ALCAFTADINE - alcaftadine solution/ drops
Aurohealth LLC

Drug Facts

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 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 between 15° to 25°C (59° to 77°F)

Inactive ingredients

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

Questions?

✆1-855-274-4122
(Monday – Friday 8:30 AM to 5:00 PM EST).

Distributed by:
AUROHEALTH LLC
2572 Brunswick Pike
Lawrenceville, NJ 08648

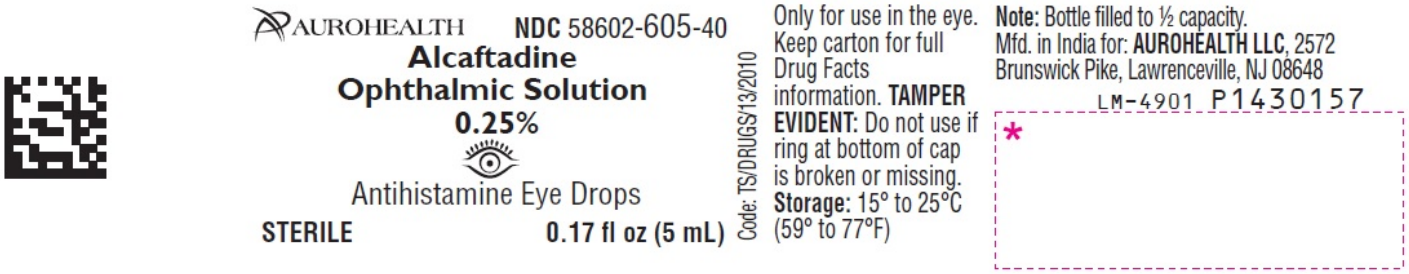
Made in India

Revised: May 2023

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL-0.25 % (5 mL Container Label)

AUROHEALTH **NDC** 58602-605-40
Alcaftadine
Ophthalmic Solution
0.25%

Antihistamine Eye Drops
STERILE **0.17 fl oz (5 mL)**



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL-0.25% (5 mL Container-Carton)

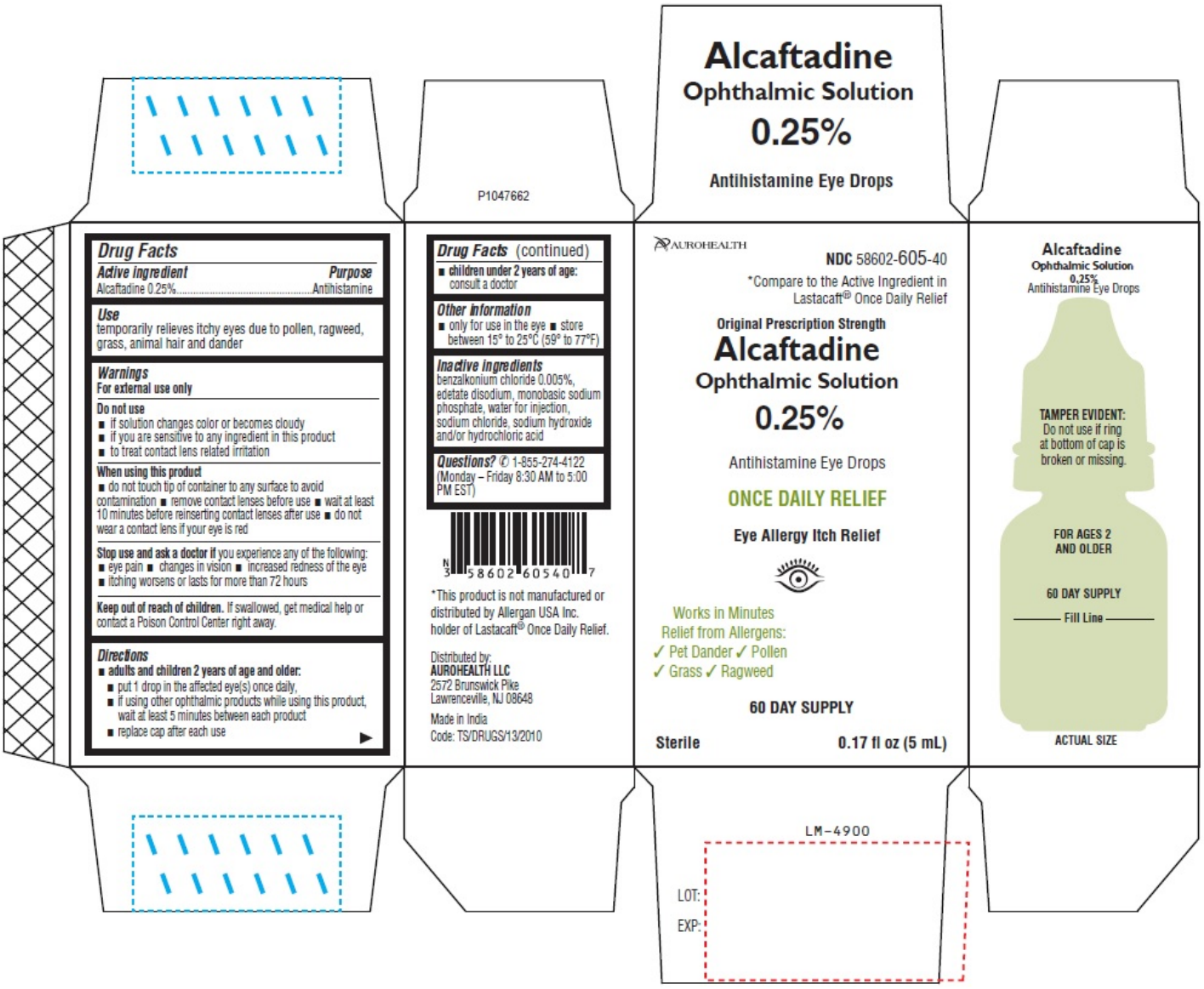
AUROHEALTH **NDC** 58602-605-40
*Compare to the Active Ingredient in
Lastacaft® Once Daily Relief

