WIPE OUT ANTIBACTERIAL WIPES FRESH SCENT- benzalkonium chloride solution TZUMI INNOVATIONS LLC

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.

Zhangzhou Zhongnan Nursing Products Co., Ltd.,

Style 9516, 9599, Fresh Scent NA

Active Ingredient(s)

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

To decrease bacteria on the skin that could cause disease

Warnings

For external use only

When using this product keep out of eyes. In case of contact with eyes, flush thoroughly with water.

Avoid contact with broken skin

Stop use and ask a doctor if irritation and redness develop, 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

Wet hands thoroughly with product and allow to dry without wiping

For children under 6, use only under adult supervision

Not recommended for infants

Other information

- Keep containers tightly closed in a dry, cool and well ventilated place
- Recommended storage temperature: 32F to 104F (0C to 40C)

Inactive ingredients

Aloe Barbadensis Leaf Juice, Water, Fragrance, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Tocopheryl Acetate



WIPE OUT ANTIBACTERIAL WIPES FRESH SCENT

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77878-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Str	ength Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	6.8 mg		
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

PHENOXYETHANOL (UNII: HIE492ZZ3T)

.ALPHA.-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)

Packaging

L				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:77878-004-01	20 in 1 BAG; Type 0: Not a Combination Product	06/25/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/25/2020		

Labeler - TZUMI INNOVATIONS LLC (117426322)

Establishment

Name	Address	ID/FEI	Business Operations
Zhangzhou Zhongnan Nursing Products Co., Ltd.		416376835	manufacture(77878-004)

Revised: 6/2020

TZUMI INNOVATIONS LLC