

**RUGBY OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION- olopatadine hydrochloride ophthalmic solution solution**  
**RUGBY LABORATORIES**

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

***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 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.

***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)
- protect from light

***Inactive ingredients***

benzalkonium chloride 0.01%, dibasic sodium phosphate, hydrochloric acid/sodium hydroxide (to adjust pH), sodium chloride and water for injection

***Questions?***

**Call**1-877-758-1480

**Package/Label Principal Display Panel**

3801



## RUGBY OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION

olopatadine hydrochloride ophthalmic solution solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1445
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM</b> (UNII: 3980JIH2SW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1445-40	1 in 1 CARTON	04/15/2025	
1		5 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206046	04/15/2025	

Labeler - RUGBY LABORATORIES (079246066)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	manufacture(0536-1445)