

**OLOPATADINE HYDROCHLORIDE - olopatadine hydrochloride solution/ drops**  
**Alembic Pharmaceuticals Limited**

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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

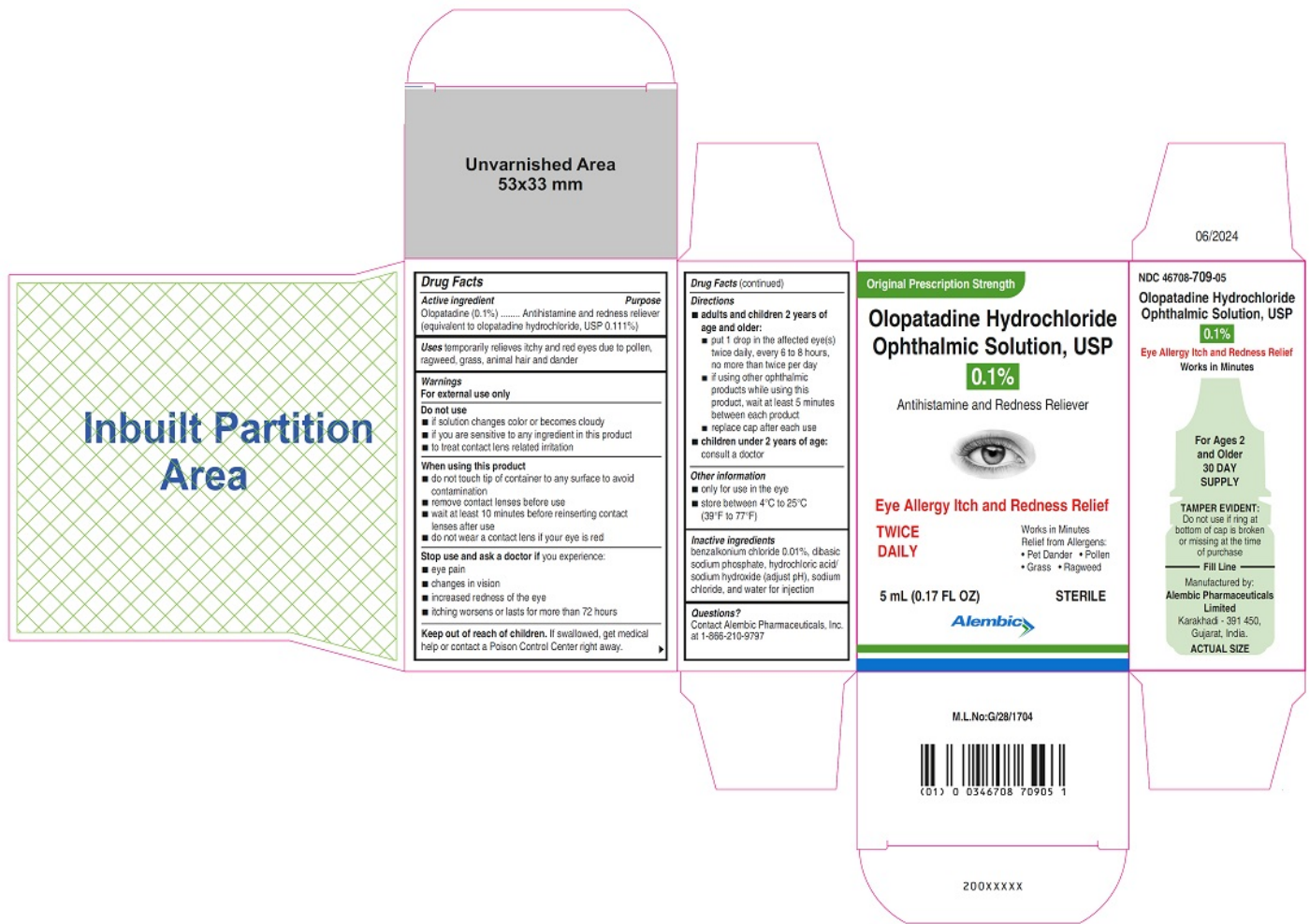
## PRINCIPAL DISPLAY PANEL

### Olopatadine Hydrochloride Ophthalmic Solution 0.1%-Bottle Label: Alembic

The image shows a simulated bottle label for Olopatadine Hydrochloride Ophthalmic Solution 0.1%. The label is rectangular with a white background and a pink border. It contains the following information:

- NDC 46708-709-05**
- Olopatadine Hydrochloride Ophthalmic Solution, USP**
- 0.1%** (in a green box)
- Antihistamine and Redness Reliever
- Eye Allergy Itch and Redness Relief**
- TWICE DIALY**
- 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 by: **Alembic Pharmaceuticals Limited**, Karakhadi - 391 450, Gujarat, India. (with Alembic logo)
- A barcode with the number **(01) 0 0346708 70905 1** below it.
- LOT: **200XXXXX**
- EXP: (blank)
- M.L.No: **G/28/1704**
- 06/2024
- A grey rectangular area labeled **Unvarnished Area 17 x 7 mm**.
- Decorative pink chevron patterns on the right side.

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



# OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution/ drops

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:46708-709
<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
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>SODIUM PHOSPHATE, DIBASIC</b> (UNII: GR686LBA74)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	

**WATER** (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46708-709-05	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 Limited (650574663)

### Establishment

Name	Address	ID/FEI	Business Operations
Alembic Pharmaceuticals Limited (F3)		675480734	MANUFACTURE(46708-709)

Revised: 6/2024

Alembic Pharmaceuticals Limited