

ANTIBACTERIAL WIPES- benzalkonium chloride swab
Kangna (Zhejiang) Medical Supplies 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.

75109-001 Antibacterial Wipes

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antiseptic

USE

- For hand sanitizing to decrease bacteria on the skin.
- Apply topically to the skin to help prevent cross contamination.
- Recommended for repeated use.
- Dries in seconds.

Warning

- For external use only.
- May irritate eyes.
- Keep out of reach of children unless under adult supervision.

Directions

- Tear V notch located on top of plastic bag.
Pull first wipe from the center of roll up through opening of bag.
- Thread first wipe through the dispensing nozzle in lid of floor stand OR.
Thread first wipe through the dispensing nozzle in top of wall mounted dispenser.
Close dispenser door. Wipe dispensing tension may be adjusted on top of dispenser. Dispenser must be mounted with wipes dispensing up.

Inactive ingredients

| Water, Polysorbate 20, EDTA 2Na, Phenoxyethanol, Sodium Hydroxide.



ANTIBACTERIAL WIPES

benzalkonium chloride swab

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75109-001

Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	WATER (UNII: 059QF0K00R)			
	DISODIUM EDTA-COPPER (UNII: 6V475AX06U)			
	POLYSORBATE 20 (UNII: 7T1F30V5YH)			
	PHENOXYETHANOL (UNII: HIE492ZZ3T)			
	SODIUM HYDROXIDE (UNII: 55X04QC32I)			
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	GRAPE, APPLE, BLUEBERRY, CITRUS, ORANGE, PEACH, STRAWBERRY, LEMON, MINT, VANILLA	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75109-001-01	50 in 1 BAG	03/21/2020	
1		270 g in 1 POUCH; 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	03/21/2020		

Labeler - Kangna (Zhejiang) Medical Supplies Co., Ltd. (554530173)

Establishment

Name	Address	ID/FEI	Business Operations
Kangna (Zhejiang) Medical Supplies Co., Ltd.		554530173	manufacture(75109-001)

Revised: 4/2020

Kangna (Zhejiang) Medical Supplies Co., Ltd.