Original Prescription Strength
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

60 DAY SUPPLY
Sterile **0.17 fl oz (5 mL)**



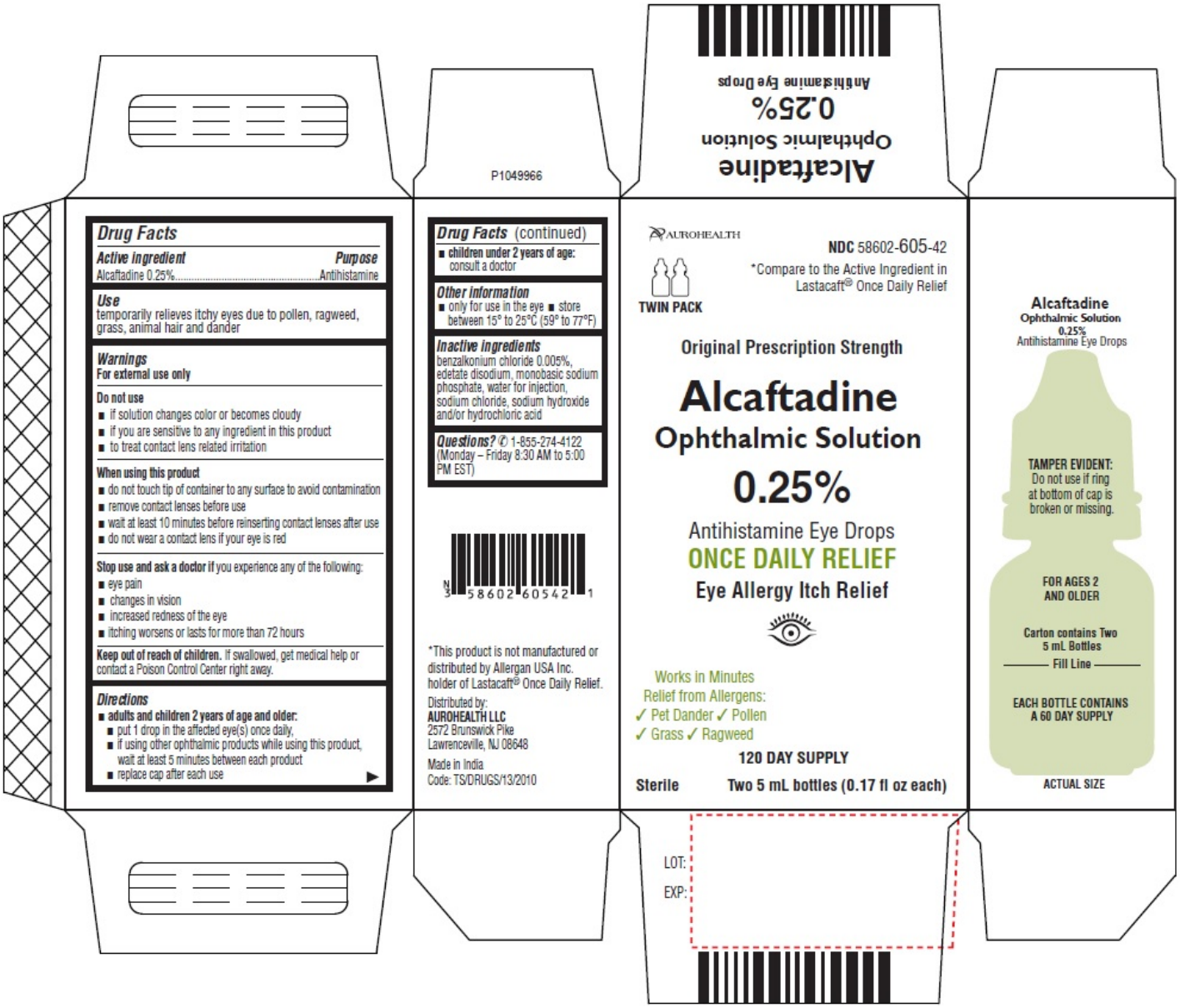
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL-0.25% (5 mL Container-Carton) Twin Pack

AUROHEALTH **NDC** 58602-605-42
*Compare to the Active Ingredient in
Lastacaft® Once Daily Relief
TWIN PACK
Original Prescription Strength
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
120 DAY SUPPLY
Sterile **Two 5 mL bottles (0.17 fl oz each)**



ALCAFTADINE

alcaftadine solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-605
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:58602-605-40	1 in 1 CARTON	06/23/2023	
1		5 mL in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:58602-605-42	2 in 1 CARTON	06/23/2023	
2		5 mL in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210659	06/23/2023	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Eugia Pharma Specialities Limited		650498244	ANALYSIS(58602-605) , MANUFACTURE(58602-605) , PACK(58602-605)

Revised: 6/2023 Aurohealth LLC