

OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION- olopatadine hydrochloride ophthalmic solution
Rugby Laboratories

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

**Olopatadine Hydrochloride
Ophthalmic Solution, USP
0.2%**



Once Daily Relief
Olopatadine HCl
Ophthalmic Solution, USP
0.2%

Drug Facts

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

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

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) 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
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Other information

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- store between 2° -25°C (36° -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

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



NDC 0536-1307-23

Compare to the active ingredient in Pataday® Once Daily Relief*

NOW AVAILABLE without a prescription

Once Daily Relief
Olopatadine HCl
Ophthalmic Solution, USP

0.2%

Antihistamine

Eye Allergy Itch Relief

Works in Minutes

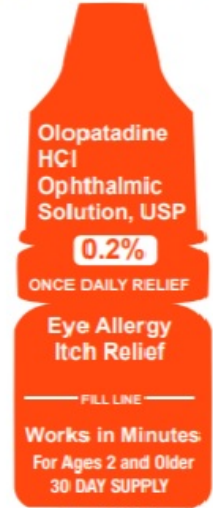
Relief from Allergens:

- Pet Dander
- Pollen
- Grass
- Ragweed

Once Daily Sterile

2.5 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. 371043



LOT

EXP

no coating area

OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION

olopatadine hydrochloride ophthalmic solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-1307 |
| 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:0536-1307-23 | 1 in 1 CARTON | 01/15/2021 | |
| 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 | 01/15/2021 | |

Labeler - Rugby Laboratories (079246066)

Revised: 6/2023

Rugby Laboratories