: Benzalkonium Chloride 0.01%. It has a pH of approximately 7 and an osmolality of approximately 300 mOsm/kg.

CLINICAL PHARMACOLOGY

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. Following topical ocular administration in man, Olopatadine was shown to have low systemic exposure. Two studies in normal volunteers (totaling 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 half-life in plasma was approximately 3 hours, and elimination was predominantly through renal excretion. Approximately 60 to 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.

Results from an environmental study demonstrated that Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1% was effective in the treatment of the signs and symptoms of allergic conjunctivitis when dosed twice daily for up to 6 weeks. Results from conjunctival antigen challenge studies demonstrated that Olopatadine

Hydrochloride Ophthalmic Solution USP, 0.1%, when subjects were challenged with antigen both initially and up to 8 hours after dosing, was significantly more effective than its vehicle in preventing ocular itching associated with allergic conjunctivitis.

INDICATIONS AND USAGE

Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1% is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

CONTRAINDICATIONS

Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1% is contraindicated in persons with a known hypersensitivity to Olopatadine Hydrochloride or any components of Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1%.

WARNINGS

Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1% is for topical use only and not for injection or oral use.

PRECAUTIONS

Information for Patients: 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.

Patients should be advised not to wear a contact lens if their eye is red. Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1% should not be used to treat contact lens related irritation. The preservative in Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1%, 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 Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1% before they insert their contact lenses.

Carcinogenesis, Mutagenesis, Impairment of Fertility: 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 μ L drop size, these doses were 78,125 and 31,250 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 62,500 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 7,800 times the maximum recommended ocular human use level.

Pregnancy: 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

Olopatadine HCl
Ophthalmic Solution, USP
0.1%
FOR USE IN THE EYES ONLY
Rx only 5 mL

2071
OLPTAL Rev. 01/17

Each mL contains:
Active: Olopatadine HCl
1.11 mg, equivalent to
Olopatadine 1 mg.
Inactives: Dibasic Sodium
Phosphate, Sodium Chloride,
Hydrochloric Acid and/or
Sodium Hydroxide (to adjust
pH), and Water for Injection.
Preservative: Benzalkonium
Chloride 0.01%.

NDC 17478-105-05
Olopatadine HCl
Ophthalmic Solution, USP
0.1%
FOR USE IN THE EYES ONLY
Rx only **5 mL**

Usual Dosage:
See enclosed insert.
Storage: Store at 4°
to 25°C (39° to 77°F).

Mfd. by: **Akorn, Inc.**
Lake Forest, IL 60045

(01)00317478105053

Principal Display Panel Text for Carton Label:

NDC 17478-105-05
Olopatadine
HCl
Ophthalmic
Solution, USP
0.1%
FOR USE IN THE EYES
ONLY
5 mL
Rx only Akorn Logo



017701

NDC 17478-105-05

NDC 17478-105-05

Usual Dosage:
See enclosed insert.

Storage: Store at 4° to 25°C
(39° to 77°F).

Warning: Do not touch
dropper tip to any surface, as
this may contaminate the
solution.

**Olopatadine
HCl
Ophthalmic
Solution, USP**

0.1%

**FOR USE IN THE EYES
ONLY**

Each mL contains:
Active: Olopatadine
Hydrochloride 1.11 mg,
equivalent to Olopatadine
1 mg.
Inactives: Dibasic Sodium
Phosphate, Sodium Chloride,
Hydrochloric Acid and/or
Sodium Hydroxide (to adjust
pH), and Water for Injection.
Preservative: Benzalkonium
Chloride 0.01%.

**Olopatadine
HCl
Ophthalmic
Solution, USP**

0.1%

**FOR USE IN THE EYES
ONLY**

This package is not child
resistant.

Keep out of reach of
children.

5 mL



N 17478-105-05 3

Manufactured by:
Akorn, Inc.
Lake Forest, IL 60045

Rx only



OLPTAC Rev. 01/17

Rx only



5 mL

OLOPATADINE

olopatadine hydrochloride solution/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:17478-105
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Olopatadine Hydrochloride (UNII: 2XG66W44KF) (Olopatadine - UNII:D27V6190PM)	Olopatadine	1 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
Sodium Phosphate, Dibasic (UNII: GR686LBA74)	
Sodium Chloride (UNII: 451W47IQ8X)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	
Benzalkonium Chloride (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17478-105-05	1 in 1 CARTON	01/10/2017	
1		5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204532	01/10/2017	

Labeler - Akorn (117696770)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(17478-105) , ANALYSIS(17478-105) , STERILIZE(17478-105) , PACK(17478-105) , LABEL(17478-105)

Revised: 2/2022

Akorn