OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION- olopatadine hydrochloride ophthalmic solution
Chain Drug Marketing Association INC

ACTIVE INGREDIENT

Olopatadine (0.2%) (equivalent to olopatadine hydrochloride 0.222%)

PURPOSE

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 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) once daily, no more than once 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 2° to 25°C (36° to 77°F)

INACTIVE INGREDIENTS

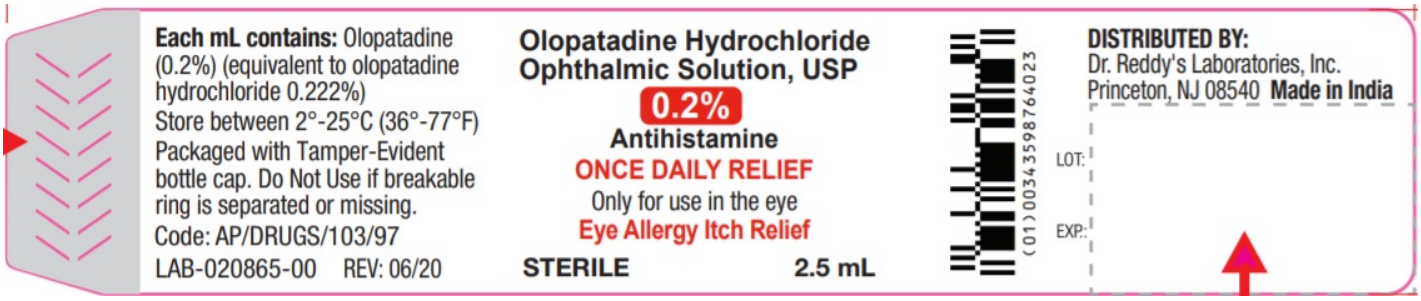
Benzalkonium chloride 0.01%, Dibasic sodium phosphate, Edetate disodium, Hydrochloric acid/Sodium hydroxide (adjust pH), Povidone, Sodium chloride, and Water for Injection.

QUESTIONS?

Call 1-888-375-3784

PRINCIPAL DISPLAY PANEL

NDC 63868-821-25
Olopatadine Hydrochloride
Ophthalmic Solution, USP
0.2%
Bottle Label:



Olopatadine Hydrochloride
Ophthalmic Solution, USP
0.2%
Carton Label:

OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION

olopatadine hydrochloride ophthalmic solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-821(NDC:43598-764)
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)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-821-25	1 in 1 CARTON	01/01/2021	
1		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	ANDA209752	01/01/2021	

Labeler - Chain Drug Marketing Association INC (011920774)

Revised: 2/2021 Chain Drug Marketing Association INC