

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.

Luxury Antibacterial Liquid Hand Soap - Aloe Vera

Active ingredients

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

Purpose

Antibacterial

Use

for handwashing to decrease bacteria on the skin

Warnings

For external use only

When using this product

- avoid contact with eyes. If contact occurs, rinse eyes 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 c

water, sodium laureth sulfate , cocamidopropyl betaine, sodium chloride, glycerin,
fragrance, polyquatemium-10 , PEG-8 , cidric acid, tetrasodium EDTA, cocamidopropyl pg-dimonium
chrolide,
methylchloroisoithiazolinone , methlisoithiazolinone, blue 1, red 33

Adverse Reactions

TSM BRANDS LLC

540 Equinox Ln Manlapan, NJ 07726

Made in TURKEY.

principal display panel



ANTIBACTERIAL

benzalkonium chloride 0.13% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76772-003
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: 059QF0K00R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
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)	
EDETIC ACID (UNII: 9G34HU7RV0)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76772-003-80	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

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

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