

LEADER OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION-
olopatadine hydrochloride ophthalmic solution solution
CARDINAL HEALTH

Leader [™] 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

3803



LEADER OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION

olopatadine hydrochloride ophthalmic solution solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70000-0717

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)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0717-1	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 - CARDINAL HEALTH (063997360)

Establishment			
Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	manufacture(70000-0717)