**OLOPATADINE HYDROCHLORIDE - olopatadine hydrochloride solution/ drops**
**Alembic Pharmaceuticals Inc.**

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## ACTIVE INGREDIENT(S)

Olopatadine (0.1%).....(equivalent to olopatadine hydrochloride 0.111%)

## PURPOSE

Antihistamine and redness reliever

## USE(S)

temporarily relieves itchy 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 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 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°C to 25°C (39°F to 77°F)

## INACTIVE INGREDIENTS

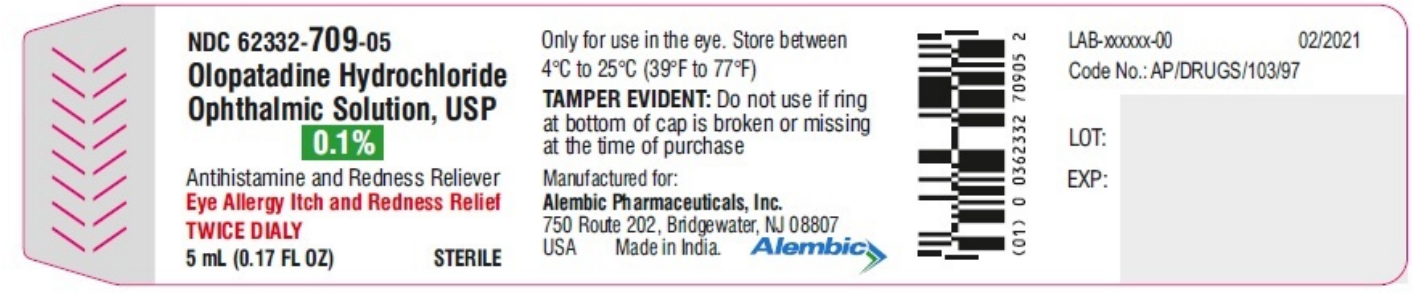
benzalkonium chloride 0.01%, dibasic sodium phosphate, hydrochloric acid/sodium hydroxide (adjust pH), sodium chloride, and water for Injection

## QUESTIONS?

Contact Alembic Pharmaceuticals Inc. at 1-866-210-9797

## PRINCIPAL DISPLAY PANEL

**Olopatadine Hydrochloride Ophthalmic Solution 0.1%-Bottle Label:**




**Olopatadine Hydrochloride Ophthalmic Solution 0.1%- Carton Label:**


# OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution/ drops

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:62332-709 |
| **Route of Administration** | OPHTHALMIC | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **OLOPATADINE HYDROCHLORIDE** (UNII: 2XG66W44KF) (OLOPATADINE - UNII:D27V6190PM) | OLOPATADINE HYDROCHLORIDE | 1 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) | |
| **SODIUM PHOSPHATE, DIBASIC** (UNII: GR686LBA74) | |
| **HYDROCHLORIC ACID** (UNII: QTT17582CB) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | |
| **WATER** (UNII: 059QF0KO0R) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:62332-709-05 | 1 in 1 CARTON | 02/18/2021 | |
| **1** | | 5 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA209919 | 02/18/2021 | |

## Labeler - Alembic Pharmaceuticals Inc. (079288842)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Gland Pharma Limited | | 918601238 | MANUFACTURE(62332-709) |

Revised: 2/2021 Alembic Pharmaceuticals Inc.