

OLOPATADINE HYDROCHLORIDE - olopatadine hydrochloride solution
TOPCO ASSOCIATES LLC

Drug Facts

Active ingredient

Olopatadine (0.2%)
(equivalent to olopatadine hydrochloride, USP 0.222%)

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 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 (1-800-222-1222) 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 2° to 25°C (36° to 77°F)

Inactive ingredients

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

Questions?

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PRODUCT OF INDIA

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL-0.2% (2.5 mL Container)

+ **Top Care®** NDC 76162-044-39
health ONCE DAILY
Eye Allergy Itch Relief
Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2%
Antihistamine
STERILE 0.085 FL OZ (2.5 mL)



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL-0.2% (2.5 mL Container Carton)

+ **TopCare®** NDC 76162-044-39
health

COMPARE TO PATADAY® ONCE DAILY
RELIEF ACTIVE INGREDIENT*

**Olopatadine Hydrochloride
Ophthalmic Solution, USP 0.2%**

**Eye Allergy
Itch Relief**

Antihistamine

Works in Minutes

Relief from Allergens:

- **Pet Dander • Pollen**
- **Grass • Ragweed**

**ONCE
DAILY**

STERILE 0.085 FL (2.5 mL)



OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-044
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-044-39	1 in 1 CARTON	07/15/2020	
1		2.5 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	ANDA209995	07/15/2020	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
EUGIA PHARMA SPECIALITIES LIMITED		650498244	ANALYSIS(76162-044) , MANUFACTURE(76162-044) , PACK(76162-044)

Revised: 6/2024

TOPCO ASSOCIATES LLC