ADVANCED HAND SANITIZER- benzalkonium chloride liquid Vitane Pharmaceuticals, 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.

Vitane Pharmaceuticals Advanced Hand Sanitizer (Alcohol-Free)

Drug Facts

Active ingredient

Benzalkonium Chloride 0.13%

Purpose

Antimicrobial

Uses

For hand sanitizing to decrease bacteria on the skin. 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.

Discontinue use

if irritation or redness develops. If condition persists for more than 72 hours consult a doctor.

Keep out of reach of children.

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

Directions

• Apply on hands as needed. Rub briskly together until dry.

Inactive ingredients

Ionized water, Carbamide

Storage

Store at room temperature 68 to 77F (20 to 25C) in original container.

Company Information

Distributed by:

Vitane Pharmaceuticals, Inc.

125 Wells Avenue, Congers, New York 10920 www.vitanepharma.com MADE IN THE U.S.A.

Product Packaging - 100ml

VITANE

Quality to Life

MADE IN USA

ADVANCED

Hand Sanitizer

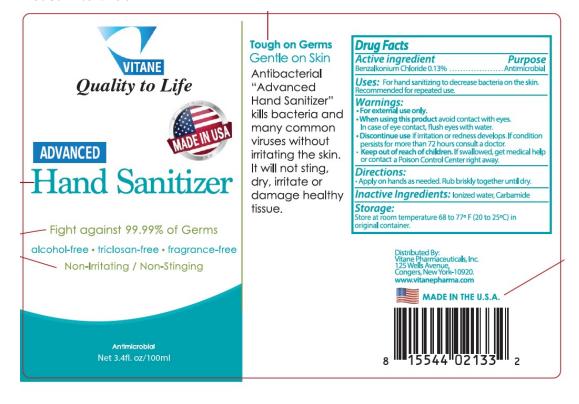
Fight against 99.99% of Germs

alcohol-free triclosan-free fragrance-free

Non-Irritating / Non-Stinging

Antimicrobial

Net 3.4fl.oz/100ml



ADVANCED HAND SANITIZER

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60577-474
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
UREA (UNII: 8 W8 T178 47 W)	

ı	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:60577-474- 01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	
		NDC:60577-474- 02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/18/2020		

Labeler - Vitane Pharmaceuticals, Inc. (029029638)

Revised: 5/2020 Vitane Pharmaceuticals, Inc.