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

Drug Facts

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

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

Distributed by:

Glenmark Therapeutics Inc., USA

Mahwah, NJ 07430

Product of Spain

May 2023

PRINCIPAL DISPLAY PANEL

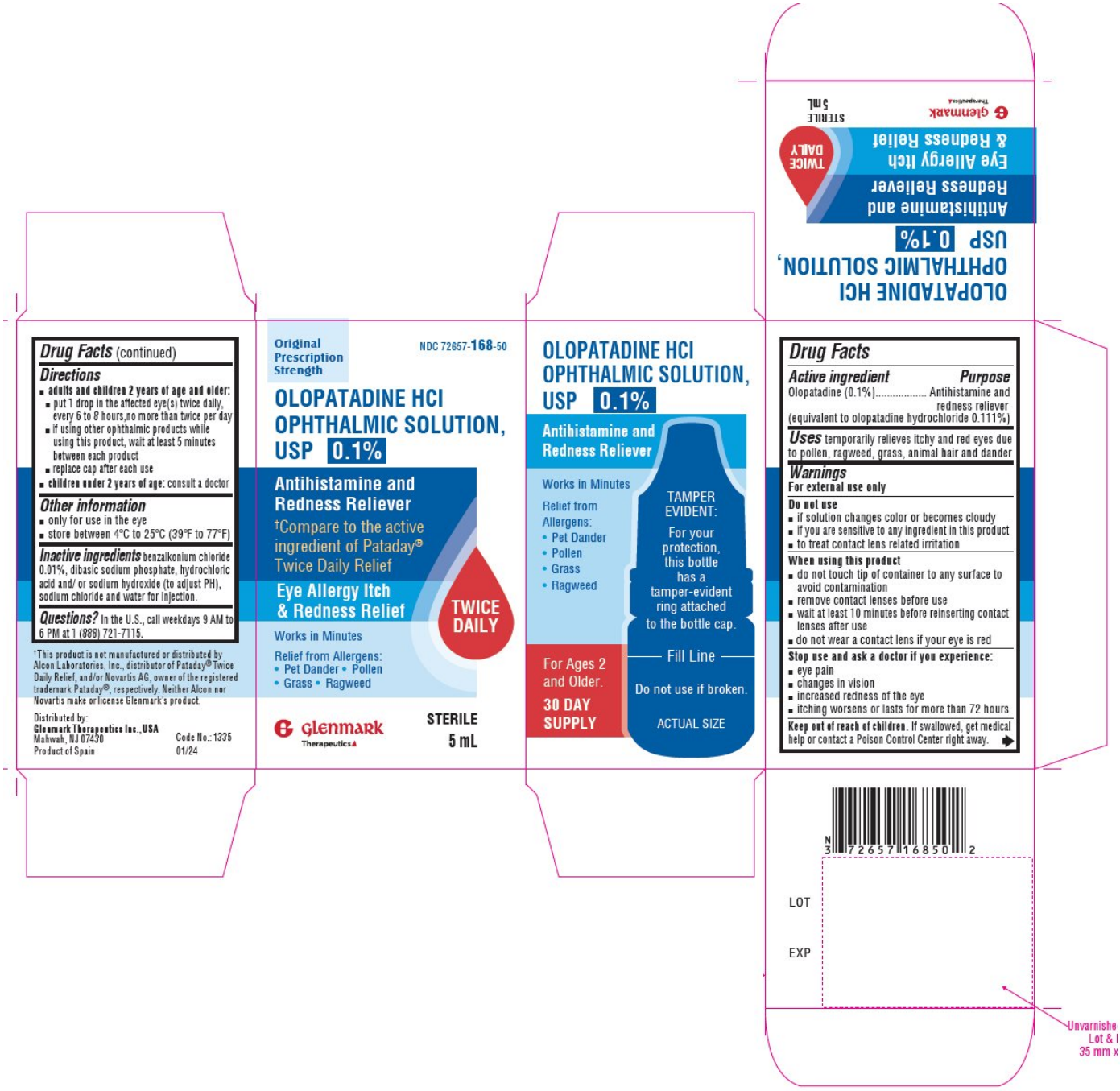
NDC 72657-168-50

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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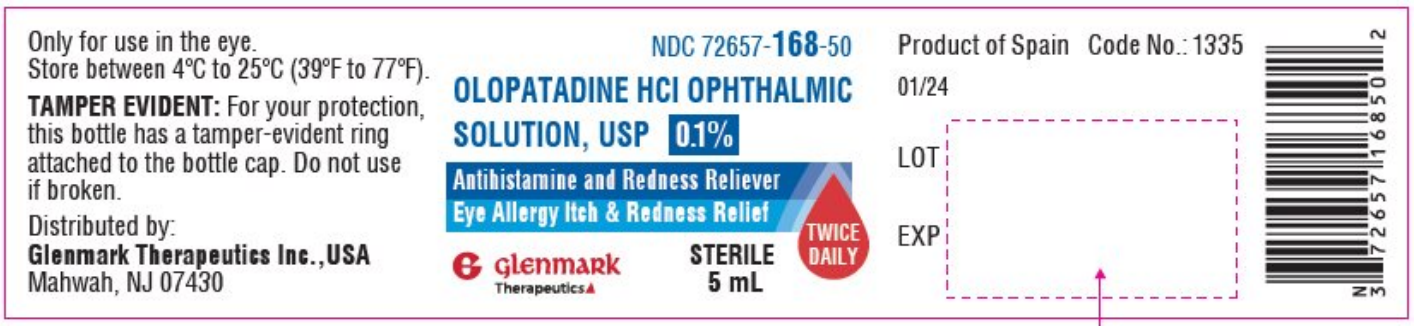

OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride ophthalmic solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72657-168
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	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:72657-168-50	1 in 1 CARTON	07/26/2024	
1		5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA200810	07/26/2024	

Labeler - GLENMARK THERAPEUTICS INC., USA (969085666)

Establishment

Name	Address	ID/FEI	Business Operations
SamChunDang Pharm Co, Ltd		687792325	MANUFACTURE(72657-168)

Revised: 7/2024 GLENMARK THERAPEUTICS INC., USA