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

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

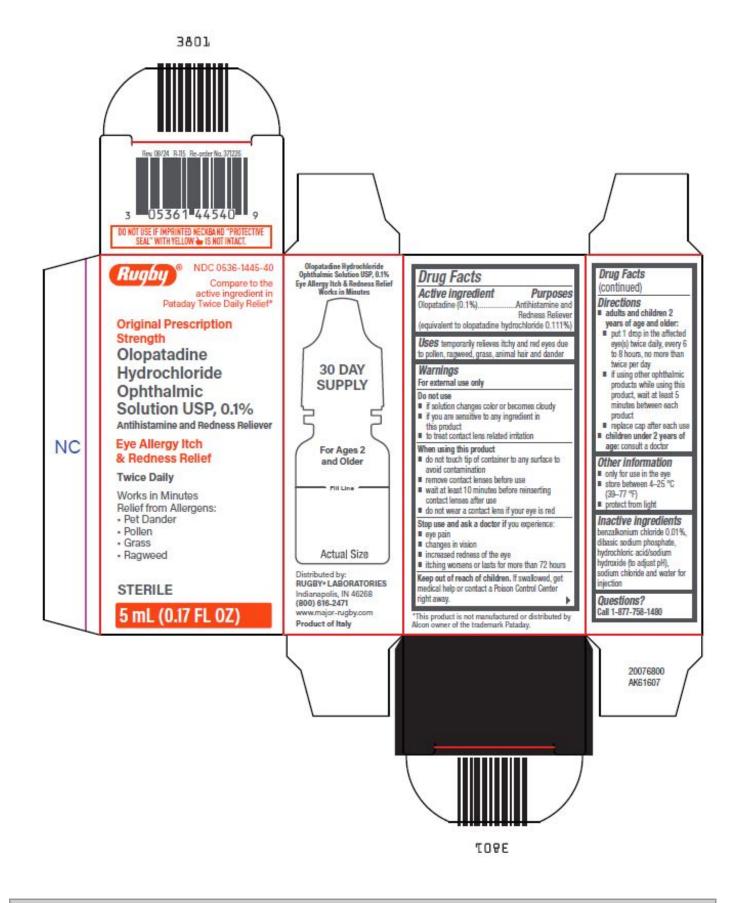
Inactive ingredients

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

Questions?

Call1-877-758-1480

Package/Label Principal Display Panel



RUGBY OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION

olopatadine hydrochloride ophthalmic solution solution

Product Information

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

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

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

P	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 I	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)		

Revised: 4/2025 RUGBY LABORATORIES