

BODY PRESCRIPTIONS ROSEWATER ANTIBACTERIAL HAND WIPES- benzalkonium chloride solution

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.

G0ABCW10

Active Ingredient

Benzalkonium Chloride 0.1%

Purpose

Antibacterial

Use

- To decrease bacteria on hands

WARNINGS

For external use only

Stop Use

Do not use if you are allergic to any ingredients listed

Discontinue use if irritation or redness occur. Consult a doctor if condition lasts for more than 72 hours

Do not get into eyes. Rinse thoroughly with water if contact occurs

keep out of reach of children

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Directions

For adults and children two years and over

Peel over reusable label and remove a wipe from the packet.

Wet hands thoroughly and air dry.

Place used wipes in to waste basket. Do not flush.

Inactive ingredients

Water, Glycerin, Ethylhexylglycerin, Rose Extract, Phenoxyethanol, Propylene Glycol, Fragrance



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benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-228
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	4.5 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-228-01	2 in 1 PACKAGE	06/13/2020	

1	30 in 1 PACKET; Type 0: Not a Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/13/2020	

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment			
Name	Address	ID/FEI	Business Operations
Zhejiang Ruolin Hygienic Products Co., Ltd.		415426870	manufacture(50563-228)

Revised: 6/2020

ENCHANTE ACCESSORIES INC.