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?

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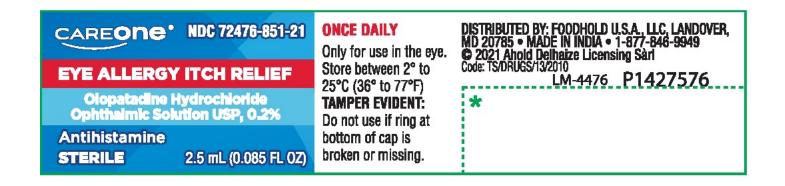
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL-0.2% (2.5 mL Container)

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)



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 - OLOPATADINE UNII:D27V6190PM) 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: FZ 989GH94E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	

P	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.