OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION - olopatadine hydrochloride ophthalmic solution
Gland Pharma Limited

ACTIVE INGREDIENT

Olopatadine (0.7%).....(equivalent to olopatadine hydrochloride 0.776%)

PURPOSE

Antihistamine

USE

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 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.

DIRECTIONS

- **adults and children 2 years of age and older:**
  - put **1 drop** in the affected eye(s) **once daily**
  - **do not use more than 1 drop in each eye per day**
  - if using other ophthalmic products while using this product, wait at least 5minutes 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° - 25°C (36° - 77°F)

INACTIVE INGREDIENTS

benzalkonium chloride 0.015% (preservative), boric acid, hydrochloric acid/sodium hydroxide (to adjust pH), hydroxypropyl-gamma-cyclodextrin, hypromellose, mannitol, polyethylene glycol 400, povidone, and purified water.

QUESTIONS?

call 866-770-7144 (Monday – Friday 9:00 AM to 6:00 PM EST)

PRINCIPAL DISPLAY PANEL

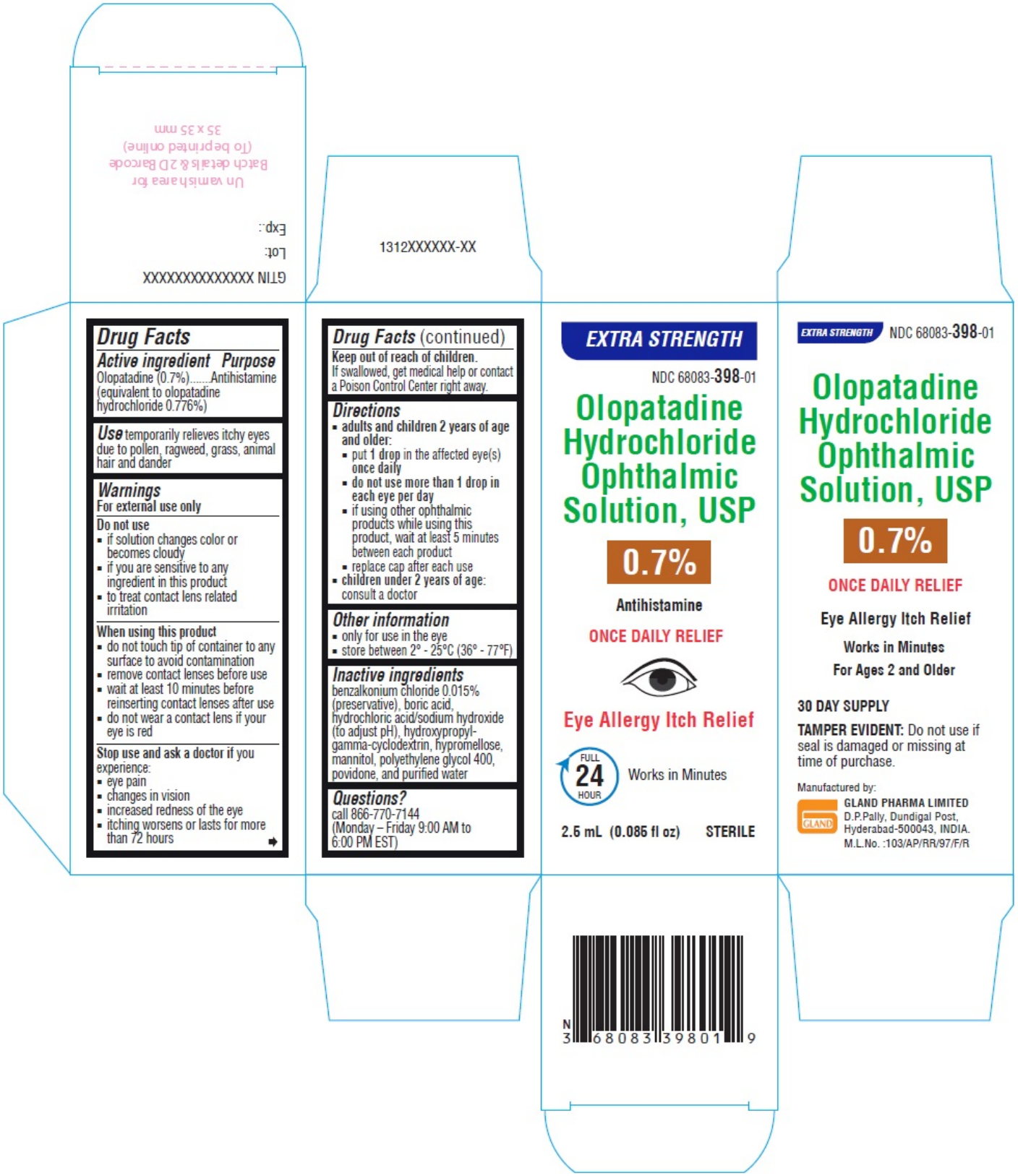
Carton Label:

EXTRA STRENGTH

NDC 68083-**398**-01
Olopatadine
Hydrochloride
Ophthalmic
Solution, USP
0.7%
Antihistamine
ONCE DAILY RELIEF
Eye Allergy Itch Relief

FULL
24
HOUR

Works in Minutes
2.5 mL (0.085 fl oz)
STERILE



Bottle Label:
NDC 68083-**398**-01
EXTRA STRENGTH
Olopatadine

Hydrochloride
Ophthalmic
Solution, USP
0.7%
Antihistamine
ONCE DAILY RELIEF
EYE ALLERGY ITCH RELIEF

STERILE

2.5 mL (0.085 fl oz)

OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION

olopatadine hydrochloride ophthalmic solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68083-398
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OLOPATADINE HYDROCHLORIDE (UNII: 2XG66W44KF) (OLOPATADINE - UNII:D27V6190PM)	OLOPATADINE	7 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
HYDROXYPROPYL .GAMMA.-CYCLODEXTRIN (UNII: P6BYU725IU)	
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68083-398-01	1 in 1 CARTON	01/06/2026	
1		2.5 mL in 1 BOTTLE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213514	01/06/2026	

Labeler - Gland Pharma Limited (918601238)

Establishment

Name	Address	ID/FEI	Business Operations
GLAND PHARMA LIMITED		918601238	ANALYSIS(68083-398) , LABEL(68083-398) , MANUFACTURE(68083-398) , PACK(68083-398)

Revised: 1/2026 Gland Pharma Limited