

**CAREONE ANTIMICROBIAL FOAMING HAND SP FALLING RAIN - benzethonium
chloride liquid
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

BENZETHONIUM CHLORIDE 0.1 PERCENT

PURPOSE

ANTIBACTERIAL

USES

FOR HAND WASHING TO DECREASE BACTERIA ON THE SKIN.

WARNINGS

FOR EXTERNAL USE ONLY.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT POISON CONTROL CENTER IMMEDIATELY.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE EYES THOROUGHLY WITH WATER.

STOP USING THIS PRODUCT AND ASK A DOCTOR

IF IRRITATION OR RASH DEVELOPS AND LASTS.

DIRECTIONS

PUMP ONTO DRY HANDS, WORK INTO A LATHER AND RINSE THOROUGHLY.

OTHER INFORMATION

STORE AT ROOM TEMPERATURE.

INACTIVE INGREDIENTS

WATER, COCAMIDOPROPYL BETAINE, GLYCERIN, DECYL GLUCOSIDE, POLYQUATERNIUM-7, POLYSORBATE 20, FRAGRANCE, CAMELLIA SINENSIS LEAF EXTRACT, ZINGIBER OFFICINALE (GINGER) ROOT EXTRACT, HIBISCUS SABDARIFFA FLOWER EXTRACT, CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT, CITRIC ACID, ORIGANUM VULGARE LEAF EXTRACT, THYMUS VULGARE (THYME) FLOWER/

LEAF EXTRACT, CINNAMOMUM ZEYLANICUM BARK EXTRACT, ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT, LAVANDULA ANGUSTIFOLIA (LAVENDER) FLOWER EXTRACT, HYDRASTIS CANADENSIS (GOLDEN SEAL) ROOT EXTRACT, TETRASODIUM EDTA, GREEN 5 (CI 61570), RED 33 (CI 17200), YELLOW 5 (CI 19140).



CAREONE ANTIMICROBIAL FOAMING HAND SP FALLING RAIN

benzethonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-241
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.1 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CO CAMIDO PROPYL BETAINE (UNII: 5OCF3011KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	

POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
GINGER (UNII: C5529G5JPQ)
HIBISCUS SABDARIFFA FLOWER (UNII: 45TGG6IU6M)
CHAMOMILE (UNII: FGL3685T2X)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
OREGANO (UNII: 0E5AT8T16U)
THYME (UNII: CW6570BU4N)
CINNAMON BARK OIL (UNII: XE54U569EC)
ROSEMARY (UNII: IJ67X351P9)
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AHIRAF4M)
GOLDENSEAL (UNII: ZW3Z11D0JV)
EDETATE SODIUM (UNII: MP1J8420LU)
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-241-08	221 mL in 1 BOTTLE, PUMP		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/25/2011	

Labeler - AMERICAN SALES COMPANY (809183973)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment			
Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture