

**OLOPATADINE HYDROCHLORIDE - olopatadine hydrochloride solution**  
**Retail Business Services, 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?***

☎1-855-274-4122

Distributed by:

**FOODHOLD U.S.A., LLC,**  
LANDOVER, MD 20785  
MADE IN INDIA

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

**CAREOne**                      **NDC 72476-852-64**  
**EYE ALLERGY ITCH**  
**& REDNESS RELIEF**  
**Olopatadine Hydrochloride**  
**Ophthalmic Solution USP, 0.1%**  
Antihistamine and Redness Reliever  
**STERILE**                      **5 mL (0.17 FL OZ)**



### **TWICE DAILY**

Only for use in the eye.  
Store between 4° to 25°C (39° to 77°F)  
**TAMPER EVIDENT:**  
Do not use if ring at bottom of cap is broken or missing.

DISTRIBUTED BY: FOODHOLD U.S.A., LLC, LANDOVER, MD 20785, MADE IN INDIA, © 2021 Ahold Delhaize Licensing Sàrl  
Quality guaranteed or your money back. Code: TS/DRUGS/13/2010

LM-4547

P1427916



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

**CAREOne NDC 72476-852-64**  
**Compare to the Active Ingredient in**  
**Pataday® Twice Daily Relief®**

**EYE ALLERGY ITCH**

**& REDNESS RELIEF**

**Olopatadine Hydrochloride**

**Ophthalmic Solution USP, 0.1%**

**TWICE DAILY**

Now available without a prescription

Antihistamine and Redness Reliever

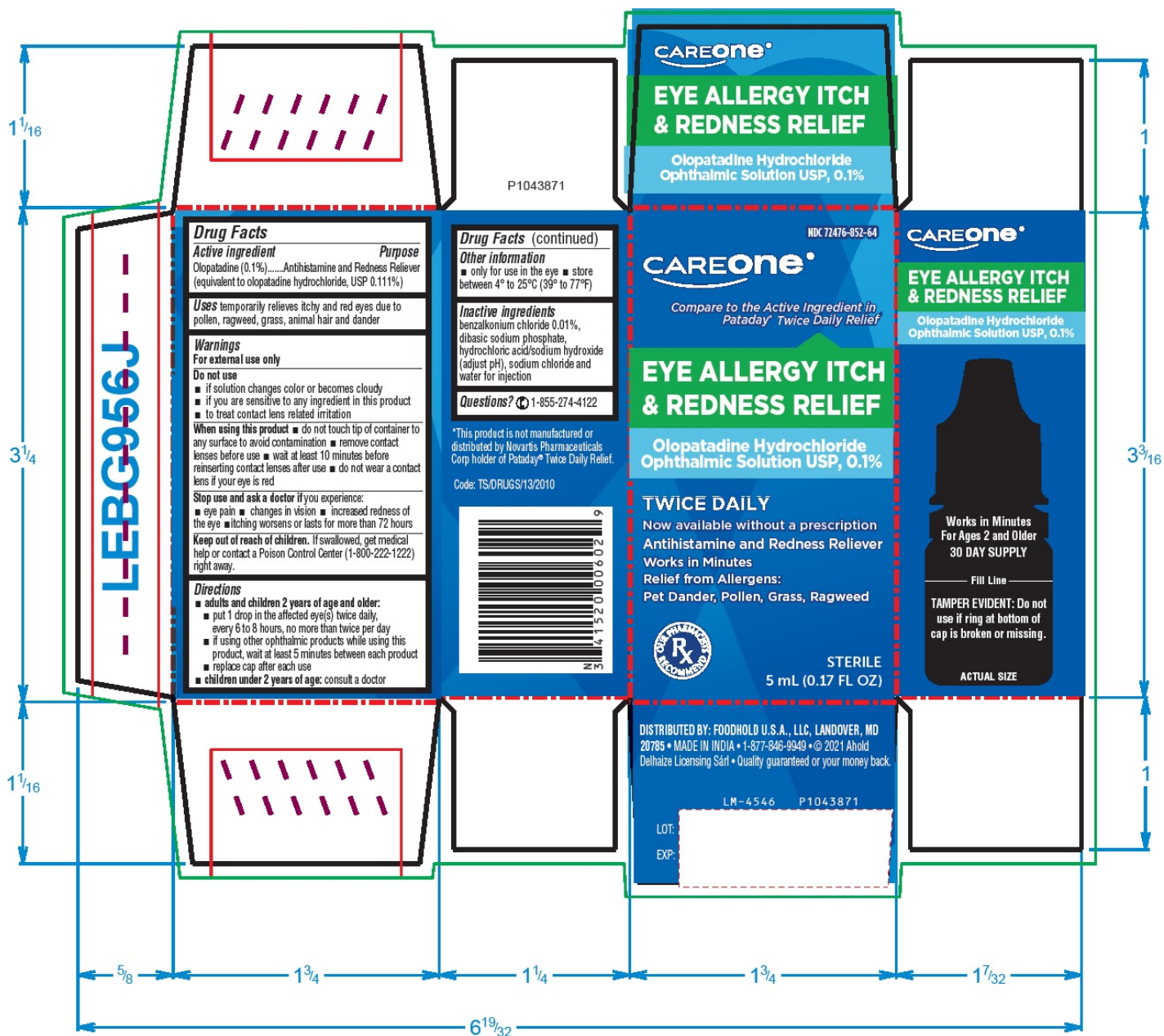
Works in Minutes

Relief from Allergens:

Pet Dander, Pollen, Grass, Ragweed

**STERILE**

**5 mL (0.17 FL OZ)**



## OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-852
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OLOPATADINE HYDROCHLORIDE</b> (UNII: 2XG66W44KF) (OLOPATADINE - UNII:D27V6190PM)	OLOPATADINE HYDROCHLORIDE	1 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM</b> (UNII: GR686LBA74)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-852-64	1 in 1 CARTON	05/06/2021	
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	05/06/2021	

**Labeler** - Retail Business Services, LLC. (967989935)

**Registrant** - Aurobindo Pharma Limited (650082092)

### Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650498244	ANALYSIS(72476-852) , MANUFACTURE(72476-852)

Revised: 5/2021

Retail Business Services, LLC.