OLOPATADINE- olopatadine hydrochloride solution/ drops
Akorn

Drug Facts

Active ingredient

Olopatadine (0.2%)

(equivalent to olopatadine hydrochloride 0.222%)

Purpose

Antihistamine

Use

temporarily relieves itchy eyes due to pollen, ragweed, grass, animal hair and dander.

Warnings

For external use only

Do not use

- if solution changes color or becomes cloudy
- if you are sensitive to any ingredient in this product
- to treat contact lens related irritation

When using the product

- do not touch tip of container to any surface to avoid contamination
- remove contact lenses before use
- wait at least 10 minutes before reinserting contact lenses after use
- do not wear a contact lens if your eye is red

Stop use and ask a doctor if you experience:

- eye pain
- changes in vision
- increased redness of the eye
- itching worsens or lasts for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **adults and children 2 years of age and older:**
  - put 1 drop in the affected eye(s) once daily, no more than once per day

- if using other ophthalmic products while using this product, wait at least 5 minutes between each product
- replace cap after each use

- **children under 2 years of age:** consult a doctor

Other information

- only for use in the eye
- store at 4° to 25°C (39° to 77°F).

Inactive ingredients

benzalkonium chloride 0.01%, dibasic sodium phosphate, edetate disodium, hydrochloric acid/sodium hydroxide (adjust pH), povidone, sodium chloride, and water for injection

Questions?

Call toll-Free 1-800-932-5676 weekdays, 7:00 AM - 5:30 PM CST

Principal Display Panel Text for Container Label:

NDC 17478-312-12

Olopatadine HCl Ophthalmic

Solution, USP 0.2%

Antihistamine

ONCE DAILY

STERILE 2.5 mL (0.085 FL OZ)

Principal Display Panel Text for Carton Label:

Original NDC 17478-312-12

Prescription

Strength Akorn logo

Olopatadine

HCl Ophthalmic

Solution, USP

0.2%

Antihistamine

Eye Allergy Itch Relief

Works in Minutes

Relief from Allergens:

- Pet Dander
- Pollen
- Grass
- Ragweed

ONCE DAILY

STERILE

2.5 mL (0.085 FL OZ)

OLOPATADINE

olopatadine hydrochloride solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17478-312
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

Olopatadine Hydrochloride (UNII: 2XG66W44KF) (Olopatadine - UNII:D27V6190PM)	Olopatadine	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
benzalkonium chloride (UNII: F5UM2KM3W7)	
sodium phosphate, dibasic, unspecified form (UNII: GR686LBA74)	
edetate disodium (UNII: 7FLD91C86K)	
hydrochloric acid (UNII: QTT17582CB)	
sodium hydroxide (UNII: 55X04QC32I)	
povidone, unspecified (UNII: FZ989GH94E)	
sodium chloride (UNII: 451W47IQ8X)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17478-312-12	1 in 1 CARTON	09/01/2021	
1		2.5 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	ANDA204723	09/01/2021	

OLOPATADINE

olopatadine hydrochloride solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17478-305
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength

benzalkonium chloride (UNII: F5UM2KM3W7)	
sodium phosphate, dibasic, unspecified form (UNII: GR686LBA74)	
edetate disodium (UNII: 7FLD91C86K)	
hydrochloric acid (UNII: QTT17582CB)	
sodium hydroxide (UNII: 55X04QC32I)	
povidone, unspecified (UNII: FZ989GH94E)	
sodium chloride (UNII: 451W47IQ8X)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17478-305-11	2 in 1 CARTON	09/01/2021	
1		2.5 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	ANDA204723	09/01/2021	

Labeler - Akorn (117696770)

Registrant - AKORN OPERATING COMPANY LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	LABEL(17478-312, 17478-305) , MANUFACTURE(17478-312, 17478-305) , PACK(17478-312, 17478-305) , ANALYSIS(17478-312, 17478-305) , STERILIZE(17478-312, 17478-305)

Revised: 2/2022 Akorn