ALCAFTADINE - alcaftadine solution/ drops
Gland Pharma Limited

Alcaftadine Ophthalmic Solution 0.25%

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 a doctor if

you experience any of the following:
■ eye pain
■ changes in vision

■ increased redness of the eye
■ itching that 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

- only for use in the eye
- 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, water for injection

Questions or comments?

866-770-7144

(Monday – Friday 9:00 AM to 6:00 PM EST)

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL

Container Label - 0.25% (3 mL)

NDC-68083-649-01
Alcaftadine
Ophthalmic Solution
0.25%
Antihistamine Eye Drops
0.10 fl oz (3 mL) Sterile

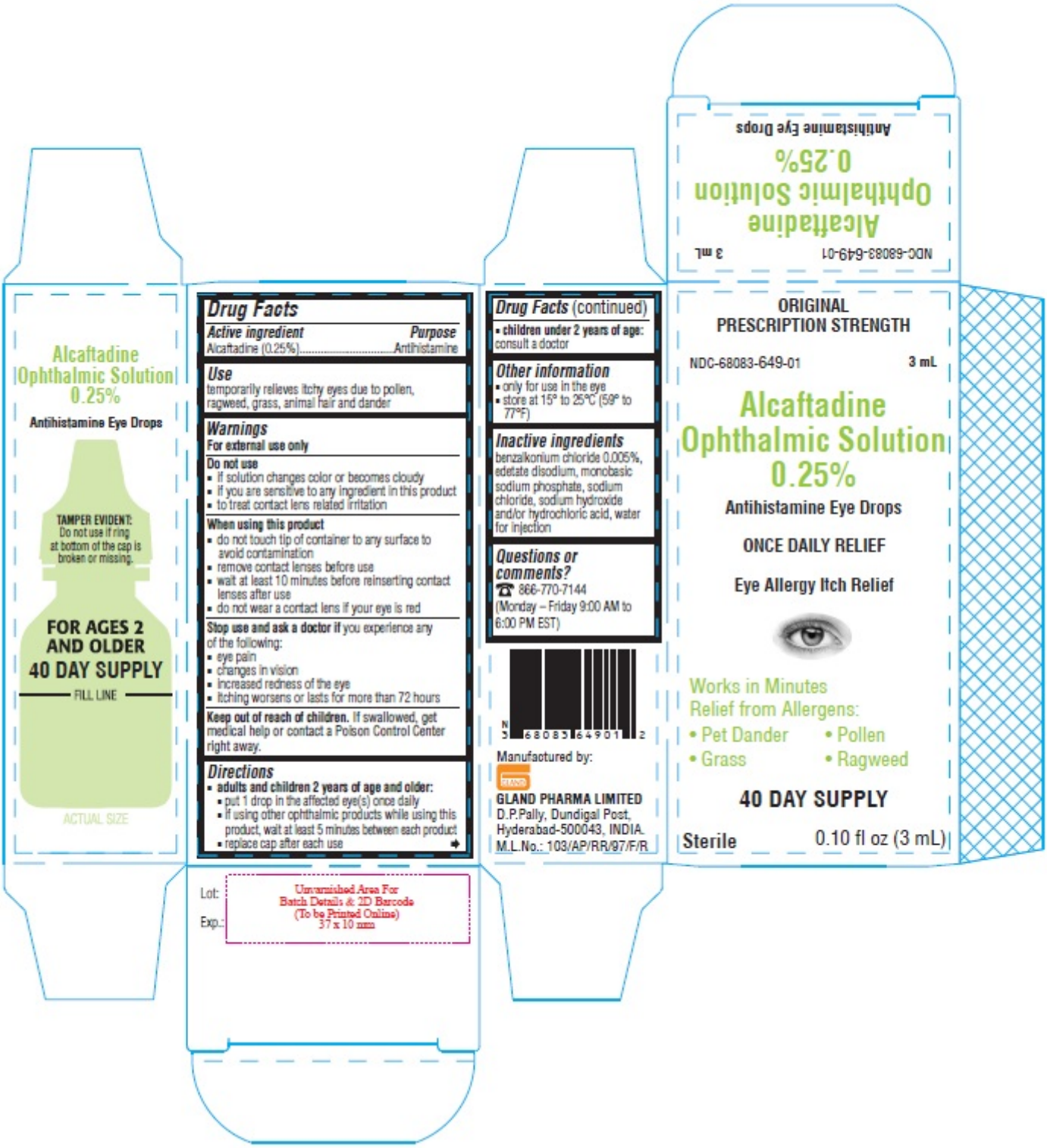
Container Carton - 0.25% (3 mL)

ORIGINAL PRESCRIPTION STRENGTH
NDC-68083-649-01 **3 mL**
Alcaftadine
Ophthalmic Solution
0.25%
Antihistamine Eye Drops
ONCE DAILY RELIEF
Eye Allergy Itch Relief

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

40 DAY SUPPLY

Sterile 0.10 fl oz (3 mL)



Container Carton - 0.25% (3 mL) - Twin Pack

ORIGINAL PRESCRIPTION STRENGTH

TWIN PACK
NDC-68083-649-02 **3 mL**
Alcaftadine

Ophthalmic Solution
0.25%
Antihistamine Eye Drops
ONCE DAILY RELIEF
Eye Allergy Itch Relief

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

80 DAY SUPPLY

Sterile Two 3 mL bottles (0.10 fl oz each)

ALCAFTADINE

alcaftadine solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68083-649

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)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68083-649-01	1 in 1 CARTON	03/01/2024	
1		3 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
2	NDC:68083-649-02	2 in 1 CARTON	03/01/2024	
2		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	ANDA209706	03/01/2024	

Labeler - Gland Pharma Limited (918601238)

Establishment

Name	Address	ID/FEI	Business Operations
GLAND PHARMA LIMITED		918601238	ANALYSIS(68083-649) , LABEL(68083-649) , MANUFACTURE(68083-649) , PACK(68083-649)

Revised: 3/2024 Gland Pharma Limited