

OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION- olopatadine hydrochloride ophthalmic solution/ drops
Rugby Laboratories

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?

Call 1-888-375-3784

PRINCIPAL DISPLAY PANEL

**Olopatadine Hydrochloride
Ophthalmic Solution USP, 0.1%**



Twice Daily Relief
Olopatadine HCl
Ophthalmic Solution, USP

0.1%

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

Keep out of reach of children.
 If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Drug Facts (continued)

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°-25°C (39°-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?
 call 1-888-375-3784

*This product is not manufactured or distributed by Alcon Laboratories Inc., distributor of Pataday® Twice Daily Relief. Pataday® is a registered trademark of Novartis AG.



NDC 0536-1308-40
 Compare to the active ingredient in Pataday® Twice Daily Relief*

NOW AVAILABLE without a prescription

Twice Daily Relief
Olopatadine HCl
Ophthalmic Solution, USP

0.1%

Antihistamine and Redness Reliever

Eye Allergy Itch & Redness Relief Works in Minutes

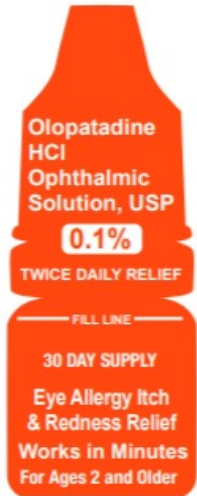
Relief from Allergens:

- Pet Dander
- Pollen
- Grass
- Ragweed

Twice Daily Sterile

5 mL

Retain carton for complete Drug Facts. Packaged with Tamper-Evident bottle cap. Do Not Use if breakable ring is separated or missing.



Distributed by: **RUGBY® LABORATORIES**
 17177 N Laurel Park Drive, Suite 233
 Livonia, MI 48152 Made in India
 www.rugbylaboratories.com
 Code: AP/DRUGS/103/97



Rev. 08/20 R-145 Re-order No. 371044



LOT

EXP

no coating area

OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION

olopatadine hydrochloride ophthalmic solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1308
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:0536-1308-40	1 in 1 CARTON	01/05/2021	
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	01/05/2021	

Labeler - Rugby Laboratories (079246066)

Establishment

Name	Address	ID/FEI	Business Operations
Reed Lane Inc.		001819879	pack(0536-1308)

Revised: 6/2023

Rugby Laboratories