OLOPATADINE HYDROCHLORIDE- olopatadine hydrochloride solution
BluePoint Laboratories

Olopatadine Hydrochloride Ophthalmic Solution, USP 0.2%

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?

✆1-855-274-4122

Manufactured by:

Eugia Pharma Specialities Limited, Unit III
IDA, Pashamylaram – 502307, TS., India.

Code: TS/DRUGS/13/2010

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

NDC 68001-520-69
Olopatadine Hydrochloride

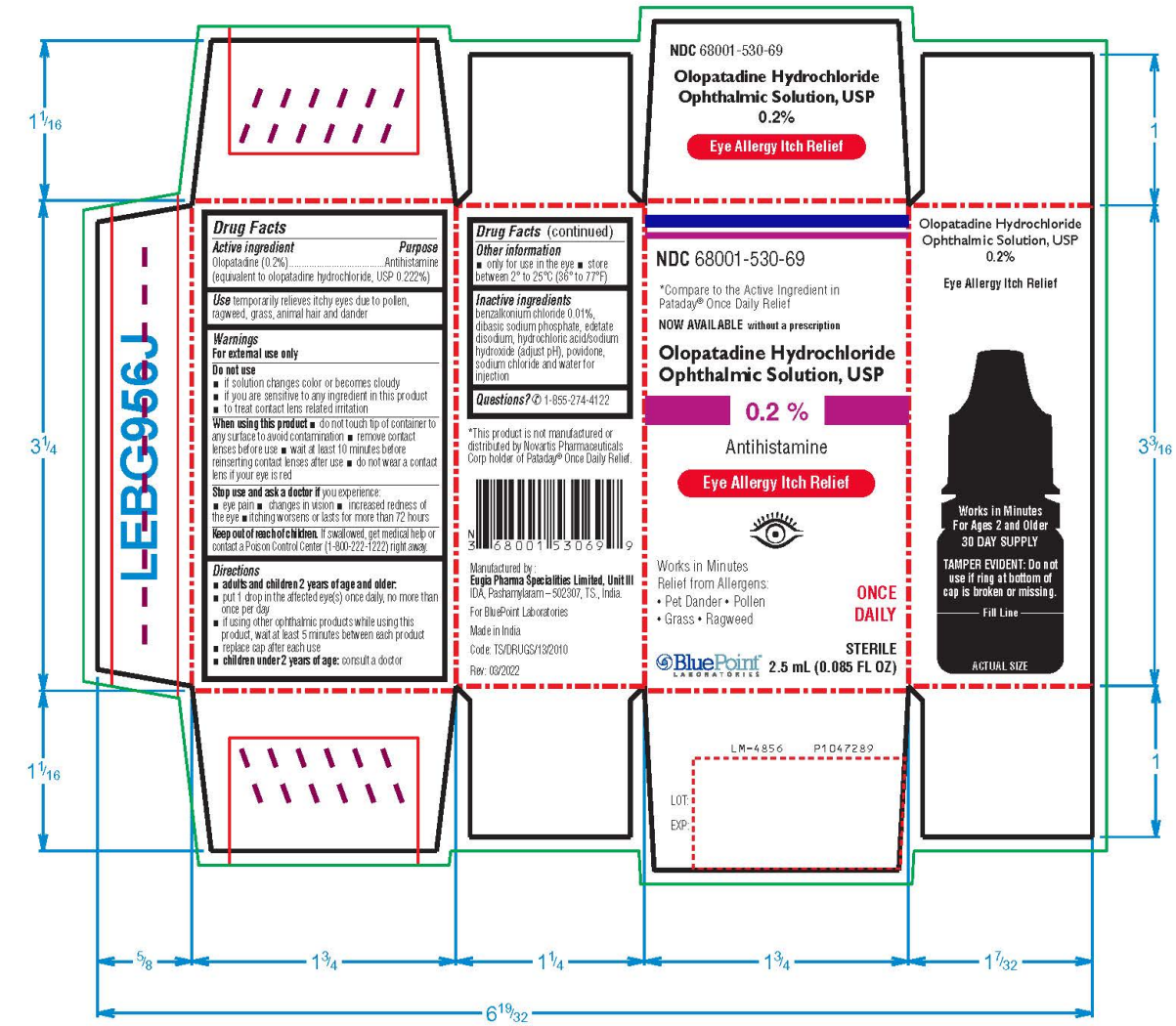
Ophthalmic Solution, USP

0.2%

Antihistamine

Eye Allergy Itch Relief

STERILE 2.5 mL (0.085 FL OZ)



