ANTIBACTERIAL HAND WIPES- antibacterial hand wipes cloth Shenzhen Shierjie Biological Engineering Co., 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.

43116-010 ANTIBACTERIAL HAND WIPES

Active Ingredient(s)

Benzalkonium chloride 0.1%

Purpose

Antibacterial

Use

Use decrease bacteria on skin

Warnings

Warnings for external use only.

Do not use

Do not use over large areas of the body if you are allergic to any of the ingredients.

When using this product do not get into eyes. If contact occurs, rinse thoroughly with water

Keep out of reach of children

If swallowed, seek medical attention or contact a poison control center right away.

Directions

For adults and children of 3 years and over, use on hands to clean and refresh, allow skin to air dry For children under 3 years of age, consult with a doctor before use

Other information

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Inactive ingredients

Water, Phenoxyethanol, Aloe Barbadensis Leaf Extract, Glycerin, Fragrance

Package Label - Principal Display Panel



ANTIBACTERIAL HAND WIPES

antibacterial hand wipes cloth

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43116-010	
Route of Administration	TOPICAL			

2020.7.23

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100		

Inactive Ingredients		
Ingredient Name	Strength	
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)		
GLYCERIN (UNII: PDC6 A3C0 OX)		

PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0 X)	

l	Packaging				
# Item Code Packa		Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:43116-010-01	20 in 1 BAG; Type 0: Not a Combination Product	03/30/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

$\pmb{Labeler - \text{Shenzhen Shierjie Biological Engineering Co., LTD (547610261)}}$

Establishment				
Name	Address	ID/FEI	Business Operations	
Shenzhen Shierjie Biological Engineering Co., LTD		547610261	manufacture(43116-010)	

Revised: 11/2020 Shenzhen Shierjie Biological Engineering Co., LTD