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 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

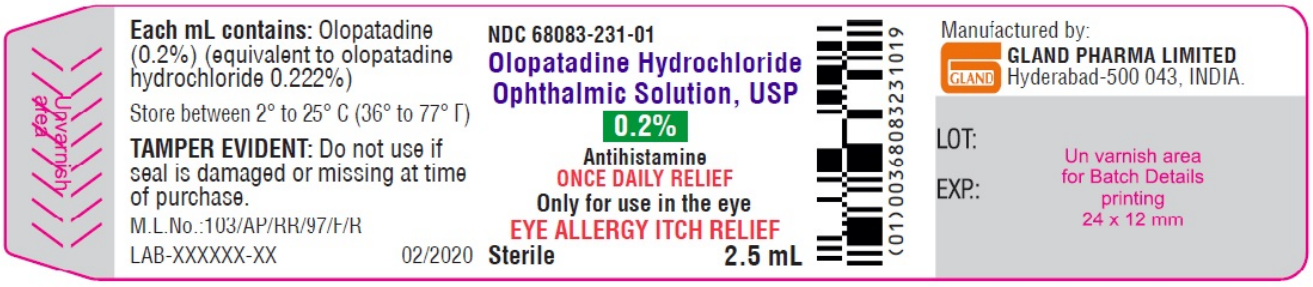
Benzalkonium chloride 0.01%, Dibasic sodium phosphate, Edetate disodium, Hydrochloric acid/Sodium hydroxide (adjust pH), Povidone, Sodium chloride, and Water for Injection.

QUESTIONS?

contact Gland Pharma at 864-879-9994 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

PRINCIPAL DISPLAY PANEL

NDC 68083-231-01
Olopatadine Hydrochloride
Ophthalmic Solution, USP
0.2%
Bottle Label:



Olopatadine Hydrochloride
Ophthalmic Solution, USP
0.2%
Carton Label:

Un varnish area for
Batch details & 2D Barcode
(To be printed online)
35 x 35 mm

GTIN XXXXXXXXXXXXX

CAR-XXXXXX-XX

Drug Facts

Active ingredient **Purpose**
Olopatadine (0.2%) (equivalent to olopatadine hydrochloride 0.222%) ..... 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

➡

Drug Facts (continued)

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?
contact Gland Pharma at 864-879-9994 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

NOW AVAILABLE without a prescription

Olopatadine Hydrochloride Ophthalmic Solution, USP

0.2%

Antihistamine

ONCE DAILY RELIEF

Eye Allergy Itch Relief

ONCE DAILY

Works in Minutes
Relief from Allergens:
- Pet Dander
- Pollen
- Grass
- Ragweed

2.5 mL **STERILE**

NDC 68083-231-01

Olopatadine Hydrochloride Ophthalmic Solution, USP

0.2%

ONCE DAILY RELIEF

Eye Allergy Itch Relief
Works in Minutes

For Ages 2 and Older

30 DAY SUPPLY

TAMPER EVIDENT: Do not use if seal is damaged or missing at time of purchase.

Manufactured by:
GLAND PHARMA LIMITED
Hyderabad-500 043, INDIA.
M.L.No. :103/AP/RR/97/F/R

Labeling Format Information	
Font type :	Helvetica LT Condensed
Barline :	2.5 pt
Hairline :	0.5 pt
Drug facts :	8 pt
Drug facts (continued) **:**	7 pt
Header :	8 pt
Subheader :	6 pt
Leading :	0.5 pt
Body text :	6 pt
Bullets :	6 pt

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)