OLOPATADINE HYDROCHLORIDE - olopatadine hydrochloride solution/ drops
Alembic Pharmaceuticals Limited

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

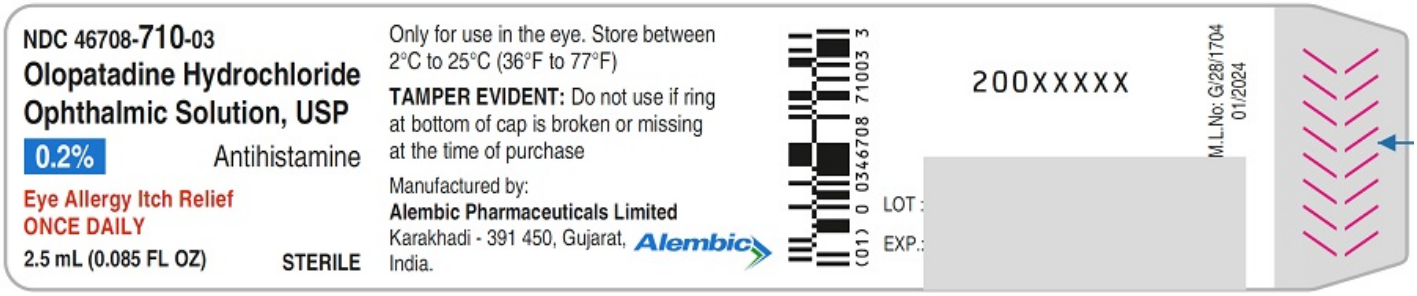
benzalkonium chloride 0.01%, dibasic sodium phosphate, edetate disodium, hydrochloric acid/sodium hydroxide (adjust pH), povidone, sodium chloride, and water for Injection.

QUESTIONS?

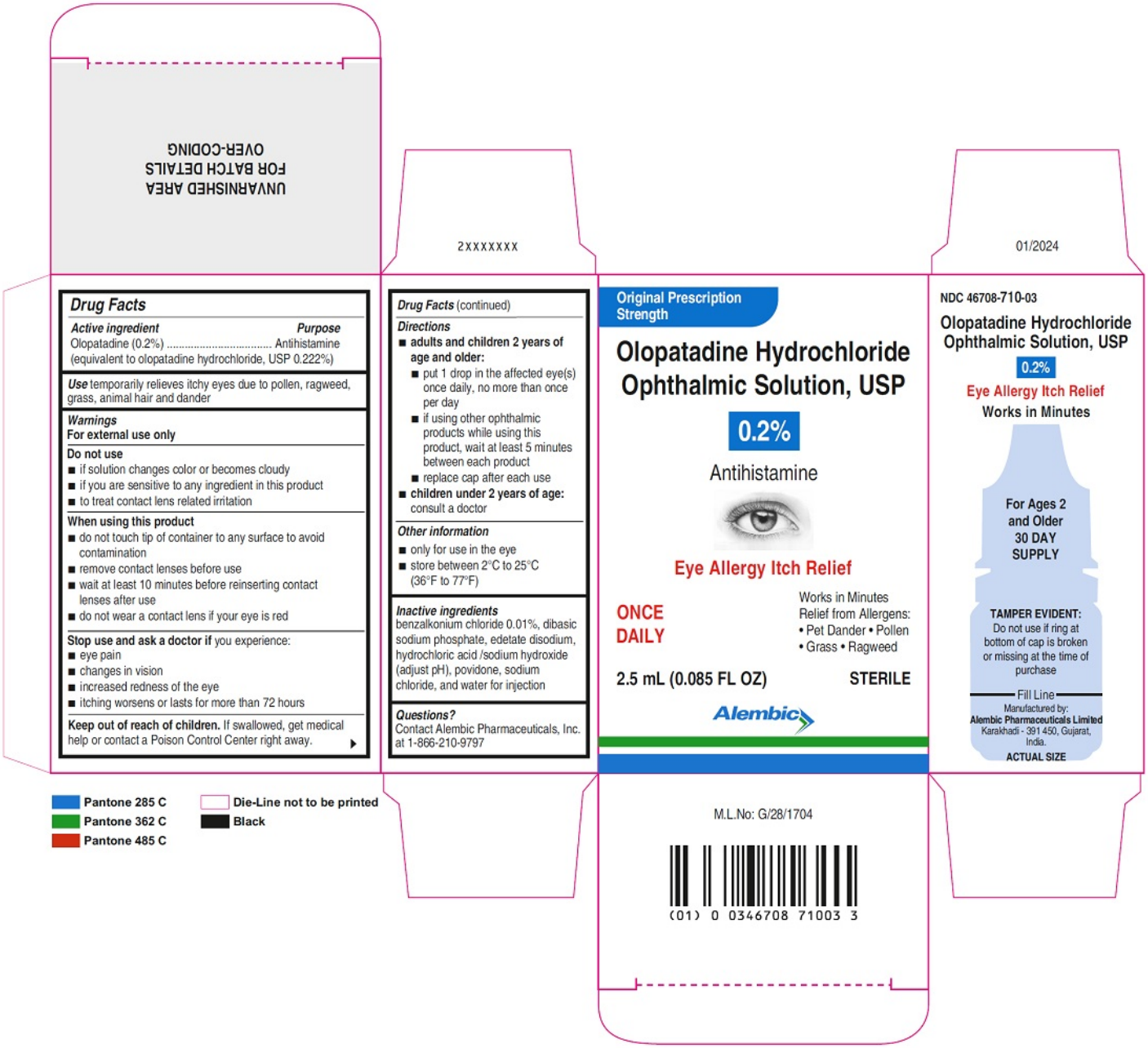
Contact Alembic Pharmaceuticals Inc. at 1-866-210-9797

PRINCIPAL DISPLAY PANEL

Olopatadine Hydrochloride Ophthalmic Solution, USP 0.2% - Bottle Label - ALEMBIC



Olopatadine Hydrochloride Ophthalmic Solution, USP 0.2% - Carton Label - ALEMBIC



OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:46708-710
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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46708-710-03	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 Limited (650574663)

Establishment

Name	Address	ID/FEI	Business Operations
Alembic Pharmaceuticals Limited (F3)		675480734	MANUFACTURE(46708-710)

Revised: 10/2024 Alembic Pharmaceuticals Limited