HAND WASH- benzalkonium chloride soap
American Sales

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.

Care One_403.002/403AC

Active ingredients

Benzalkonium chloride 0.13%

purpose

Antibacterial

Use

for handwashing to decrease bacteria on the skin

warnings

For external use only: hands only

When using this product

- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

- irritation or redness develops
- condition persists 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

- wet hands
- apply palmful to hands
- scrub thoroughly
- rinse thoroughly

Inactive ingredients

water, lauramine oxide, cocamidopropyl betaine, lauramidopropylamine oxide, sodium chloride, myristamidopropylamine oxide, glycerin, fragrance, distearetth-75 IPDI, PEG-150 distearate, citric acid, tetrasodium EDTA, benzophenone-4, sodium benzoate, red 4, yellow 5

adverse reaction

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LANDOVER, MS 20785

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CARE ONE

ANTIBACTERIAL

Hand

Soap

with moisturizers

7.5 FL OZ (221 mL)

HAND WASH

benzalkonium chloride soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-952
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)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MYRISTAMIDOPROPYLAMINE OXIDE (UNII: 3HSF539C9T)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISTEARETH-75 ISOPHORONE DIISOCYANATE (UNII: 5365FJ30SC)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SULISOBENZONE (UNII: 1W6L629B4K)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-952-64	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/02/2014	
2	NDC:41520-952-96	221 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/02/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/02/2014	

Labeler - American Sales (809183973)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-jon		088520668	manufacture(41520-952)

Revised: 5/2020 American Sales