

GIANT EAGLE GOLDEN AMBER- benzalkonium chloride liquid

Apoll Health and Beauty Care

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Uses

Helps eliminate bacteria on hands.

Warnings

For external use only.

When using this product

avoid contact with eyes. In case of contact, rinse thoroughly with water.

Stop use and ask a doctor if
irritation or redness develops and lasts.

Keep out of reach of children.

In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

- Apply onto wet hands.
- Lather and rinse thoroughly.

Other information

Store at room temperature.

Inactive ingredients

Water (Aqua), Cetrimonium Chloride, Glycerin, Lauramidopropylamine Oxide, Sodium Chloride, Cocamide MEA, PEG-120 Methyl Glucose Dioleate, Fragrance (Parfum), Citric Acid, Tetrasodium EDTA, Sodium Sulfate, Methylchloroisothiazolinone, Methylisothiazolinone, Red 40 (CI 16035), Yellow 5 (CI 19140), Red 33 (CI 17200).

Label Copy



GIANT EAGLE GOLDEN AMBER

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM-UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)
GLYCERIN (UNII: PDC6A3C0OX)
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
COCO MONOETHANOLAMIDE (UNII: C80684146D)
PEG-120 METHYL GLUCOSE DIOLATE (UNII: YM0K64F20V)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
EDETATE SODIUM (UNII: MP1J8420LU)
SODIUM SULFATE (UNII: 0YPR65R21J)
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
FD&C RED NO. 40 (UNII: WZB9127XOA)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63148-101-07	222 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/27/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/27/2016	

Labeler - Apoll Health and Beauty Care (201901209)

Registrant - Apollo Health and Beauty Care (201901209)

Establishment			
Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care		201901209	manufacture(63148-101)

Revised: 10/2016

Apoll Health and Beauty Care