OLOPATADINE HYDROCHLORIDE - olopatadine hydrochloride solution
Aurohealth LLC

Drug Facts

Active ingredient
Olopatadine (0.2%)
(equivalent to olopatadine hydrochloride, USP 0.222%)

Purpose

Antihistamine

Use

temporarily relieves itchy 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) once daily, no more than once 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, edetate disodium, hydrochloric acid/sodium hydroxide (adjust pH), povidone, 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-0.2% (2.5 mL Container)

AUROHEALTH **NDC** 58602-007-39
Olopatadine Hydrochloride
Ophthalmic Solution, USP
0.2%
Antihistamine
Eye Allergy Itch Relief
STERILE **2.5 mL (0.085 FL OZ)**

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL-0.2% (2.5 mL Container Carton)

AUROHEALTH **NDC** 58602-007-39

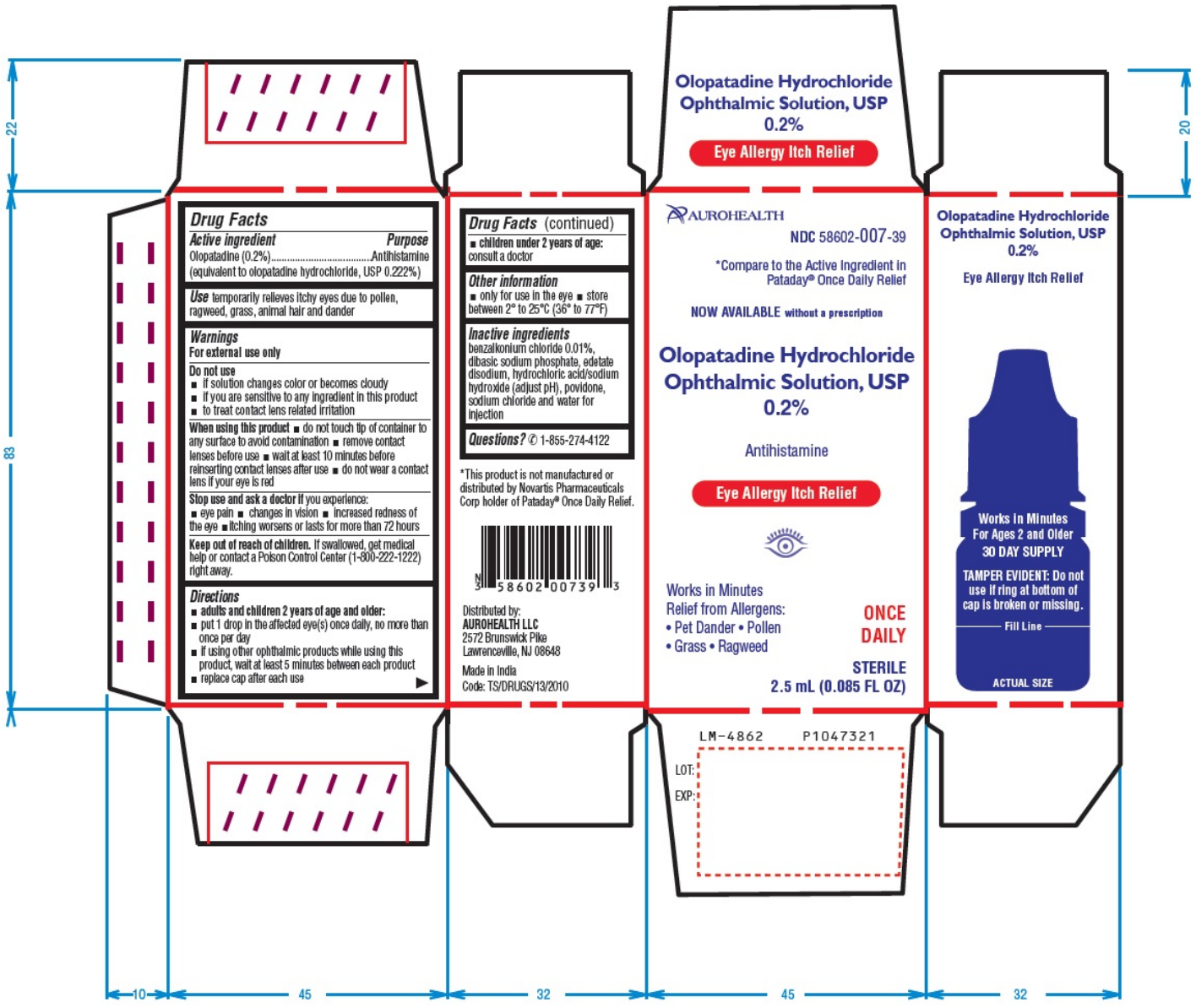
*Compare to the Active Ingredient in
Pataday® Once Daily Relief

NOW AVAILABLE without a prescription

Olopatadine Hydrochloride
Ophthalmic Solution, USP
0.2%

Antihistamine
Eye Allergy Itch Relief
Works in Minutes
Relief from Allergens:
• Pet Dander • Pollen
• Grass • Ragweed

ONCE DAILY
STERILE
2.5 mL (0.085 FL OZ)



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL-0.2% (2.5 mL Container Carton)

Twin Pack

Twin Pack
AUROHEALTH **NDC** 58602-007-41
*Compare to the Active Ingredient in
Pataday® Once Daily Relief
NOW AVAILABLE without a prescription
Olopatadine Hydrochloride
Ophthalmic Solution, USP
0.2%
Antihistamine
Eye Allergy Itch Relief
Works in Minutes
Relief from Allergens:
• Pet Dander • Pollen
• Grass • Ragweed
ONCE DAILY
STERILE
Two 2.5 mL Bottles
(0.085 FL OZ Each)

OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-007
Route of Administration	OPHTHALMIC		

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

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58602-007-39	1 in 1 CARTON	07/15/2020	
1		2.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:58602-007-41	2 in 1 CARTON	07/15/2020	
2		2.5 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	ANDA209995	07/15/2020	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Eugia Pharma Specialities Limited		650498244	ANALYSIS(58602-007) , MANUFACTURE(58602-007)

Revised: 5/2022

Aurohealth LLC