OLOPATADINE HYDROCHLORIDE- olopatadine hydrochloride solution GLENMARK THERAPEUTICS INC., USA

Drug Facts

Active Ingredients	Purpose
Olopatadine 0.2% (equivalent to olopatadine hydrochloride 0.222%)	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 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 eve
- 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:
 - o put 1 drop in the affected eye(s) once daily, no more than once per day
 - o if using other ophthalmic products while using this product, wait at least 5

- minutes between each product
- o replace cap after each use
- children under 2 years of age: consult a doctor

Other information

- only for use in the eye
- store between 2°C to 25°C (36°F to 77°F)

Inactive ingredients

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

Questions?

In the U.S., call toll free weekdays 9 AM to 6 PM EST at 1 (888) 721-7115.

Distributed by:

Glenmark Therapeutics Inc., USA

Mahwah, NJ 07430

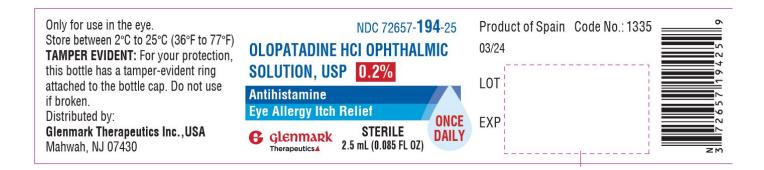
March 2025

PRINCIPAL DISPLAY PANEL

Olopatadine hydrochloride ophthalmic solution 0.2%

Antihistamine 2.5 mL STERILE

EYE ALLERGY ITCH RELIEF



ONCE DAILY RELIEF

Olopatadine hydrochloride ophthalmic solution 0.2% Antihistamine

Eye Allergy Itch Relief

STERILE 2.5 mL

NDC: 72657-194-25



OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:72657-194

Route of Administration OPHTHALMIC

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

Inactive Ingredients				
Ingredient Name	Strength			
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				
POVIDONE K30 (UNII: U725QWY32X)				
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:72657- 194-25	1 in 1 CARTON	02/28/2025	
1		2.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:72657- 194-11	2 in 1 CARTON	02/28/2025	
2		2.5 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	ANDA219557	02/28/2025	

Labeler - GLENMARK THERAPEUTICS INC., USA (969085666)

Establishment					
Name	Address	ID/FEI	Business Operations		
SamChunDang Pharm Co, Ltd		687792325	MANUFACTURE(72657-194)		

Revised: 2/2025 GLENMARK THERAPEUTICS INC., USA