

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

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: Gland

NDC 62332-709-05
**Olopatadine Hydrochloride
Ophthalmic Solution, USP**
0.1%
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 for:
Alembic Pharmaceuticals, Inc.
Bedminster, NJ 07921, **Alembic**
USA. Made in India.

(01) 0 0362332 70905 2

LAB-xxxxxx-00 12/2024
Code No.: AP/DRUGS/103/97

LOT:
EXP:

Olopatadine Hydrochloride Ophthalmic Solution 0.1%-Bottle Label: Alembic

NDC 62332-709-05
Olopatadine Hydrochloride
Ophthalmic Solution, USP

0.1%

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 for:
Alembic Pharmaceuticals, Inc.
 Bedminster, NJ 07921, USA.
 Made in India.



200XXXXX

M.L.No.:
 G/281704

LOT : **Unvarnished Area**
 EXP.: **17 x 7 mm**

06/2024



Olopatadine Hydrochloride Ophthalmic Solution 0.1%- Carton Label: Gland

GTIN:00362332709052

CAR-xxxxxx-00

12/2024

Drug Facts

Active ingredient	Purpose
Olopatadine (0.1%) Antihistamine and redness reliever (equivalent to olopatadine hydrochloride, USP 0.111%)	

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 right away.

Drug Facts (continued)

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

Original Prescription Strength

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**

Works in Minutes
 Relief from Allergens:
 •Pet Dander •Pollen
 •Grass •Ragweed

NDC 62332-709-05
Olopatadine Hydrochloride
Ophthalmic Solution, USP

0.1%

Eye Allergy Itch and Redness Relief
Works in Minutes

For Ages 2 and Older
30 DAY SUPPLY

TAMPER EVIDENT:
 Do not use if ring at bottom of cap is broken or missing at the time of purchase

— **Fill Line** —

Manufactured for:
Alembic Pharmaceuticals, Inc.
 Bedminster, NJ 07921, USA.
 Made in India.

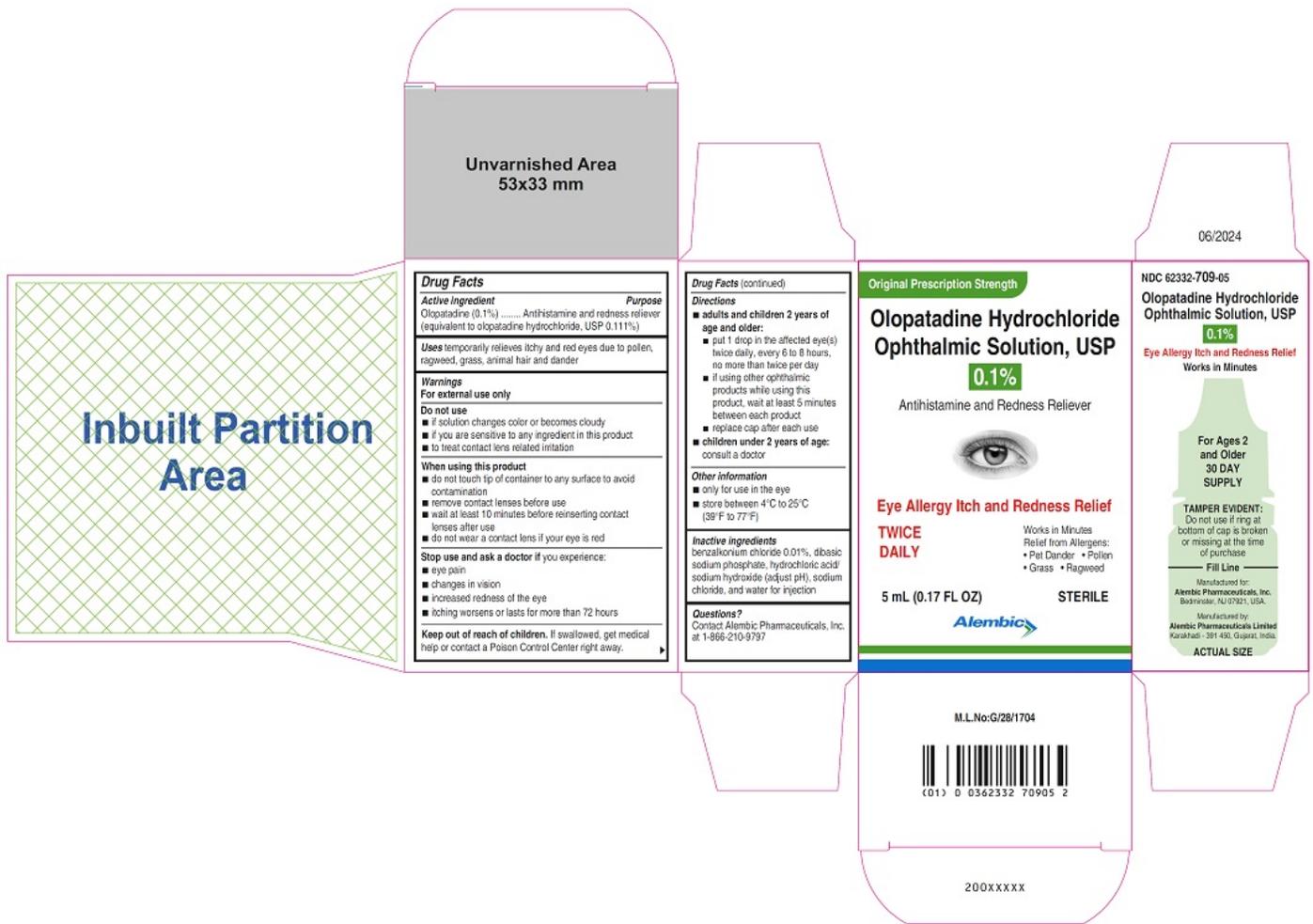
ACTUAL SIZE

Code No.: AP/DRUGS/103/97

Batch Coding and Barcode
 (For Reference Only)

S.N.O.: ABCD12345
 EXP.: DEC. 2020
 LOT: 1234567890

Olopatadine Hydrochloride Ophthalmic Solution 0.1%- Carton Label: Alembic



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)

Establishment

Name	Address	ID/FEI	Business Operations
Alembic Pharmaceuticals Limited (F3)		675480734	MANUFACTURE(62332-709)

Revised: 12/2024

Alembic Pharmaceuticals Inc.