

LEADER OLOPATADINE HYDROCHLORIDE- olopatadine hydrochloride solution
CARDINAL HEALTH

Leader Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2%

Active ingredient

Olopatadine (0.2%)

(equivalent to olopatadine hydrochloride 0.222%)

Purpose

Antihistamine

Uses

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 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 4 –25 °C (39 –77 °F)
- protect from light

Inactive ingredients

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

Questions?

Call 1-877-758-1480

Principle Display Panel

1042



NDC 70000-0716-1

**Opatadine
Hydrochloride
Ophthalmic
Solution USP, 0.2%
Antihistamine**

Once Daily
Eye Allergy
Itch Relief

Works in Minutes

Relief from Allergens:
Pet Dander
Pollen, Grass
Ragweed

ORIGINAL
PRESCRIPTION
STRENGTH

STERILE

3.5 ml (0.12 FL OZ)

2007701
FB61705

LEADER OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0716
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
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0716-1	1 in 1 CARTON	04/15/2025	
1		3.5 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		ANDA206087	04/15/2025	

Labeler - CARDINAL HEALTH (063997360)

Establishment			
Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	manufacture(70000-0716)

Revised: 4/2025

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