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

Olopatadine Hydrochloride Ophthalmic Solution, USP 0.1%

ACTIVE INGREDIENT(S)

Olopatadine (0.1%) (equivalent to olopatadine hydrochloride USP, 0.111%)

PURPOSE

Antihistamine and redness reliever

USE(S)

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 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 anhydrous, hydrochloric acid/sodium hydroxide (adjust pH), water for injection, and sodium chloride

Questions?

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

PRINCIPAL DISPLAY PANEL

Rising NDC 16571-882-05

Olopatadine Hydrochloride Ophthalmic Solution, USP 0.1%

Antihistamine and Redness Reliever

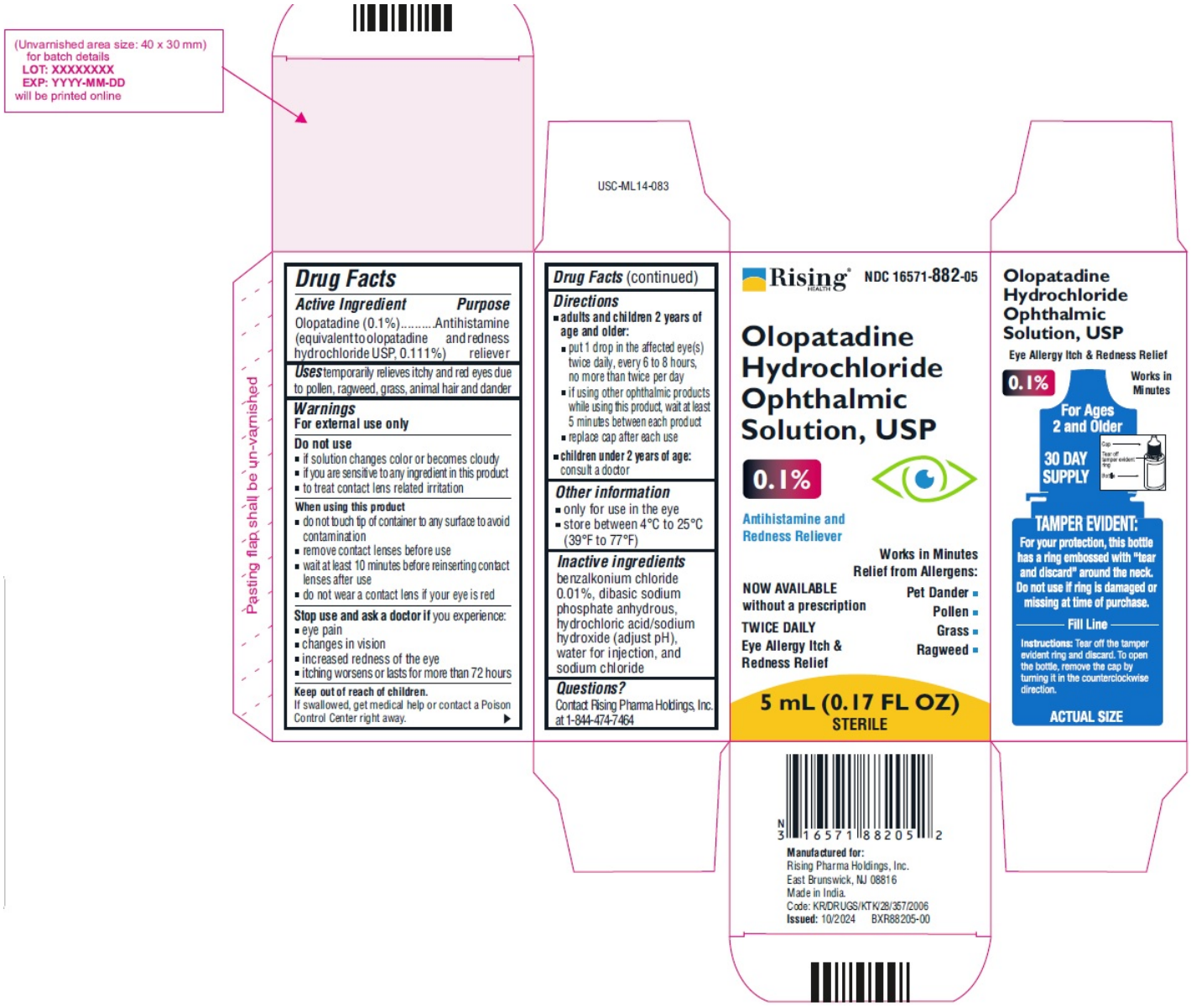
NOW AVAILABLE without a prescription
TWICE DAILY

