ANTISEPTIC- benzalkonium chloride swab MCL Enterprises

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.

Antis eptic Wipe

Drug Facts

Active Ingredient

Benzalkonium Chloride, 0.13% W/W

Purpose

First Aid Antiseptic

Use:

To prevent infection in minor cuts, scrapes and burns

Warnings:

• For external use only

Do not use:

- for deep puncture wounds, animal bites, or serious burns.
- in eyes or over large areas of the body

Stop use and ask a doctor if:

- irritation, redness, or symptoms develop
- the condition persists or gets worse

Keep out of reach of children.

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

Directions:

Tear pouch and clean the affected area

Inactive Ingredient:

Purified Water

Package Labeling:



Contains: Benzalkonium Chloride







ONE WIPE
FOR PROFESSIONAL AND HOSPITAL USE

LOT: EXP:

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MANUFACTURED FOR MCL ENTERPRISES CORONA, CA 92883 MADE IN CHINA

------TEAR HERE -----

ANTISEPTIC

benzalkonium chloride swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71622-001
1 I U u u c t 1 y p c	HOME IN O I C DICC	item code (bource)	1100.71022 001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 g

Inactive Ingredients

I	Ingredient Name	Strength
ı		

WATER (UNII: 059QF0KO0R)

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:71622- 001-00	1 in 1 POUCH	07/25/2017	
1	1.4 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/25/2017	

Labeler - MCL Enterprises (784754173)

Revised: 12/2017 MCL Enterprises