

OLOPATADINE HYDROCHLORIDE - olopatadine hydrochloride solution
Retail Business Services, 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 2° to 25°C (36° 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?

☎ 1-866-850-2876

DISTRIBUTED BY:
FOODHOLD U.S.A., LLC,
LANDOVER, MD 20785
MADE IN INDIA

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

CAREone NDC 72476-851-21
EYE ALLERGY ITCH RELIEF
Olopatadine Hydrochloride
Ophthalmic Solution USP, 0.2%
Antihistamine
STERILE 2.5 mL (0.085 FL OZ)

CAREone NDC 72476-851-21	ONCE DAILY Only for use in the eye. Store between 2° to 25°C (36° to 77°F)	DISTRIBUTED BY: FOODHOLD U.S.A., LLC, LANDOVER, MD 20785 • MADE IN INDIA • 1-877-848-9949 © 2021 Ahold Delhaize Licensing Sàrl Code: TS/DRUGS/13/2010
EYE ALLERGY ITCH RELIEF	TAMPER EVIDENT: Do not use if ring at bottom of cap is broken or missing.	LM-4476 P1427576
Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2%		
Antihistamine		
STERILE 2.5 mL (0.085 FL OZ)		

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

NDC 72476-851-21

CAREone

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

EYE ALLERGY

ITCH RELIEF

Olopatadine Hydrochloride

Ophthalmic Solution USP, 0.2%

ONCE DAILY

Now available without a prescription

Antihistamine

Works in Minutes

Relief from Allergens:

Pet Dander, Pollen, Grass, Ragweed

STERILE

2.5 mL (0.085 FL OZ)



OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-851
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:72476-851-21	1 in 1 CARTON	04/02/2021	
1		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	04/02/2021	

Labeler - Retail Business Services, LLC. (967989935)

Registrant - Aurobindo Pharma Limited (650082092)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650498244	ANALYSIS(72476-851) , MANUFACTURE(72476-851)

Revised: 4/2021

Retail Business Services, LLC.