CAREONE AMBER ANTIBACTERIAL HAND- benzalkonium chloride soap
American Sales Company

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), Lauramidopropylamine Oxide, Glycerin, Cetrimonium Chloride, 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 19040), Red 33 (CI 17200).

Questions or comments?

1-877-846-9949

Label copy

CAREONE AMBER ANTIBACTERIAL HAND

benzalkonium chloride soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-320
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)	

LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
PEG-120 METHYL GLUCOSE DIOLEATE (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:41520-320-56	1656 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/14/2018	
2	NDC:41520-320-07	222 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/14/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	02/14/2018	

Labeler - American Sales Company (809183973)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(41520-320)

Revised: 2/2018 American Sales Company