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

ACTIVE INGREDIENT

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

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, 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° to 25°C (36° to 77°F)

INACTIVE INGREDIENTS

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

QUESTIONS?

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

PRINCIPAL DISPLAY PANEL

Carton Label

Original Prescription Strength

NDC 68083 **-231** -01

Olopatadine
Hydrochloride
Ophthalmic
Solution, USP

0.2%

Antihistamine

ONCE DAILY

Eye Allergy Itch Relief

Works in Minutes

2.5 mL (0.085 fl oz) STERILE

Bottle Label

NDC 68083-**231**-01

Olopatadine Hydrochloride Ophthalmic Solution, USP

0.2%

Antihistamine

ONCE DAILY

EYE ALLERGY ITCH RELIEF

2.5 mL (0.085 fl oz) **STERILE**

OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION

olopatadine hydrochloride ophthalmic solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68083-231
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**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	

EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68083-231-01	1 in 1 CARTON	05/20/2020	
1		2.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209752	05/20/2020	

Labeler - Gland Pharma Limited (918601238)

Establishment

Name	Address	ID/FEI	Business Operations
Gland Pharma Limited		918601238	ANALYSIS(68083-231) , MANUFACTURE(68083-231) , PACK(68083-231)

Revised: 4/2026 Gland Pharma Limited