

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

Code: TS/DRUGS/13/2010

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

PrimaryHealth NDC 58602-013-39
Olopatadine Hydrochloride
Ophthalmic Solution, USP
0.2%
Antihistamine
Eye Allergy Itch Relief
STERILE 2.5 mL (0.085 FL OZ)

 **PrimaryHealth** NDC 58602-013-39 **ONCE DAILY**
Olopatadine Hydrochloride Only for use in the eye.
Ophthalmic Solution, USP Store between 2° to 25°C (36° to 77°F)
0.2% **TAMPER EVIDENT:**
Antihistamine Do not use if ring at
Eye Allergy Itch Relief bottom of cap is
STERILE 2.5 mL (0.085 FL OZ) broken or missing.

Distributed by: **AUROHEALTH LLC**, 2572 Brunswick Pike,
Lawrenceville, NJ 08648 Made in India
Code: TS/DRUGS/13/2010
LM-4340 P1426882



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

NDC 58602-013-39
PrimaryHealth
*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

NDC 58602-013-41

PrimaryHealth

**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:58602-013
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OLOPATADINE HYDRO CHLORIDE (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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-013-39	1 in 1 CARTON	07/15/2020	
1		2.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:58602-013-41	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)**Registrant** - Aurobindo Pharma Limited (650082092)**Establishment**

Name	Address	ID/FEI	Business Operations
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Revised: 10/2020

Aurohealth LLC