

OLOPATADINE HYDROCHLORIDE - olopatadine hydrochloride solution/ drops
Cipla USA Inc.

OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION

ACTIVE INGREDIENT

Olopatadine 0.2% (equivalent to olopatadine hydrochloride 0.222%)

PURPOSE

Antihistamine

INDICATIONS AND USAGE

Use temporarily relieves itchy eyes due to pollen, ragweed, grass, animal hair and dande

WARNINGS

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

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTION

- **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
 - o if using other ophthalmic products while using this product, wait at least 5 minutes between each product
 - o 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°-25°C (36°-77°F)

INACTIVE INGREDIENT

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

Questions

Call 1-866-604-3268

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Original Prescription

Strength

NDC 69097-600-33

Olopatadine

Hydrochloride

Ophthalmic

Solution, USP 0.2%

Antihistamine

ONCE DAILY

Eye allergy itch relief
 Works in Minutes
 Relief from Allergens:

- Pet Dander
- Pollen
- Grass
- Ragweed

Cipla
 STERILE
 2.5 mL (0.085 FL OZ)



NDC 69097-600-33
 Opatadine
 Hydrochloride
 Ophthalmic Solution,

USP, 0.2%

Once Daily

Antihistamine

Eye Allergy Itch Relief

Sterile 2.5 mL (0.085 FL OZ)

Olopatadine Hydrochloride
Ophthalmic Solution,
USP 0.2%
Antihistamine
Eye Allergy Itch Relief
ONCE DAILY
STERILE 2.5 mL (0.085 FL OZ)

NDC 69097-600-33

Only for use in the eye. Store between 4°C - 25°C (39°F - 77°F) Protect from light.
TAMPER EVIDENT: For your protection, this bottle has a seal imprinted with 'seal for protection' around the neck. Do not use if seal is damaged or missing at time of purchase.

Cipla Mfd. by: **Cipla Ltd., India**
Mfd. for: **Cipla USA, Inc., Warren, NJ 07059**

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Rev. 12/2020
Code No.: MFD/DRUGS/28/2/2010

LOT
EXP.

OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69097-600
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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69097-600-33	1 in 1 CARTON	03/19/2021	
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	ANDA206087	03/19/2021	

Labeler - Cipla USA Inc. (078719707)

Registrant - Cipla USA Inc. (078719707)

Establishment

Name	Address	ID/FEI	Business Operations
Cipla Ltd. Indore		918596409	ANALYSIS(69097-600) , MANUFACTURE(69097-600) , LABEL(69097-600) , PACK(69097-600)

Revised: 11/2021

Cipla USA Inc.