

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

(Unvarnished area size: 40 x 30 mm)
for batch details
LOT: XXXXXXXX
EXP: YYYY-MM-DD
will be printed online

Peeling flap shall be un-varnished

USC-ML14-083

<p>Drug Facts</p> <p>Active Ingredient Purpose</p> <p>Olopatadine (0.1%).....Antihistamine and redness hydrochloride USP, 0.111% reliever</p> <p>Uses temporarily relieves itchy and red eyes due to pollen, ragweed, grass, animal hair and dander</p> <p>Warnings For external use only</p> <p>Do not use</p> <ul style="list-style-type: none"> if solution changes color or becomes cloudy if you are sensitive to any ingredient in this product to treat contact lens related irritation <p>When using this product</p> <ul style="list-style-type: none"> 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 <p>Stop use and ask a doctor if you experience:</p> <ul style="list-style-type: none"> eye pain changes in vision increased redness of the eye itching worsens or lasts for more than 72 hours <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. ▶</p>		<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> adults and children 2 years of age and older: <ul style="list-style-type: none"> 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 <p>Other information</p> <ul style="list-style-type: none"> only for use in the eye store between 4°C to 25°C (39°F to 77°F) <p>Inactive ingredients</p> <p>benzalkonium chloride 0.01%, dibasic sodium phosphate anhydrous, hydrochloric acid/sodium hydroxide (adjust pH), water for injection, and sodium chloride</p> <p>Questions? Contact Rising Pharma Holdings, Inc. at 1-844-474-7464</p>		<p>Rising NDC 16571-882-05</p> <p>Olopatadine Hydrochloride Ophthalmic Solution, USP</p> <p>0.1% </p> <p>Antihistamine and Redness Reliever</p> <p>Works in Minutes Relief from Allergens:</p> <p>NOW AVAILABLE without a prescription</p> <p>TWICE DAILY</p> <p>Eye Allergy Itch & Redness Relief</p> <p>5 mL (0.17 FL OZ) STERILE</p> <p>0.1% Works in Minutes</p> <p>For Ages 2 and Older</p> <p>30 DAY SUPPLY</p> <p>TAMPER EVIDENT: For your protection, this bottle has a ring embossed with "tear and discard" around the neck. Do not use if ring is damaged or missing at time of purchase.</p> <p>— Fill Line —</p> <p>Instructions: Tear off the tamper evident ring and discard. To open the bottle, remove the cap by turning it in the counterclockwise direction.</p> <p>ACTUAL SIZE</p>	
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N 3165718820512
Manufactured for:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816
Made in India
Code: KRDRUGS/KT K28/357/2006
Issued: 10/2/04 BXR88205-00

Rising

NDC 16571-882-05

Olopatadine Hydrochloride Ophthalmic Solution, USP

0.1%

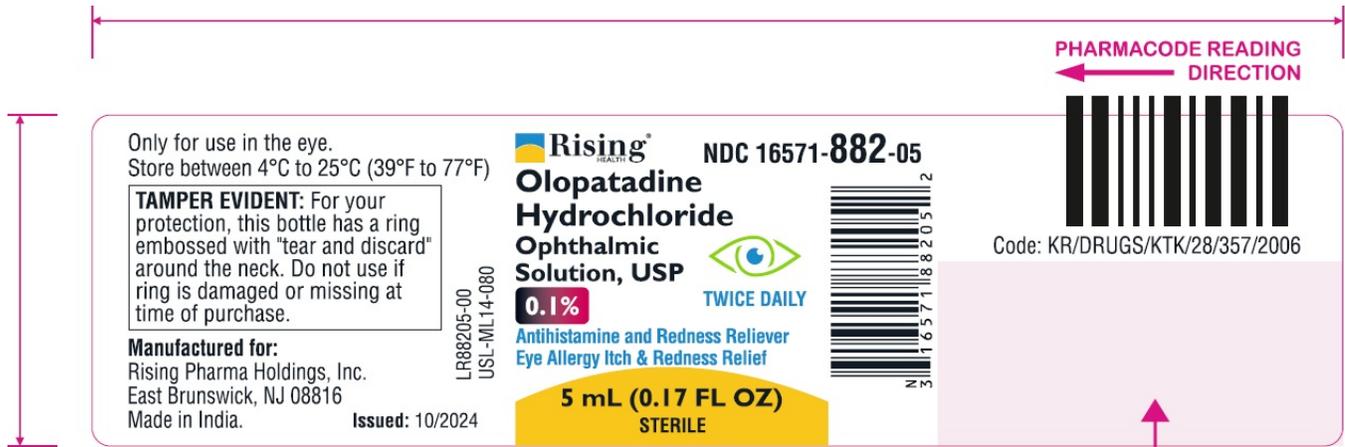
Antihistamine and Redness Reliever

Eye Allergy Itch & Redness Relief

TWICE DAILY

5 mL (0.17 FL OZ)

STERILE



68(L) x 18(W) mm

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	05/01/2025	

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	05/01/2025	

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: 4/2025

Rising Pharma Holdings, Inc.