BODY PRESCRIPTIONS FRESH COTTON INFUSED WITH VITAMIN E ANTIBACTERIAL FOAMING HAND- benzalkonium chloride soap ENCHANTE ACCESSORIES 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.

50563-263/JAS21F03

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

■ For hand washing to decrease bacteria on the skin

WARNINGS

For external use only

When suing this product, keep out of eyes. In case of contact with eyes, flush thoroughly with water. Stop use and ask a doctor if skin irritation develops.

keep out of reach of children

Keep out of reach of children. In case of accidenta ingestion, seek professional assistance or contact a Poison Control Center immdiately.

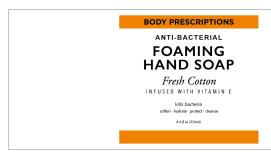
Directions

Apply a small amount to hands, lather for seconds, then rinse with warm water.

Inactive ingredients

Water, Cocamidopropyl Betaine, DMDM Hydantoin, Fragrance, Disodium EDTA, Citric Acid, Tocopheryl Acetate

224*50mm





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benzalkonium chloride soap

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-263	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL		

Inactive Ingredients		
Ingredient Name	Strength	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)		
DMDM HYDANTO IN (UNII: BYR0 546 TOW)		
DISO DIUM HEDTA (UNII: KME849 MC7A)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
WATER (UNII: 059QF0KO0R)		

Packaging					
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:50563-263-01	254 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/23/2020		

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment				
Name	Address	ID/FEI	Business Operations	
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-263)	

Revised: 9/2020 ENCHANTE ACCESSORIES INC.