

ANTIBACTERIAL 2X ULTRA CLEANSING- benzalkonium chloride liquid

Sante Manufacturing Inc

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.

Spa Soap 2X Ultra cleansing

Benzalkonium Chloride - 0.13%

Purpose: Antiseptic skin cleanser

Uses for handwashing or decrease bacteria to the skin

Direction

- Adults and children over two years: For occasional and personal domestic use
- Supervise children when they use this product
- Lather in hands with water for at least 30 seconds. Rinse well

For external use only

Stop use and ask a doctor if irritation or redness develops

When using this product

- do not get it into eyes. If contact occurs, rinse eye thoroughly with water

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Citric Acid, Glycerin, Fragrance, Tetrasodium EDTA, Methylchloroisoithiazolinone, Methylisoithiazolinone, Yellow# 5 (CI 19140), Red# 4 (CI 14700)



ANTIBACTERIAL 2X ULTRA CLEANSING

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71020-020
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCERIN (UNII: PDC6A3C0OX)	
DITETRACYCLINE TETRASODIUM EDETATE (UNII: WX0A0IT7K5)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71020-020-19	1900 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/21/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/21/2021	

Labeler - Sante Manufacturing Inc (242048747)

Registrant - Sante Manufacturing Inc (242048747)

Establishment

Name	Address	ID/FEI	Business Operations
Brands International Corporation		243748238	manufacture(71020-020) , label(71020-020)

Revised: 8/2021

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