

**OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION- olopatadine hydrochloride ophthalmic solution**  
**Dr. Reddy's Laboratories Inc.**

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**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?

Call 1-888-375-3784

## PRINCIPAL DISPLAY PANEL

**NDC 68083-231-01**

**Olopatadine Hydrochloride  
Ophthalmic Solution, USP**

**0.2%**

**Bottle Label:**

Each mL contains: Olopatadine (0.2%) (equivalent to olopatadine hydrochloride 0.222%)  
Store between 2°-25°C (36°-77°F)  
Packaged with Tamper-Evident bottle cap. Do Not Use if breakable ring is separated or missing.  
Code: AP/DRUGS/103/97  
LAB-020865-00 REV: 06/20

**Olopatadine Hydrochloride  
Ophthalmic Solution, USP**  
**0.2%**  
**Antihistamine**  
**ONCE DAILY RELIEF**  
Only for use in the eye  
**Eye Allergy Itch Relief**  
**STERILE**                      **2.5 mL**

(01)00343598764023  
DISTRIBUTED BY:  
Dr. Reddy's Laboratories, Inc.  
Princeton, NJ 08540 **Made in India**  
LOT:  
EXP:

**Olopatadine Hydrochloride  
Ophthalmic Solution, USP**

**0.2%**

**Carton Label:**



OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION			
olopatadine hydrochloride ophthalmic solution			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43598-764(NDC:68083-231)

Route of Administration OPTHALMIC

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-764-02	1 in 1 CARTON	09/01/2020	
1		2.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:43598-764-25	2 in 1 CARTON	09/01/2020	
2		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	09/01/2020	

**Labeler** - Dr. Reddy's Laboratories Inc. (802315887)

Revised: 12/2025

Dr. Reddy's Laboratories Inc.