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?

1-855-274-44122

Distributed by:
AUROHEALTH LLC
2572 Brunswick Pike
Lawrenceville, NJ 08648

Made in India
Code: TS/DRUGS/13/2010

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

PrimaryHealth **NDC 58602-012-40**
Olopatadine Hydrochloride
Ophthalmic Solution, USP
0.1%
Antihistamine and Redness Reliever
Eye Allergy Itch & Redness Relief
STERILE **5 mL (0.17 FL OZ)**

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

NDC 58602-012-40
PrimaryHealth
*Compare to the Active Ingredient
in Pataday® Once 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:58602-012
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**
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:58602-012-40	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)

Registrant - Aurobindo Pharma Limited (650082092)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650498244	ANALYSIS(58602-012) , MANUFACTURE(58602-012)

Revised: 8/2020 Aurohealth LLC