

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.

Top Care Antibacterial Liquid Hand Soap - With Moisturizer

Active ingredients

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

Purpose

Antibacterial Hand Soap

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 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

- Squeeze onto wet hands or body sponge
- Work into lather
- Wash skin,rinse and dry thoroughly

water, sodium laureth sulfata , cocamidopropyl betaine, sodium chloride, glycerin,
fragrance, polyquatemium-10 , PEG-8 , citric acid, tetrasodium EDTA, cocamidopropyl
pg-dimonium chrolide,

methylchloroisothiazolinone, methlisothiazolinone, Yellow (CI 19140),Red 33

Principal display panel



ANTIBACTERIAL

benzalkonium chloride 0.13% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76772-033
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)	
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)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76772-033-50	500 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(76772-033)

Revised: 7/2021

TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI