

ANTIBACTERIAL HAND - benzalkonium chloride gel
ORGANICA (UK) LTD

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.

Drug Facts

Active ingredient

Benzalkonium Chloride 0.1%

Purpose

Antimicrobial

Uses

Hand sanitizer to help reduce bacteria on the skin that could cause disease

Recommended for repeated use.

Warnings

For external use only.

When using this product avoid contact with eyes.

In case of eye contact, flush eyes with water.

Stop use and ask a doctor if irritation or redness develops, or if 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

Pump a small amount of gel into the palm of hand

Rub thoroughly over all surfaces of both hands

Rub hands together until dry.

Inactive ingredients

Water, cetrimonium chloride, glycereth-2 cocoate, behentrimonium chloride, acrylates/diethylaminoethyl methacrylate copolymer, lactic acid, tetrasodium EDTA.

ANTIBACTERIAL HAND GEL

CLEANS IN SECONDS

KILLS 99.9% of BACTERIA

FREE from ALCOHOL

CHLORINE, FRAGRANCE and DYES

5.07fl Oz

(150ml)

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76268-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	
BEHENTRIMONIUM CHLORIDE (UNII: X7GNG3S47T)	
LACTIC ACID (UNII: 33X04XA5AT)	
EDETATE SODIUM (UNII: MP1J8420LU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76268-001-01	50 mL in 1 BOTTLE, PLASTIC		
2	NDC:76268-001-02	150 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/27/2011	

Labeler - ORGANICA (UK) LTD (235330151)

Establishment

Name	Address	ID/FEI	Business Operations
ORGANICA (UK) LTD		235330151	manufacture