

**OLOPATADINE HYDROCHLORIDE - olopatadine hydrochloride solution**  
**Aurohealth LLC**

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***Drug Facts***

***Active ingredient***

Olopatadine (0.1%).

(equivalent to olopatadine hydrochloride, USP 0.111%)

***Purpose***

Antihistamine and Redness 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 (1-800-222-1222)

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° to 25°C (39° to 77°F)

**Inactive ingredients**

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

**Questions?**

☎1-855-274-4122

Distributed by:

**Aurohealth LLC**

279 Princeton-Hightstown Road  
East Windsor, NJ 08520

Made in India

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL-0.1% (5 mL Container)**

**AUROHEALTH            NDC 58602-006-40**

**Olopatadine Hydrochloride**

**Ophthalmic Solution, USP**

**0.1%**

Antihistamine and Redness Reliever

**Eye Allergy Itch & Redness Relief**

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

**AUROHEALTH** NDC 58602-006-40  
**Olopatadine Hydrochloride**  
**Ophthalmic Solution, USP**  
**0.1%**  
Antihistamine and Redness Reliever  
**Eye Allergy Itch & Redness Relief**  
STERILE 5 mL (0.17 FL OZ)

**TWICE DAILY**  
Only for use in the eye.  
Store between 4° to 25°C (39° to 77°F)  
**TAMPER EVIDENT:**  
Do not use if ring at bottom of cap is broken or missing.

Distributed by: **Aurohealth LLC**, 279 Princeton-Hightstown Road, East Windsor, NJ 08520  
Made in India  
Code: TS/DRUGS/13/2010  
**P1436866**

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**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL-0.1% (5 mL Container Carton)**

**AUROHEALTH** NDC 58602-006-40  
\*Compare to the Active Ingredient in  
Pataday® Twice Daily Relief

**NOW AVAILABLE without a prescription**  
**Olopatadine Hydrochloride**  
**Ophthalmic Solution, USP**  
**0.1%**

Antihistamine and Redness Reliever

**Eye Allergy Itch & Redness Relief**

Works in Minutes

Relief from Allergens:

- Pet Dander • Pollen
- Grass • Ragweed

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



## OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-006
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
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<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM</b> (UNII: GR686LBA74)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-006-40	1 in 1 CARTON	07/15/2020	
1		5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204812	07/15/2020	

**Labeler** - Aurohealth LLC (078728447)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
EUGIA PHARMA SPECIALITIES LIMITED		650498244	ANALYSIS(58602-006) , MANUFACTURE(58602-006)

Revised: 10/2025

Aurohealth LLC