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

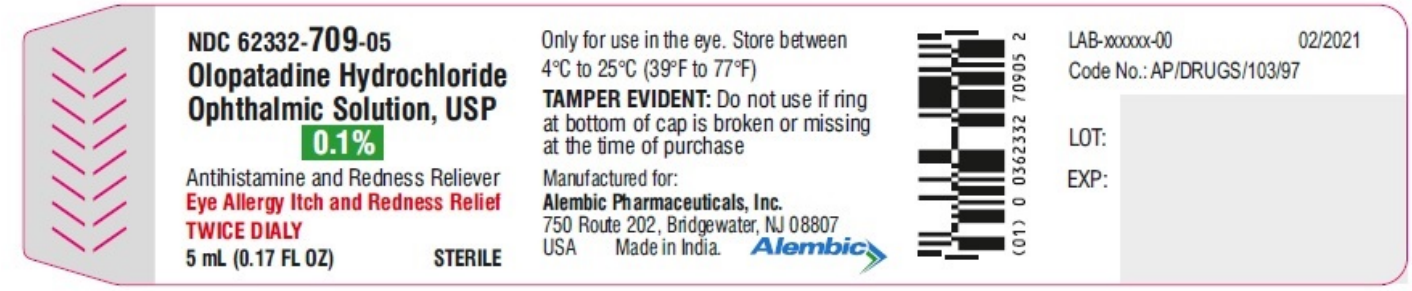
benzalkonium chloride 0.01%, dibasic sodium phosphate, hydrochloric acid/sodium hydroxide (adjust pH), sodium chloride, and water for Injection

QUESTIONS?

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

PRINCIPAL DISPLAY PANEL

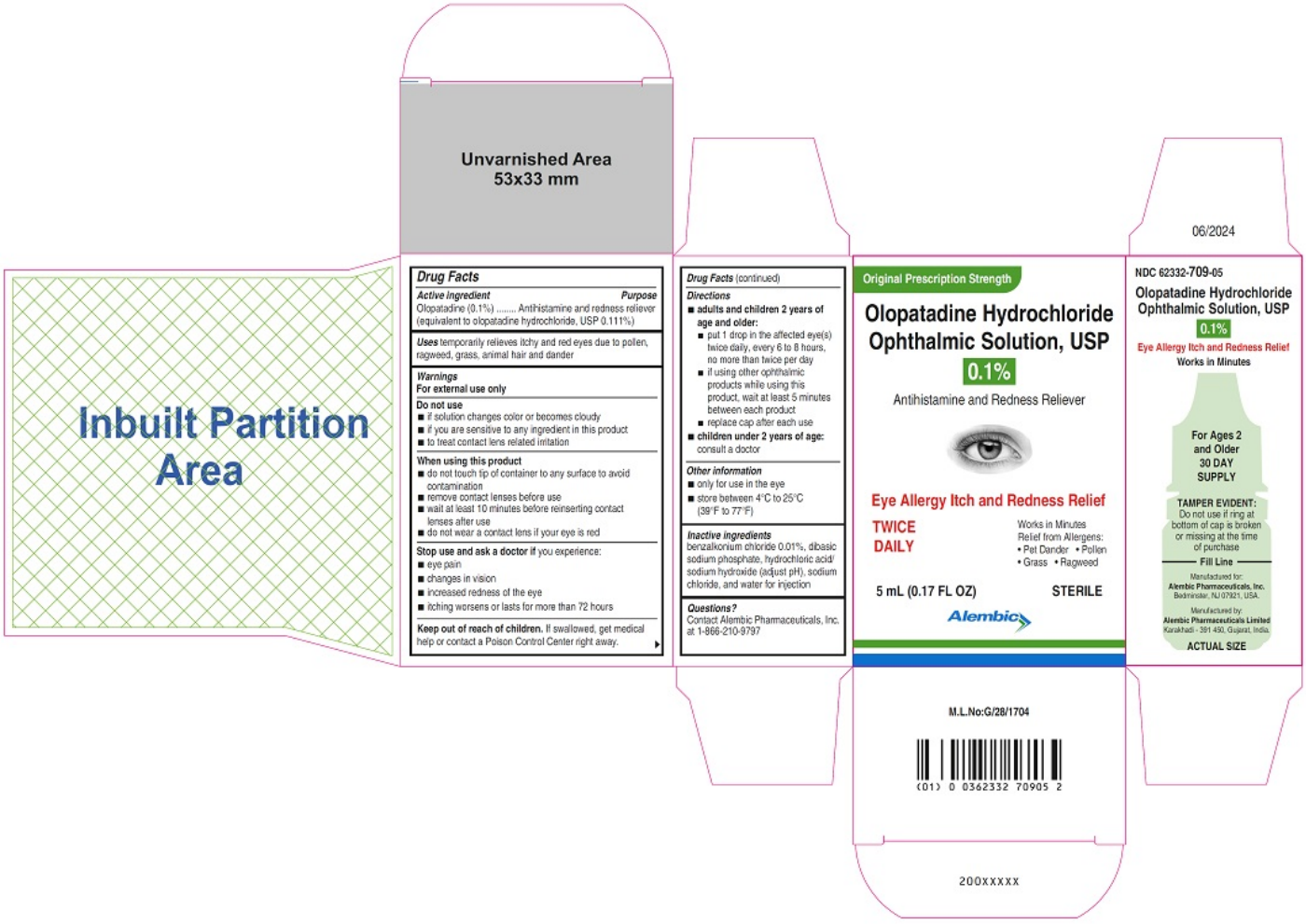
Olopatadine Hydrochloride Ophthalmic Solution 0.1%-Bottle Label: Gland



Olopatadine Hydrochloride Ophthalmic Solution 0.1%-Bottle Label: Alembic

Olopatadine Hydrochloride Ophthalmic Solution 0.1%- Carton Label: Gland

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: 6/2024 Alembic Pharmaceuticals Inc.