OLOPATADINE HYDROCHLORIDE- olopatadine hydrochloride solution
Rising Pharma Holdings, Inc.

Olopatadine Hydrochloride Ophthalmic Solution, USP 0.2%

ACTIVE INGREDIENT(S)

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

PURPOSE

Antihistamine

USE(S)

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 eyes(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 4°C to 25°C (39°F to 77°F)

Inactive ingredients

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

Questions?

Contact Rising Pharma Holdings, Inc. at 1-844-474-7464

PRINCIPAL DISPLAY PANEL

Rising NDC 16571-861-25

Olopatadine Hydrochloride Ophthalmic Solution, USP 0.2%

ONCE DAILY RELIEF Antihistamine

NOW AVAILABLE without a prescription
ONCE DAILY

Eye Allergy Itch Relief

Works in Minutes

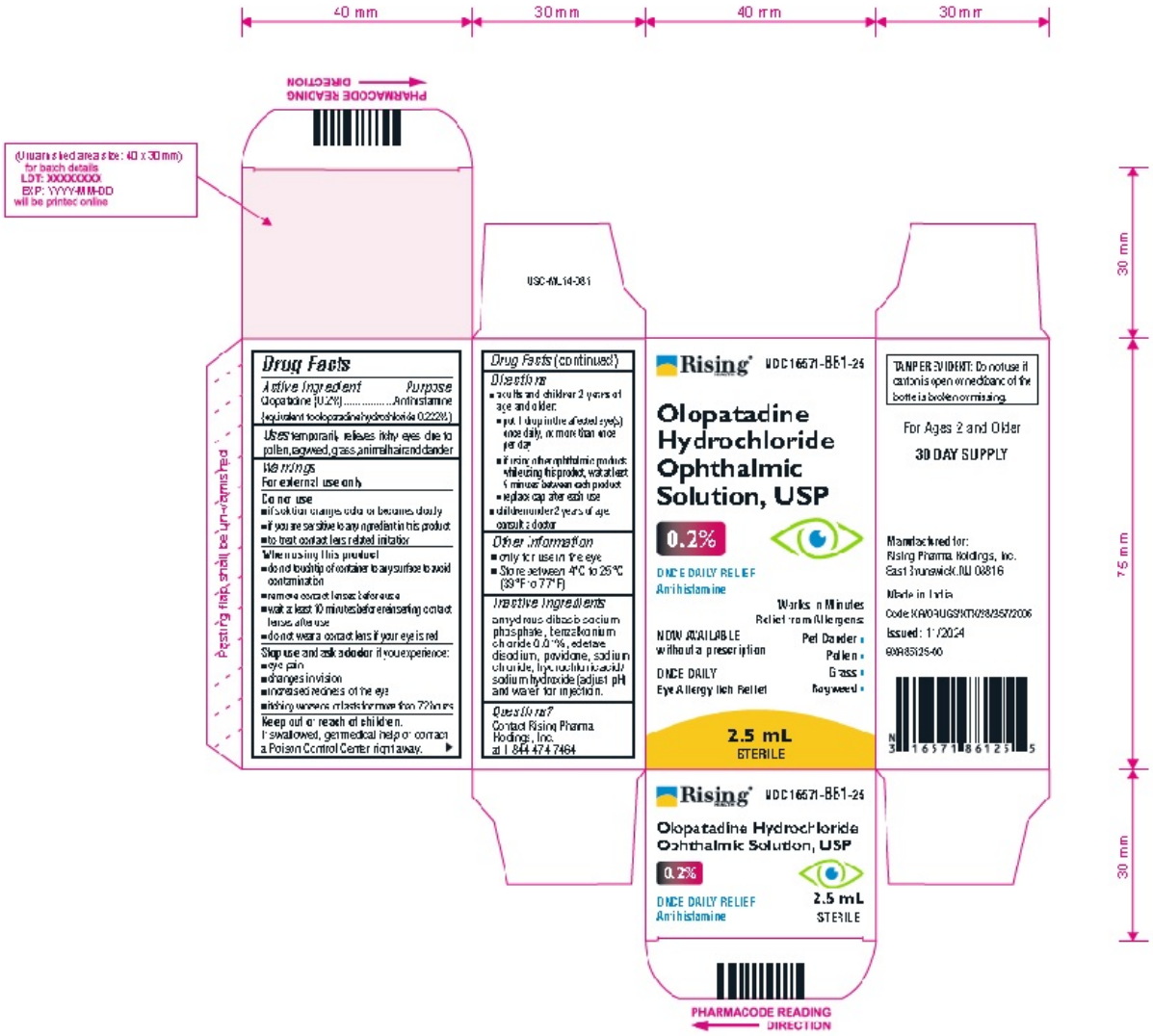
Relief from Allergens:
•Pet Dander

•Pollen

•Grass

