

OLOPATADINE HYDROCHLORIDE - olopatadine hydrochloride solution/ drops
Alembic Pharmaceuticals Limited

ACTIVE INGREDIENT(S)

Olopatadine 0.2%..... (equivalent to olopatadine hydrochloride 0.222%)

PURPOSE

Antihistamine

USE(S)

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 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) 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 INGREDIENT SECTION

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


QUESTIONS?

Contact Alembic Pharmaceuticals Inc. at 1-866-210-9797

PRINCIPAL DISPLAY PANEL

Olopatadine Hydrochloride Ophthalmic Solution, USP 0.2% - Bottle Label - ALEMBIC

NDC 46708-710-03
Olopatadine Hydrochloride Ophthalmic Solution, USP
0.2% Antihistamine
Eye Allergy Itch Relief
ONCE DAILY
2.5 mL (0.085 FL OZ) STERILE

Only for use in the eye. Store between 2°C to 25°C (36°F to 77°F)
TAMPER EVIDENT: Do not use if ring at bottom of cap is broken or missing at the time of purchase
Manufactured by:
Alembic Pharmaceuticals Limited
Karakhadi - 391 450, Gujarat, 
India.

LOT: 200XXXXX
EXP.: (01) 0 0346708 71003 3

M.L.Ncr: G/28/1704
01/2024

Olopatadine Hydrochloride Ophthalmic Solution, USP 0.2% - Carton Label - ALEMBIC

UNFINISHED AREA
FOR BATCH DETAILS
OVER-CODING

2XXXXXXX

01/2024

Drug Facts

Active ingredient Purpose
Olopatadine (0.2%) Antihistamine
(equivalent to olopatadine hydrochloride, USP 0.222%)

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. ▶

Drug Facts (continued)

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°C to 25°C (36°F 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?

Contact Alembic Pharmaceuticals, Inc. at 1-866-210-9797

Original Prescription Strength

Olopatadine Hydrochloride Ophthalmic Solution, USP

0.2%

Antihistamine



Eye Allergy Itch Relief

ONCE DAILY

2.5 mL (0.085 FL OZ)

Works in Minutes
Relief from Allergens:
• Pet Dander • Pollen
• Grass • Ragweed

STERILE



NDC 46708-710-03

Olopatadine Hydrochloride Ophthalmic Solution, USP

0.2%

Eye Allergy Itch Relief Works in Minutes

For Ages 2 and Older 30 DAY SUPPLY

TAMPER EVIDENT:
Do not use if ring at bottom of cap is broken or missing at the time of purchase

Fill Line
Manufactured by:
Alembic Pharmaceuticals Limited
Karakhad - 391 450, Gujarat, India

ACTUAL SIZE

- Pantone 285 C
- Pantone 362 C
- Pantone 485 C
- Die-Line not to be printed
- Black

M.L.No: G/28/1704



OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46708-710
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
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46708-710-03	1 in 1 CARTON	01/25/2021	
1		2.5 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209420	01/25/2021	

Labeler - Alembic Pharmaceuticals Limited (650574663)

Establishment

Name	Address	ID/FEI	Business Operations
Alembic Pharmaceuticals Limited (F3)		675480734	MANUFACTURE(46708-710)

Revised: 10/2024

Alembic Pharmaceuticals Limited