

**OLOPATADINE HCL- olopatadine hydrochloride solution/ drops**  
**Rugby Laboratories**

-----  
**ACTIVE INGREDIENT**

Olopatadine (0.7%) (equivalent to olopatadine hydrochloride 0.776%)

**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(1-800-222-

1222).

## **DIRECTIONS**

- **adults and children 2 years of age and older:**
- put **1 drop** in the affected eye(s) **once daily**
- **do not use more than 1 drop in each eye 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 0.015% (preservative), boric acid, hydrochloric acid/sodium hydroxide (to adjust pH), hydroxypropyl gamma cyclodextrin, hypromellose, mannitol, polyethylene glycol 400, povidone and purified water.

## **QUESTIONS?**

call toll-free weekdays 8 AM to 8 PM EST at **1-888-375-3784**

## **Distributed by:**

RUGBY® LABORATORIES

Indianapolis, IN 46268

(800) 616-2471

[www.major-rugby.com](http://www.major-rugby.com)

## **Made in India**

Rev. 09/25 R-145 Re-order No. 371269

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

## **PRINCIPAL DISPLAY PANEL**

### **Carton Label:**

NDC 0536-1478-23

extra strength

olopatadine HCl  
ophthalmic solution USP, 0.7%  
antihistamine

once daily relief

eye allergy itch relief

works in minutes

FULL 24 HR

relief from allergens:

- pet dander
- pollen
- grass
- ragweed

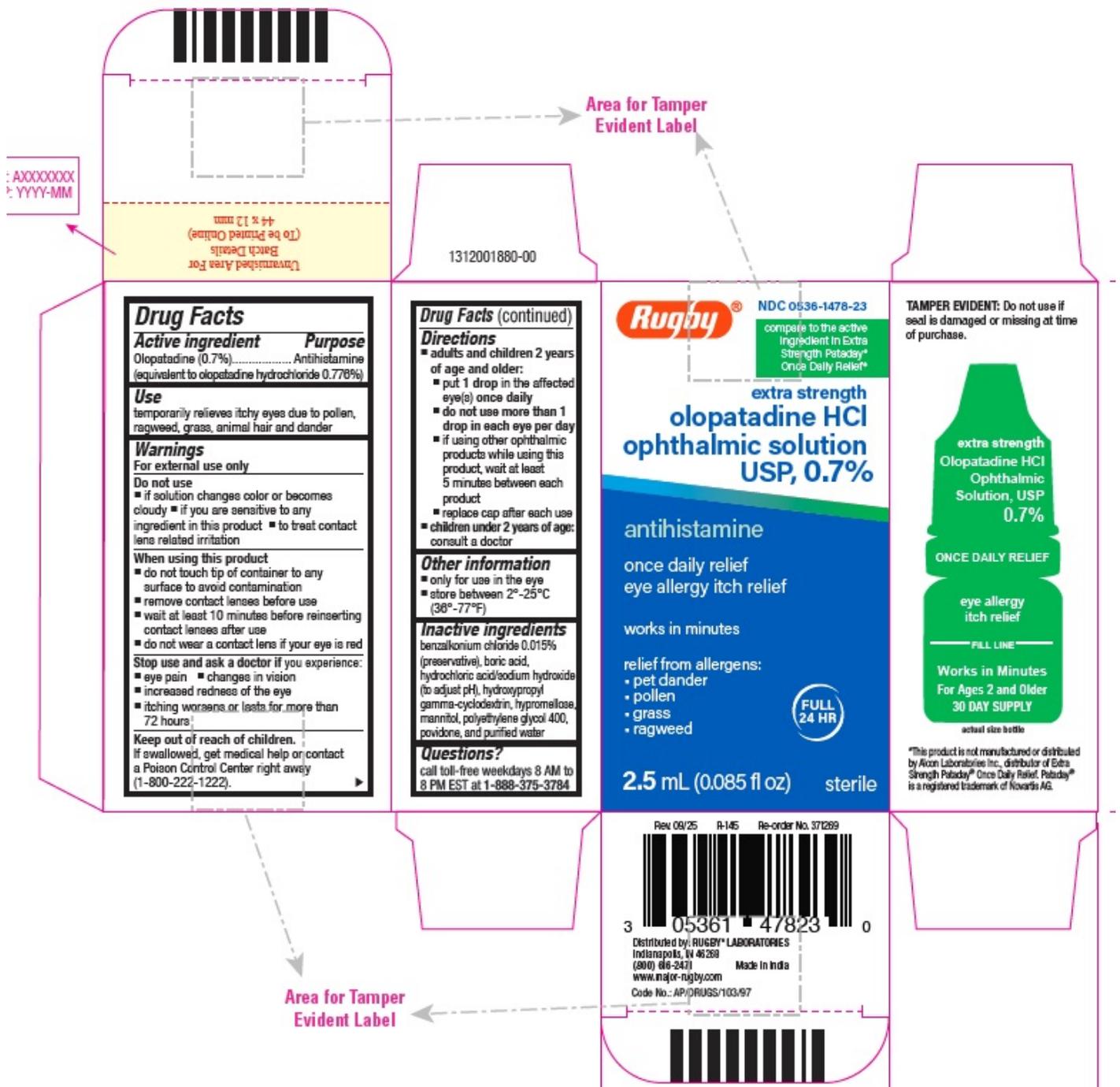
2.5 mL (0.085 fl oz)  
sterile

Compare to active ingredient in Extra Strength Pataday Once Daily Relief\*

Tamper Evident: Do not use if seal is damaged or missing at time of purchase.

For Ages 2 and Older

30 DAY SUPPLY



**Bottle Label:**

extra strength  
 olopatadine HCl  
 ophthalmic solution USP, 0.7%  
 antihistamine  
 once daily relief  
 eye allergy itch relief  
 2.5 mL (0.085 fl oz)

sterile

## OLOPATADINE HCL

olopatadine hydrochloride solution/ drops

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0536-1478 |
| <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       | 7 mg in 1 mL |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)              |          |
| <b>BORIC ACID</b> (UNII: R57ZHV85D4)                         |          |
| <b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)                  |          |
| <b>HYDROXYPROPYL .GAMMA.-CYCLODEXTRIN</b> (UNII: P6BYU725IU) |          |
| <b>HYPROMELLOSE 2910 (4000 MPA.S)</b> (UNII: RN3152OP35)     |          |
| <b>MANNITOL</b> (UNII: 3OWL53L36A)                           |          |
| <b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)            |          |
| <b>POVIDONE K30</b> (UNII: U725QWY32X)                       |          |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)                   |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                              |          |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:0536-1478-23 | 1 in 1 CARTON       | 01/15/2026           |                    |

| 1                            | 2.5 mL in 1 BOTTLE, DROPPER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.) |                      |                    |
|------------------------------|---|----------------------|--------------------|
| <b>Marketing Information</b> |   |                      |                    |
| Marketing Category           | Application Number or Monograph Citation  | Marketing Start Date | Marketing End Date |
| ANDA                         | ANDA213514  | 01/15/2026           |                    |

**Labeler** - Rugby Laboratories (079246066)

Revised: 1/2026

Rugby Laboratories