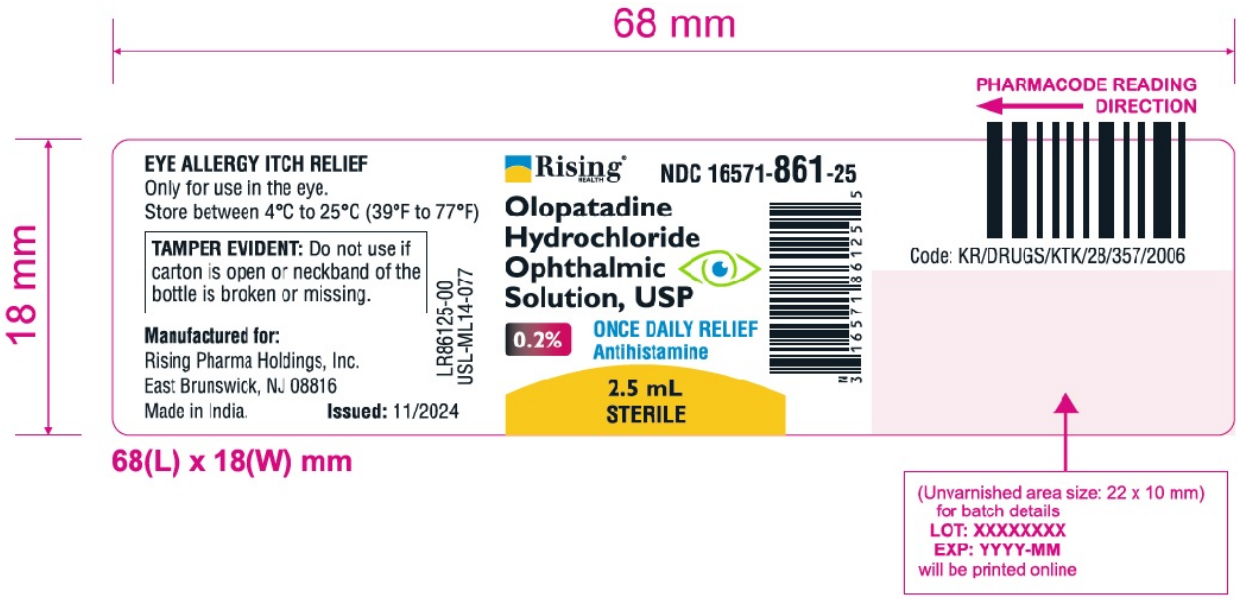
•Ragweed

2.5 mL STERILE



Rising NDC 16571-861-25

Olopatadine Hydrochloride Ophthalmic Solution, USP
0.2%
ONCE DAILY RELIEF Antihistamine
Eye Allergy Itch Relief
ONCE DAILY
2.5 mL
STERILE



OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:16571-861
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)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
POVIDONE K30 (UNII: U725QWY32X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:16571-861-25	1 in 1 CARTON	05/01/2025	
1		2.5 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204620	05/01/2025	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Establishment

Name	Address	ID/FEI	Business Operations
Micro Labs Limited		677600482	ANALYSIS(16571-861) , LABEL(16571-861) , MANUFACTURE(16571-861) , PACK(16571-861)

Revised: 4/2025 Rising Pharma Holdings, Inc.