Pantone 293 C Pantone 549 C Pantone 072 C
Pantone 185 C Pantone 241 C
Pantone Gray 75% Black

Labeling Format Information:	
Font type :	Call Sans W1 5 Helvetica Condensed
Barline	2.5 pt
Hairline	0.5 pt
Drug facts :	8 pt
Drug facts(continued):	7 pt
Header :	7 pt
Subheader :	6 pt
Body text :	6 pt
Bullets :	5 pt

AUROBINDO Packaging Development	Product Name	Component	Item Code	Date & Time
	Olopatadine HCl 0.2%	Carton_2.5 mL	LM-4856_P 1047289	03.03.2022 & 03.30 PM
	Customer / Country	Version No.	Reason Of Issue	Reviewed / Approved by
	Blue Point OTC-USA	02	Submission	
Team Leader: Sandhya	Dimensions	Colours : 07		
Initiator: Srinivas A	1.75 x 1.25 x 3.25 inch			
Artist: SCD	Pharmacode			
Additional Information :				Sign / Date

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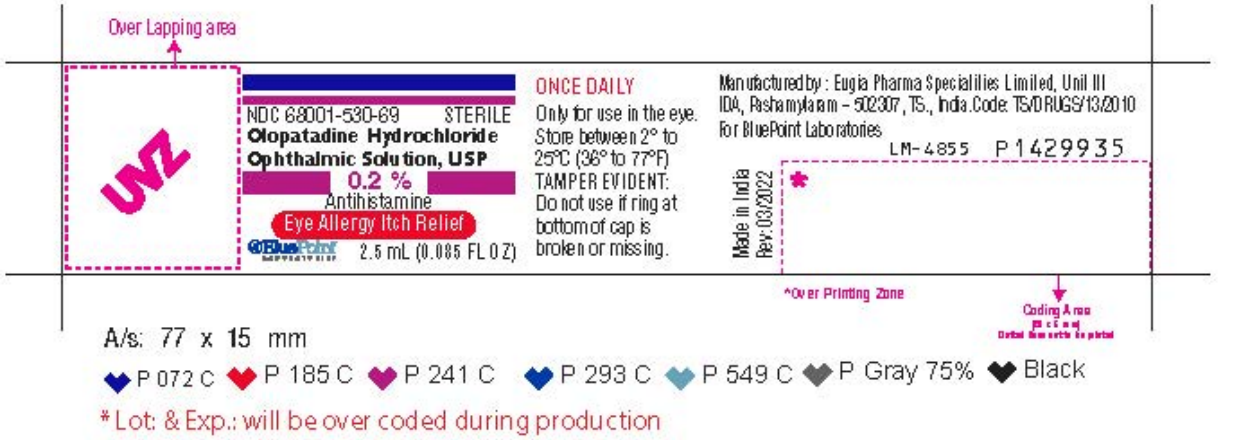

AUROBINDO Packaging Development	Product Name	Component	Item Code	Date & Time
	Olopatadine HCl 0,2%	Label_2.5 mL	LM-4855_P1429935	03.03.2022 & 03.00 pm
	Customer / Country	Version No.	Reason Of Issue	Reviewed / Approved by
	Blue Point OTC-USA	01	Submission	
Team Leader: Sandhya	Dimensions	Colours : 07		
Initiator: Srinivas A	77 x 15 mm			
Artist: SCD	Pharmacode			

Additional Information :				Sign / Date

OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68001-530
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:68001-530-69	1 in 1 CARTON	04/08/2022	
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	04/08/2022	

Labeler - BluePoint Laboratories (985523874)

Establishment

Name	Address	ID/FEI	Business Operations
Eugia Pharma Specialities Limited		650498244	analysis(68001-530) , manufacture(68001-530)

Revised: 4/2022 BluePoint Laboratories