ALCAFTADINE - alcaftadine solution/ drops
Alembic Pharmaceuticals Inc.

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ACTIVE INGREDIENT

Alcaftadine 0.25%

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 DOCTOR IF

you experience any of the following:

- 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
  - 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

- For eye use only
- store at 15° to 25°C (59° to 77°F)

INACTIVE INGREDIENTS

benzalkonium chloride 0.005%, edetate disodium, monobasic sodium phosphate, sodium chloride, sodium hydroxide and/or hydrochloric acid, and water for injection

QUESTIONS OR COMMENTS?

(**1-866-210-9797**

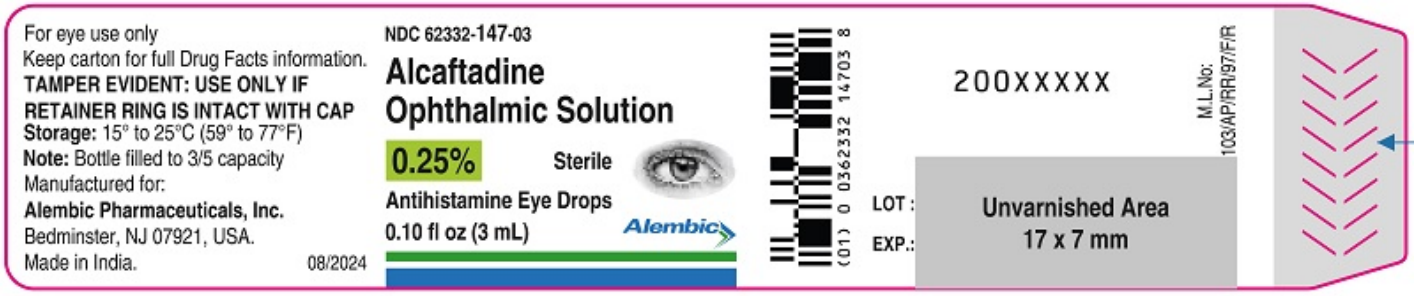
Manufactured by:
Gland Pharma Limited,
D.P. Pally, Dundigal Post,
Hyderabad - 500 043, INDIA.

Manufactured for:
Alembic Pharmaceuticals, Inc.
Bedminster, NJ 07921, USA.

Revision: 09/2024

PRINCIPAL DISPLAY PANEL

Container Label - 0.25% (3 mL)
NDC 62332-147-03
Alcaftadine Ophthalmic Solution, 0.25%
Antihistamine Eye Drops
Eye Allergy Itch Relief
Sterile
0.10 fl oz (3 mL)



Carton Label - 0.25% (3 mL)

NDC 62332-147-03
ORIGINAL PRESCRIPTION STRENGTH
Alcaftadine Ophthalmic Solution, 0.25%
Antihistamine Eye Drops
ONCE DAILY RELIEF
Eye Allergy Itch Relief
Sterile
30 DAY SUPPLY
0.10 fl oz (3 mL)

ALCAFTADINE

alcaftadine solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62332-147
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

ALCAFTADINE (UNII: 7Z8O94ECSX) (ALCAFTADINE - UNII:7Z8O94ECSX)	ALCAFTADINE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62332-147-03	1 in 1 CARTON	10/02/2024	
1		3 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209290	10/02/2024	

Labeler - Alembic Pharmaceuticals Inc. (079288842)

Establishment

Name	Address	ID/FEI	Business Operations
Gland Pharma Limited		918601238	MANUFACTURE(62332-147)

Revised: 10/2024 Alembic Pharmaceuticals Inc.