# OLOPATADINE HYDROCHLORIDE - olopatadine hydrochloride solution Kroger Company

-----

#### 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?

1-800-632-6900

DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45202 MADE IN INDIA

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

NDC 30142-064-64 Kroger<sup>®</sup> TWICE DAILY Eye Allergy Itch & Redness Relief Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1% Antihistamine and Redness Reliever STERILE 0.17 FL OZ (5 mL)



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

COMPARE TO the active ingredient in PATADAY<sup>®</sup> TWICE DAILY RELIEF \*See back panel NDC 30142-064-64 Kroger® NOW AVAILABLE without a prescription Eye Allergy Itch & Redness Relief **Olopatadine Hydrochloride Ophthalmic Solution** USP, 0.1% Antihis tamine and **Redness Reliever** TWICE DAILY Works in Minutes **Relief from** Allergens: Pet Dander, Pollen, Grass, Ragweed STERILE 0.17 FL OZ

(5 mL)



# **OLOPATADINE HYDROCHLORIDE**

olopatadine hydrochloride solution

| Product Information  |                |                                  |             |                 |          |
|--|----------------|----------------------------------|-------------|-----------------|----------|
| Product T ype  | HUMAN OTC DRUG | Item Code (Source) NDC:30142-064 |             | 064             |          |
| Route of Administration  | OPHTHALMIC     |                                  |             |                 |          |
|  |                |                                  |             |                 |          |
|  |                |                                  |             |                 |          |
| Active Ingredient/Active Moi   | ety            |                                  |             |                 |          |
| Ingr   | edient Name    |                                  | Basis of St | rength          | Strength |
| <b>OLOPATADINE HYDROCHLORIDE</b> (UNII: 2XG66W44KF) (OLOPATADINE -OLOPATADINEUNII:D27V6190PM)HYDROCHLORIDE |                |                                  | 2           | 1 mg<br>in 1 mL |          |
|  |                |                                  |             |                 |          |
| Inactive Inque diants  |                |                                  |             |                 |          |
| Inactive Ingredients   |                |                                  |             |                 |          |
| Ingredient Name  |                |                                  |             |                 | Strength |

| S | D DIUM PHO SPHA                         | <b>FE, DIBASIC, UNSPECIFIED FORM</b> (UNII: GR686LBA74)      |                         |                       |
|---|---|--|-------------------------|-----------------------|
| s | D DIUM CHLORIDI                         | E (UNII: 451W47IQ8X)   |                         |                       |
| н | YDRO CHLO RIC A                         | CID (UNII: QTT17582CB)                                       |                         |                       |
| s | D DIUM HYDRO XII                        | <b>DE</b> (UNII: 55X04QC32I)                                 |                         |                       |
| W | ATER (UNII: 059Q                        | F0KO0R)  |                         |                       |
|   |   |  |                         |                       |
|   |   |  |                         |                       |
| P | ackaging                                |  |                         |                       |
| # | Item Code                               | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |
| 1 | NDC:30142-064-<br>64                    | 1 in 1 CARTON  | 07/15/2020              |                       |
| 1 |   | 5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |
| - |   |  |                         |                       |
|   |   |  |                         |                       |
| - |   |  |                         |                       |
|   | farketing In                            | formation  |                         |                       |
| N | <b>Iarketing In</b><br>1arketing Catego |  | Marketing Start Date    | Marketing End Date    |

# Labeler - Kroger Company (006999528)

| <b>Registrant</b> - | Aurobindo | Pharma | Limited | (650082092) |
|---------------------|-----------|--------|---------|-------------|
|---------------------|-----------|--------|---------|-------------|

| Establishment            |         |           |   |  |  |
|--------------------------|---------|-----------|---|--|--|
| Name                     | Address | ID/FEI    | <b>Business Operations</b>                  |  |  |
| Aurobindo Pharma Limited |         | 650498244 | ANALYSIS(30142-064), MANUFACTURE(30142-064) |  |  |

Revised: 1/2021

Kroger Company