OLOPATADINE HYDROCHLORIDE- olopatadine hydrochloride ophthalmic solution Strategic Sourcing Services LLC

Drug Facts

Active Ingredient	Purpose
Olopatadine (0.1%).	Antihistamine and redness reliever
(equivalent to olopatadine hydrochloride	
0.111%)	

Uses

temporarily relieves itchy and red 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 this 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) twice daily, every 6 to 8 hours, no more than twice 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 between 4°C to 25°C (39°F to 77°F)

Inactive ingredients

benzalkonium chloride 0.01%, dibasic sodium phosphate, hydrochloric acid and/ or sodium hydroxide (to adjust PH), sodium chloride and water for injection.

Questions or comments?

In the U.S., call Monday to Friday 9:00am to 7:00pm EST.at (833) 358-6431.

Distributed by:

McKesson Corp.,

Via Strategic Sourcing Services LLC.

Memphis, TN 38141

Product of Spain

February 2025

PRINCIPAL DISPLAY PANEL

NDC 70677-1280-1

Olopatadine hydrochloride ophthalmic solution 0.1%

Antihistamine and Redness Reliever

Twice Daily Relief Eye Allergy Itch & Redness Relief

5 mL STERILE



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Antihistamine and Redness Reliever

Twice Daily Relief Eye Allergy Itch & Redness Relief



OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride ophthalmic solution

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70677-1280

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety Ingredient Name Basis of Strength OLOPATADINE HYDROCHLORIDE (UNII: 2XG66W44KF) (Olopatadine - UNII:D27V6190PM) Olopatadine 1 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)			
HYDROCHLORIC ACID (UNII: QTT17582CB)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)			
WATER (UNII: 059QF0KO0R)			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70677- 1280-1	1 in 1 CARTON	03/01/2025		
1		5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA200810	03/01/2025			

Labeler - Strategic Sourcing Services LLC (116956644)

Establishment						
Name	Address	ID/FEI	Business Operations			
SamChunDang Pharm Co, Ltd		687792325	MANUFACTURE(70677-1280)			

Revised: 2/2025 Strategic Sourcing Services LLC