

OLOPATADINE HYDROCHLORIDE - olopatadine hydrochloride solution
Aurohealth LLC

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

2572 Brunswick Pike

Lawrenceville, NJ 08648

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**, 2572 Brunswick Pike,
Lawrenceville, NJ 08648 Made in India
Code: TS/DRUGS/13/2010
LM-4711 P1428955

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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

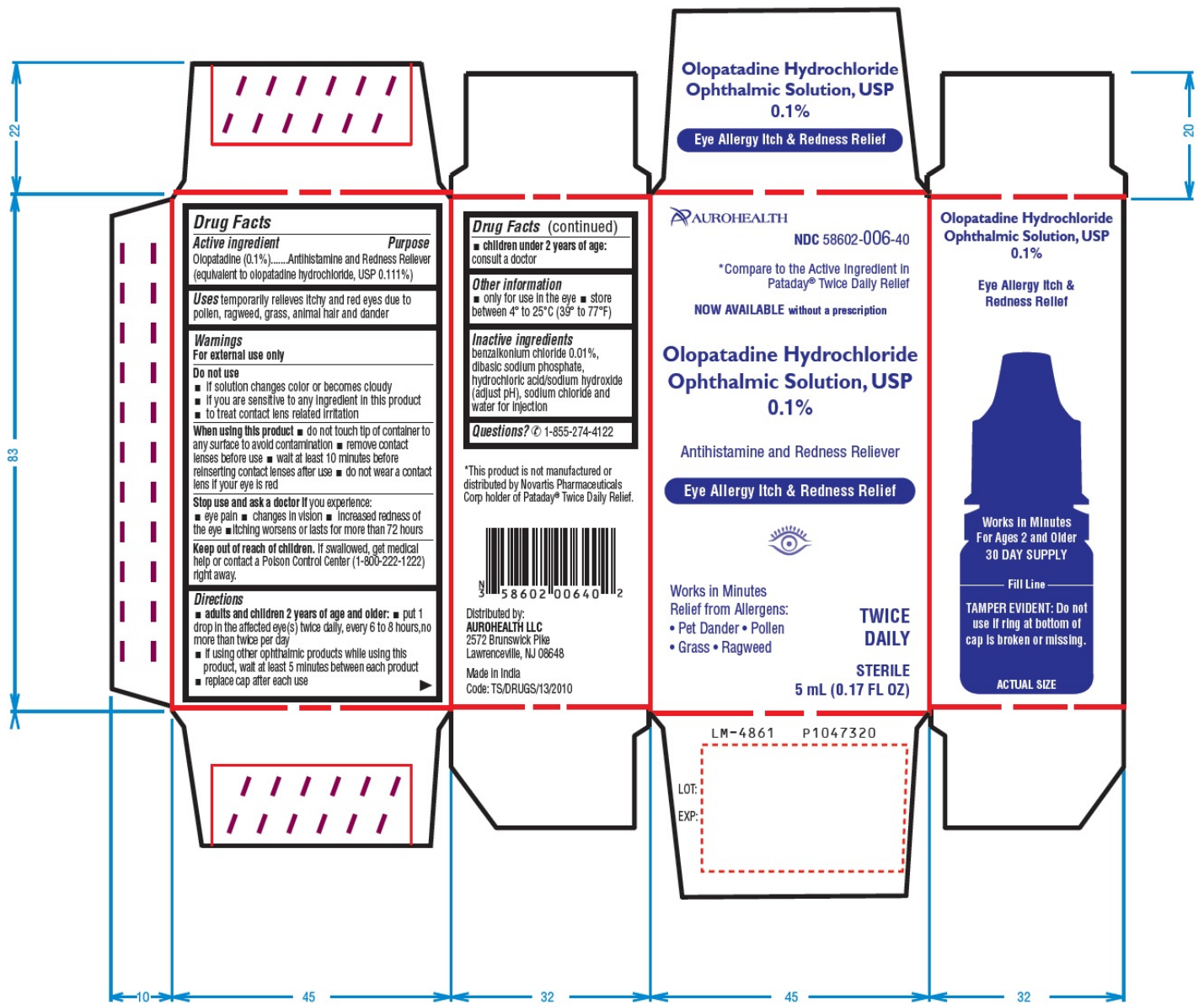
Eye Allergy Itch & Redness Relief

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-006
Route of Administration	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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BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
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:58602-006-40	1 in 1 CARTON	07/15/2020	
1		5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

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

Labeler - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
Eugia Pharma Specialities Limited		650498244	ANALYSIS(58602-006) , MANUFACTURE(58602-006)

Revised: 8/2022

Aurohealth LLC