

ANTIBACTERIAL- benzalkonium chloride 0.13% liquid

TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED Sirketi

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.

Berkley Jensen Antibacterial Liquid Hand Soap - White Tea& berry

Active ingredients

Benzalkonium chloride 0.13%.....Anitbacterial Hand soap

Purpose

Antibacterial Hand Soap

Use

helps eliminate bacteria on hands.

Warnings

For external use only: hands only

When using this product

- avoid contact with eyes.
- In case of contact,
- flush 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 and apply soap.
- Lather front and back, between your fingers and under your nails.
- Scrub for at least 20 seconds
- rinse and dry

Water, Cetrimonium Chloride , Cocamidopropyl Betaine, Sodium Chloride, Glycerin, Fragrance, Polyquaternium-10 , PEG-8 , Citric Acid, Tetrasodium EDTA, Cocamidopropyl PG-Dimonium Chloride, Methylchloroisothiazolinone, Methlisothiazolinone, Blue 1,Red 33

Principal display panel



ANTIBACTERIAL

benzalkonium chloride 0.13% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76772-035
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 g in 1 mL

Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)				
POLYQUATERNIUM-10 (1000 MPA.S AT 2%) (UNII: GMR4PEN8PK)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)				
GLYCERIN (UNII: PDC6A3C0OX)				
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE (UNII: 205Z54J075)				
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)				
CITRIC ACID ACETATE (UNII: DSO12WL7AU)				
STRAWBERRY (UNII: 4J2TY8Y81V)				
EDETIC ACID (UNII: 9G34HU7RV0)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76772-035-33	332 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/16/2021	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	07/16/2021	

Labeler - TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

Registrant - TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

Establishment				
Name		Address	ID/FEI	Business Operations
TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI			533120570	manufacture(76772-035)

Revised: 7/2021

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