

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

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**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

USC-ML14-083

**Drug Facts**

**Active Ingredient Purpose**

Olopatadine (0.1%).....Antihistamine (equivalent to olopatadine and redness hydrochloride USP, 0.111%) 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. ▶

**Drug Facts (continued)**

**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**

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**Rising** NDC 16571-882-05

**Olopatadine Hydrochloride Ophthalmic Solution, USP**

**0.1%** 

**Antihistamine and Redness Reliever**

**Works in Minutes**  
**Relief from Allergens:**

- Pet Dander
- Pollen
- Grass
- Ragweed

**NOW AVAILABLE without a prescription**

**TWICE DAILY**  
**Eye Allergy Itch & Redness Relief**

**5 mL (0.17 FL OZ)**  
**STERILE**



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**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

**Olopatadine Hydrochloride Ophthalmic Solution, USP**

**Eye Allergy Itch & Redness Relief**

**0.1%** **Works in Minutes**

**For Ages 2 and Older**

**30 DAY SUPPLY**

**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.

**Fill Line**

**Instructions:** Tear off the tamper evident ring and discard. To open the bottle, remove the cap by turning it in the counterclockwise direction.

**ACTUAL SIZE**

Peeling flap shall be un-varnished

Rising

NDC 16571-882-05

Olopatadine Hydrochloride Ophthalmic Solution, USP

0.1%

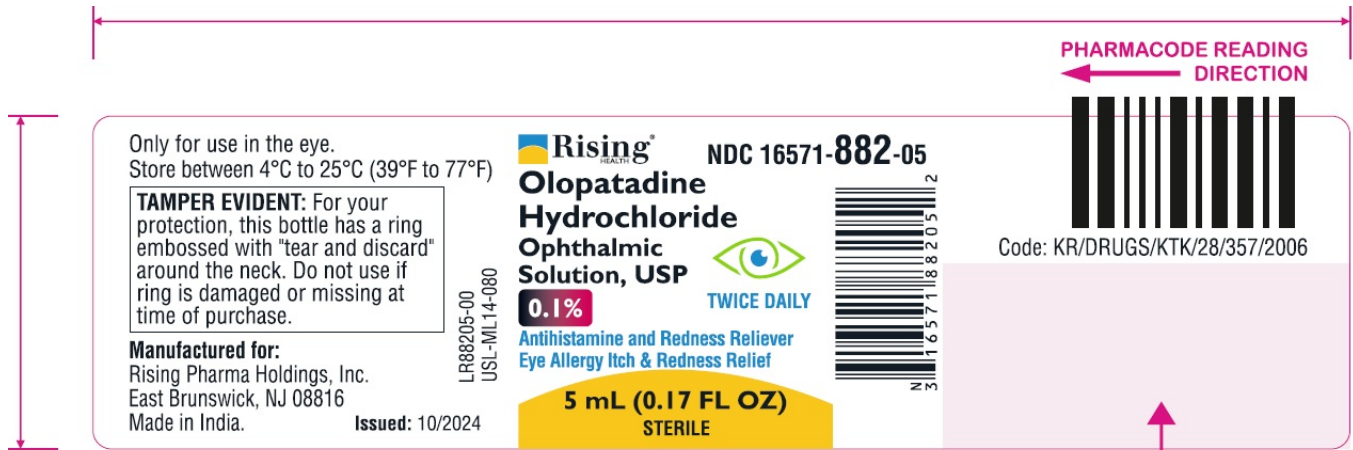
Antihistamine and Redness Reliever

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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:16571-882
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OLOPATADINE HYDROCHLORIDE</b> (UNII: 2XG66W44KF) (OLOPATADINE - UNII:D27V6190PM)	OLOPATADINE	1 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (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	

<b>1</b>	5 mL in 1 CONTAINER; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA204392	03/05/2025	

**Labeler** - Rising Pharma Holdings, Inc. (116880195)

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

Revised: 3/2025

Rising Pharma Holdings, Inc.