

BENZALKONIUM CHLORIDE ANTISEPTIC- benzalkonium chloride swab
Tongzhou Ruihong Medical Products Factory

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.

Active Ingredients

Benzalkonium Chloride 0.13%

Purpose

Antiseptic

Use

Prevent infection in minor scrapes

Warnings

For external use only

Flammable,keep away for fire or flame

Do not use:

- * In large quantities
- * over large areas of the body
- * in eyes
- * over raw or blistered areas

Stop use and ask a doctor if conditions worsen or persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children.if swallowed get medical help or contact Poison control Center right away.

Directions

Adults and Children 2 year and older; Apply to cleaned affected area not more than 3 times daily.
Children under 2 years of age ; Consult a doctor

Inactive Ingredient

Purified Water

=====**STRICT**[®]=====

NDC 58488-001-01

Benzalkonium Chloride

Antiseptic Towelette

Drug Facts	
Active Ingredients	Purpose
Benzalkonium chloride 0.13%	Antiseptic
Use prevent infection in minor scrapes	
Non-sterile Solution Applicator is sterile if package is intact	
Warnings	
■ For external use only.	

Drug Facts (continued)
Do not use: ■ in large quantities ■ over large areas of the body ■ in eyes ■ over raw or blistered areas.
Stop use and ask a doctor if conditions worsen or persist for more than 7 day or clear up and occur again within a few days.
Keep out of reach of children. If swallowed get medical help or contact Poison Control Center right away.
Directions ■ Adults and Children 2 year and older: Apply to cleaned affected area not more than 3 times daily. ■ Children under 2 years of age: Consult a doctor.
Inactive Ingredient purified water

Tongzhou Ruihong Medical Products Factory
No.28, Anxi Villege, Tongzhou District, Nantong, Jiangsu, China

BENZALKONIUM CHLORIDE ANTISEPTIC

benzalkonium chloride swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58488-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.0013 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58488-001-01	1 in 1 POUCH; Type 0: Not a Combination Product	05/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/20/2013	

Labeler - Tongzhou Ruihong Medical Products Factory (421312726)

Establishment

Name	Address	ID/FEI	Business Operations
Tongzhou Ruihong Medical Products Factory		421312726	manufacture(58488-001)

