

ANTIBACTERIAL WET WIPES- benzalkonium chloride swab
MC Group Development 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.

Antibacterial Wet Wipes

Active Ingredient

Benzalkonium Chloride

Purpose

Antibacterial

Use

For hand washing to decrease bacteria on the skin. May be used on face, arms and legs.

WARNINGS

For External use only.

Keep out of eyes, In case of contact, rinse with water. If irritation or rash develops, discontinue use. Consult doctor if irritation persists for more than 72 hours, If swallowed, seek medical attention or contact a Poison Control Center.

keep out of reach of children

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Directions

Open resealable label. Pull one sheet from pack. Clean hands or affected area and discard. Re-seal label after each use to keep wipes fresh.

Inactive ingredients

Iodopropynyl Butylcarbamate, DMDM Hydantoin, Lauryl Glucoside, Glycerin, D-Panthenol, Tocopheryl Acetate, Chamomilla Recutita Extract, PEG-12 Dimethicone, Disodium EDTA, Aloe Barbadensis Leaf Extract, Allantoin, Water

ANTIBACTERIAL WET WIPES

benzalkonium chloride swab

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50672-838

Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Benzalkonium Chloride (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	Benzalkonium Chloride	0.1 g in 100 g
Inactive Ingredients			
	Ingredient Name	Strength	
	WATER (UNII: 059QF0KO0R)		
	Iodopropynyl Butylcarbamate (UNII: 603P14DHEB)		
	DMDM Hydantoin (UNII: BYR0546TOW)		
	Lauryl Glucoside (UNII: 76LN7P7UCU)		
	GLYCERIN (UNII: PDC6A3C0OX)		
	DEXPANTHENOL (UNII: 1O6C93RI7Z)		
	TOCOPHERYL NICOTINATE, D-.ALPHA. (UNII: W11J5UCY5C)		
	MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ)		
	PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)		
	DISODIUM EDTA-COPPER (UNII: 6V475AX06U)		
	ALOE VERA LEAF (UNII: ZY81Z83H0X)		
	Allantoin (UNII: 344S277G0Z)		
Packaging			
#	Item Code	Package Description	Marketing Start Date
1	NDC:50672-838-01	3.3 g in 1 POUCH	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/12/2012	

Labeler - MC Group Development Ltd. (527868588)

Establishment

Name	Address	ID/FEI	Business Operations
MC Group Development Ltd.		527868588	manufacture(50672-838)

Revised: 11/2012

MC Group Development Ltd.