

ANTIBACTERIAL WET WIPES- benzalkonium chloride swab
Hebei Yihoucheng Commodity 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.

ASSURED ANTIBACTERIAL WET WIPES

Active ingredient

Benzalkonium chloride 0.1%

Purpose

Antibacterial

Use

decreases bacteria on skin

Warnings

For external use only.

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.

Stop use and ask a doctor if irritation or rash develops and continues for more than 72 hours.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

For adults and children of 2 years and over use on hands and face to clean and refresh, allow skin to air dry.

For children under 2 years ask a doctor before use.

water, propylene glycol,
cocamidopropyl betaine, poly(hexamethyleneguanidine)
hydrochloride, glycine, tetrasodium EDTA,
aloe barbadensis leaf extract, tocopheryl acetate, citric acid,
fragrance, methylchloroisothiazolinone, methylisothiazolinone,
PEG-40 hydrogenated castor oil.



ANTIBACTERIAL WET WIPES

benzalkonium chloride swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59575-500
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
GLYCINE (UNII: TE7660XO1C)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
EDETATE SODIUM (UNII: MP1J8420LU)	
METHYLCHLOROISO THIAZOLINONE (UNII: DEL7T5QRPN)	

POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
Water (UNII: 059QF0KO0R)	
POLYAMINOPROPYL BIGUANIDE (UNII: 322U039GMF)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59575-500-01	40 in 1 PACKAGE		
1		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	07/30/2013	

Labeler - Hebei Yihoucheng Commodity Co.,Ltd. (529305333)

Establishment

Name	Address	ID/FEI	Business Operations
Hebei Yihoucheng Commodity Co.,Ltd.		529305333	manufacture(59575-500)

Revised: 7/2013

Hebei Yihoucheng Commodity Co.,Ltd.