

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

ACTIVE INGREDIENT(S)

Olopatadine 0.2%..... (equivalent to olopatadine hydrochloride 0.222%)

PURPOSE

Antihistamine

USE(S)

temporarily relieves itchy 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) once daily, no more than once 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 2°C to 25°C (36°F to 77°F)

INACTIVE INGREDIENT SECTION

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

QUESTIONS?

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

PRINCIPAL DISPLAY PANEL

Olopatadine Hydrochloride Ophthalmic Solution, USP 0.2% - Bottle Label

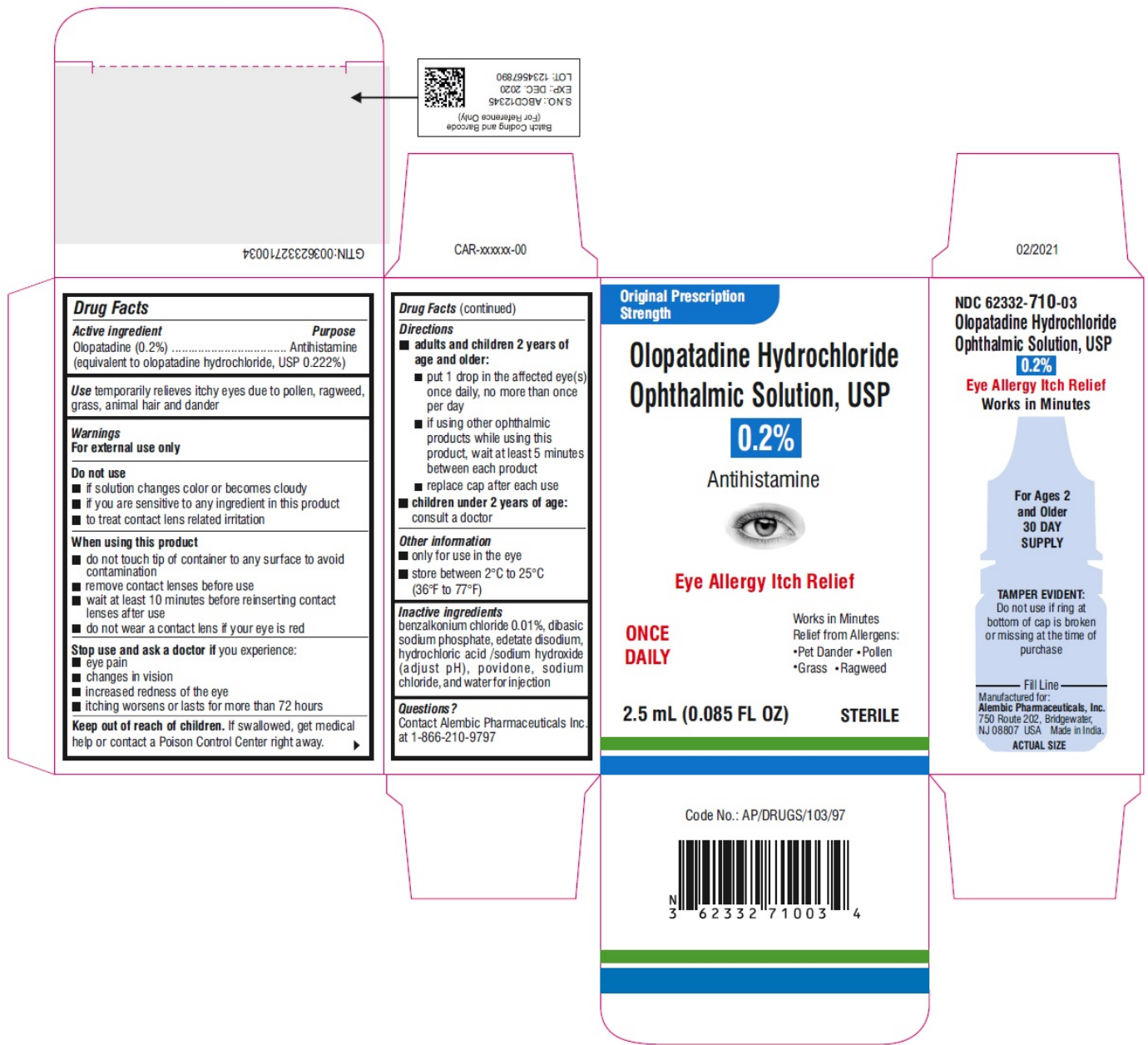
NDC 62332-710-03
Olopatadine Hydrochloride Ophthalmic Solution, USP
0.2% Antihistamine
Eye Allergy Itch Relief
ONCE DAILY
 2.5 mL (0.085 FL OZ) **STERILE**

Only for use in the eye. Store between 2°C to 25°C (36°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.

LAB-xxxxxx-00 02/2021
 Code No.: AP/DRUGS/103/97
 LOT:
 EXP:

(01) 0 0362332 71003 4

Olopatadine Hydrochloride Ophthalmic Solution, USP 0.2% - Carton Label



OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62332-710
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OLOPATADINE HYDROCHLORIDE (UNII: 2XG66W44KF) (OLOPATADINE - UNII:D27V6190PM)	OLOPATADINE	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62332-710-03	1 in 1 CARTON	01/25/2021	
1		2.5 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	ANDA209420	01/25/2021	

Labeler - Alembic Pharmaceuticals Inc. (079288842)**Establishment**

Name	Address	ID/FEI	Business Operations
Gland Pharma Limited		918601238	MANUFACTURE(62332-710)

Revised: 1/2021

Alembic Pharmaceuticals Inc.