

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?

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

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 broken. Distributed by: Glenmark Therapeutics Inc., USA Mahwah, NJ 07430	NDC 72657-194-25	Product of Spain Code No.: 1335
	OLOPATADINE HCl OPTHALMIC SOLUTION, USP 0.2% Antihistamine Eye Allergy Itch Relief  STERILE 2.5 mL (0.085 FL OZ) 	03/24
	LOT	EXP

Original Prescription Strength

ONCE DAILY RELIEF

Olopatadine hydrochloride ophthalmic solution 0.2%
Antihistamine

Eye Allergy Itch Relief

STERILE
2.5 mL

NDC: 72657-194-25

Drug Facts (continued)

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This product is not manufactured or distributed by Alcon Laboratories, Inc., distributor of Pataday® Once Daily Relief, and/or Novartis AG, owner of the registered trademark Pataday®, respectively. Neither Alcon nor Novartis make or license Glenmark's product.

Distributed by:
Glenmark Therapeutics Inc., USA
Mahwah, NJ 07430
Product of Spain

Code No.: 1335
03/24

Original Prescription Strength NDC 72657-194-25

OLOPATADINE HCl OPHTHALMIC SOLUTION, USP 0.2%

Antihistamine

Eye Allergy Itch Relief

Works in Minutes

Relief from Allergens:
• Pet Dander • Pollen
• Grass • Ragweed

glenmark Therapeutics **STERILE**
2.5 mL (0.085 FL OZ)

OLOPATADINE HCl OPHTHALMIC SOLUTION, USP 0.2%

Eye Allergy Itch Relief

Works in Minutes

Relief from Allergens:
• Pet Dander
• Pollen
• Grass
• Ragweed

For Ages 2 and Older.

30 DAY SUPPLY

TAMPER EVIDENT:
For your protection, this bottle has a tamper-evident ring attached to the bottle cap.

Fill Line

Do not use if broken.

ACTUAL SIZE

Drug Facts

Active ingredient	Purpose
Olopatadine (0.2%)	Antihistamine (equivalent to olopatadine hydrochloride 0.222%)

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N
3 72657 19425 9

LOT

EXP

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

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: 2/2025

GLENMARK THERAPEUTICS INC., USA