

**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:

The image shows a detailed view of the bottle label for Olopatadine Hydrochloride Ophthalmic Solution 0.1%. The label is rectangular with a pink border. On the left side, there is a graphic of a bottle with pink diagonal lines. The text on the label is as follows:

**NDC 62332-709-05**  
**Olopatadine Hydrochloride**  
**Ophthalmic Solution, USP**  
**0.1%**  
Antihistamine and Redness Reliever  
**Eye Allergy Itch and Redness Relief**  
**TWICE DAILY**  
5 mL (0.17 FL OZ) **STERILE**

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

Manufactured for:  
**Alembic Pharmaceuticals, Inc.**  
750 Route 202, Bridgewater, NJ 08807  
USA Made in India.

On the right side, there is a barcode with the number (01) 0 0362332 70905 2. To the right of the barcode, the text reads: LAB-xxxxxx-00 02/2021, Code No.: AP/DRUGS/103/97, LOT: [redacted], and EXP: [redacted].

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



## OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62332-709
<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
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.