# OLOPATADINE HYDROCHLORIDE- olopatadine hydrochloride solution BluePoint Laboratories

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#### **Drug Facts**

Active Ingredients	• Purpose
Olopatadine 0.2% (equivalent to olopatadine hydrochloride 0.222%)	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 right away.

#### **Directions**

- adults and children 2 years of age and older:
  - o 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°C to 25°C (36°F to 77°F)

#### 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?**

In the U.S., call toll free weekdays 9 AM to 6 PM EST at 1 (888) 721-7115.

Manufactured by: SamChunDang Pharm. Co., Ltd. 71 Jeyakgongdan-2Gil; Hyangnam-eup, Hwaseong, Gyeonggi 18622, Korea, South (KOR) For BluePoint Laboratories

**Product of Spain** 

Rev 08/25

#### PRINCIPAL DISPLAY PANEL

Original Prescription Strength

ONCE DAILY RELIEF

Olopatadine hydrochloride ophthalmic solution 0.2% Antihistamine Eye Allergy Itch Relief

STERILE 2.5 mL

NDC: 68001-674-92

#### Label



Original Prescription Strength

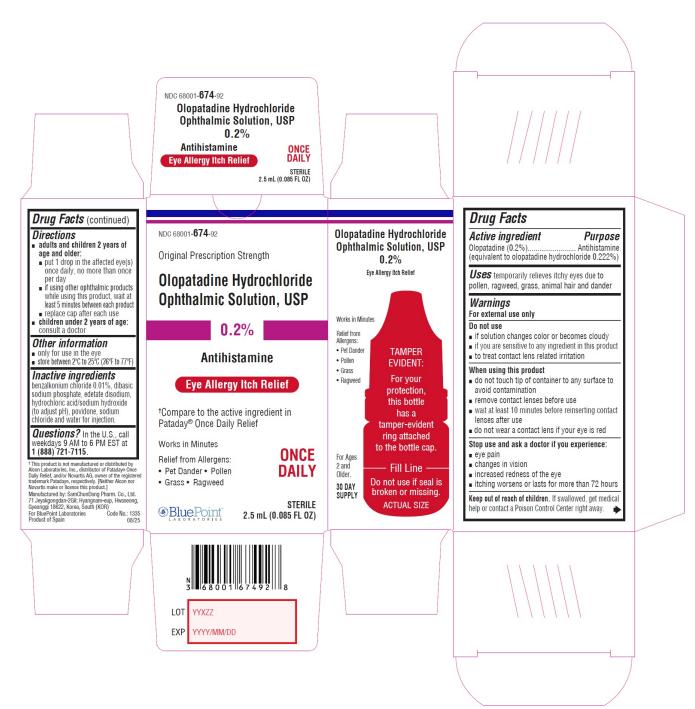
**ONCE DAILY RELIEF** 

Olopatadine hydrochloride ophthalmic solution 0.2% Antihistamine Eye Allergy Itch Relief

STERILE 2.5 mL

NDC: 68001-674-92

Carton



# **OLOPATADINE HYDROCHLORIDE**

olopatadine hydrochloride solution

# **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68001-674

**Route of Administration** OPHTHALMIC

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength OLOPATADINE HYDROCHLORIDE (UNII: 2XG66W44KF) (OLOPATADINE - UNII:D27V6190PM) Colopatadine OLOPATADINE OLOPATAD

Inactive Ingredients		
Ingredient Name	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
HYDROCHLORIC ACID (UNII: QTT17582CB)		
POVIDONE K30 (UNII: U725QWY32X)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)		
WATER (UNII: 059QF0KO0R)		

ı	Packaging						
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
:	NDC:68001- 674-92	1 in 1 CARTON	09/15/2025				
:	L	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	ANDA219557	09/15/2025			

# Labeler - BluePoint Laboratories (985523874)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
SamChunDang Pharm Co, Ltd		687792325	manufacture(68001-674)		

Revised: 9/2025 BluePoint Laboratories