

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

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**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](http://www.fda.gov/medwatch).

## PRINCIPAL DISPLAY PANEL

NDC 68083-477-01

**Olopatadine  
Hydrochloride  
Ophthalmic  
Solution, USP**

### Bottle Label:

	<p>Each mL contains: Olopatadine (0.1%) (equivalent to olopatadine hydrochloride 0.111%) Store at 4° to 25°C (39° to 77°F)</p> <p><b>TAMPER EVIDENT:</b> Do not use if seal is damaged or missing at time of purchase.</p> <p>M.L.No.:103/AP/RR/97/F/R LAB-XXXXXX-XX      03/2020</p>	<p>NDC 68083-477-01</p> <p><b>Olopatadine Hydrochloride Ophthalmic Solution, USP</b></p> <p><b>0.1%</b></p> <p>Antihistamine and Redness Reliever <b>TWICE DAILY RELIEF</b> Only for use in the eye. <b>Eye Allergy Itch &amp; Redness Relief</b> Sterile      5 mL</p>	 <p>(01)00368083477011</p>	<p>Manufactured by:  <b>GLAND PHARMA LIMITED</b> Hyderabad-500 043, INDIA.</p>
	<p>LOT:</p> <p>EXP:</p>	<p>Un varnish area for Batch Details printing 24 x 12 mm</p>		

### Carton Label:

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

CAR-XXXXXX-XX

XXXXXXXXXXXXXXXXX N1.G

**Drug Facts**

**Active ingredient Purpose**  
Olopatadine (0.1%).....Antihistamine  
and redness reliever (equivalent to  
olopatadine hydrochloride 0.111%)

**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 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)  
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.

**NOW AVAILABLE  
without a prescription**

**Olopatadine  
Hydrochloride  
Ophthalmic  
Solution, USP**

**0.1%**

Antihistamine and Redness Reliever  
**TWICE DAILY RELIEF**



**Eye Allergy Itch &  
Redness Relief**

**TWICE  
DAILY**  
Works in Minutes  
Relief from Allergens:  
• Pet Dander • Pollen  
• Grass • Ragweed  
**5 mL STERILE**

NDC 68083-477-01

**Olopatadine  
Hydrochloride  
Ophthalmic  
Solution, USP**

**0.1%**

**TWICE DAILY RELIEF**  
**Eye Allergy Itch &  
Redness 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/FF/R



**OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION**

olopatadine hydrochloride ophthalmic solution/ drops

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68083-477
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OLOPATADINE HYDROCHLORIDE</b> (UNII: 2XG66W44KF) (OLOPATADINE - UNII:D27V6190PM)	OLOPATADINE	1 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>SODIUM PHOSPHATE, DIBASIC</b> (UNII: GR686LBA74)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0K00R)	

**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