Eye Allergy Itch & Redness Relief

Works in Minutes Relief from Allergens:
•Pet Dander
•Grass

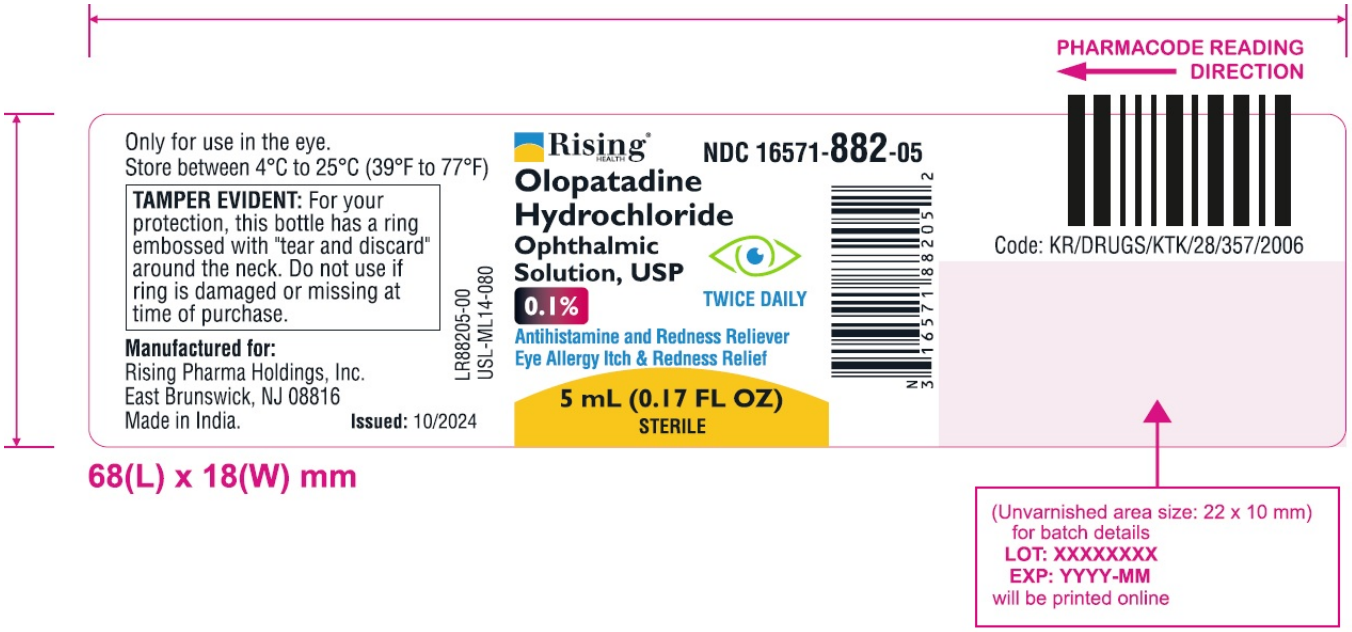
•Pollen
•Ragweed

5 mL (0.17 FL OZ) STERILE



Rising NDC 16571-882-05

Olopatadine Hydrochloride Ophthalmic Solution, USP
0.1%
Antihistamine and Redness Reliever
Eye Allergy Itch & Redness Relief
TWICE DAILY
5 mL (0.17 FL OZ)
STERILE



OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:16571-882
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)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16571-882-05	1 in 1 CARTON	03/05/2025	

1		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	ANDA204392	03/05/2025	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Establishment

Name	Address	ID/FEI	Business Operations
Micro Labs Limited		677600482	ANALYSIS(16571-882) , LABEL(16571-882) , MANUFACTURE(16571-882) , PACK(16571-882)

Revised: 3/2025 Rising Pharma Holdings, Inc.