OLOPATADINE- olopatadine solution/ drops
Somerset Therapeutics, LLC

Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1%
TWICE DAILY RELIEF

Drug Facts

Active Ingredients	***Purpose***
Olopatadine (0.1%) (equivalent to olopatadine hydrochloride 0.111%)	**Antihistamine and Redness Reliever**

Use 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)

Inactive ingredients

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

Questions?

Customer Care # 1-800-417-9175

Manufactured for:

Somerset Therapeutics, LLC

Somerset, NJ 08873

Made in India

Code No.:KR/DRUGS/KTK/28/289/97

ST-OLP11-OTC/P/01

1200809

Container Label

NDC 70069-017-01

Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1%

Antihistamine and Redness Reliever

TWICE DAILY RELIEF

Eye Allergy Itch & Redness Relief

Sterile

5 mL (0.017 FL OZ)

Carton Label

Original Prescription Strength

NDC 70069-017-01

Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1%

Antihistamine and Redness Reliever

TWICE DAILY RELIEF

Eye Allergy Itch & Redness Relief

TWICE DAILY

Works in Minutes

Relief from Allergens:

- Pet Dander
- Pollen
- Grass
- Ragweed

Sterile

5 mL (0.017 FL OZ

OLOPATADINE

olopatadine solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70069-017
Route of Administration	OPHTHALMIC		

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

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	

SODIUM CHLORIDE (UNII: 451W47IQ8X)	
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:70069-017-01	1 in 1 CARTON	04/15/2024	
1		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	ANDA206306	04/15/2024	

Labeler - Somerset Therapeutics, LLC (079947873)

Registrant - Somerset Therapeutics, LLC (079947873)

Establishment

Name	Address	ID/FEI	Business Operations
Somerset Therapeutics Limited		677236695	ANALYSIS(70069-017) , LABEL(70069-017) , PACK(70069-017) , MANUFACTURE(70069-017)

Revised: 3/2024 Somerset Therapeutics, LLC