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

ACTIVE INGREDIENT

Olopatadine (0.1%) (equivalent to olopatadine hydrochloride 0.111%)

PURPOSE

Antihistamine and redness reliever

USES

temporarily relieves itchy and red 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) twice daily, every 6 to 8 hours, no more than twice 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 4° to 25°C (39° to 77°F)

INACTIVE INGREDIENTS

Benzalkonium chloride 0.01%, Dibasic sodium phosphate, Hydrochloric acid and /or Sodium hydroxide (to adjust pH), 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 68083-477-01
Olopatadine
Hydrochloride
Ophthalmic
Solution, USP
Bottle Label:

Carton Label:

OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION

olopatadine hydrochloride ophthalmic solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68083-477
Route of Administration	OPHTHALMIC		

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

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68083-477-01	1 in 1 CARTON	02/14/2017	
1		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	ANDA209619	02/14/2017	

Labeler - Gland Pharma Limited (918601238)

Establishment

Name	Address	ID/FEI	Business Operations
Gland Pharma Limited		918601238	ANALYSIS(68083-477) , MANUFACTURE(68083-477) , PACK(68083-477)

Revised: 8/2020 Gland Pharma Limited