

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 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:**
 - 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?

Call weekdays 9 AM to 6 PM EST at **1 (888) 721-7115**.

Distributed by:

Glenmark Therapeutics Inc., USA

Elmwood Park, NJ 07407

Product of Spain

07/2025

PRINCIPAL DISPLAY PANEL

NDC 72657-194-25

Olopatadine HCl Ophthalmic Solution 0.2%

Antihistamine

Once Daily

STERILE

2.5 mL (0.085 FL OZ)

<p>Only for use in the eye. Store between 2°C to 25°C (36°F to 77°F). TAMPER EVIDENT: For your protection, this bottle has a tamper-evident ring attached to the bottle cap. Do not use if seal is broken or missing. Distributed by: Glenmark Therapeutics Inc., USA, Elmwood Park, NJ 07407 www.glenmarkpharma-us.com</p>	<p>NDC 72657-194-25</p> <p>OLOPATADINE HCl OPHTHALMIC SOLUTION, USP 0.2% ANTIHISTAMINE</p> <p>ONCE DAILY</p> <p>STERILE 2.5 mL (0.085 FL OZ)</p>	<p>Product of Spain Code No.: 1335 07/25</p>	
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NDC: 72657-194-25

Original Prescription Strength

ONCE DAILY

Olopatadine HCl Ophthalmic Solution, USP 0.2%
Antihistamine

Eye Allergy Itch Relief

STERILE

2.5 mL (0.085 FL OZ)



OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72657-194
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

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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)				
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: 1/2026

GLENMARK THERAPEUTICS INC., USA