

CLEANSING TOWELETTE- 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

Cleansing of face, hands and body without soap and water. Air dries in seconds.

Non-sterile solution

Applicator is sterile if package is intact.

Warnings

For external use only

Flammable, keep away from 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 years and older; Apply to cleaned affected area not more than 3 times daily. Children under 2 years of age; Consult a doctor

Inactive Ingredient

5% v/v alcohol, Purified Water

The logo for STRICT, featuring the word "STRICT" in a bold, blue, sans-serif font with a registered trademark symbol (®) to its upper right. The logo is centered within a white rectangular area that has a thin purple border.

NDC 58488-005-01

Benzalkonium Chloride **Cleansing Towelette**

Drug Facts

Active Ingredients	Purpose
Benzalkonium chloride 0.13%	Antiseptic

Use Cleansing of face, hands and body without soap and water.
Air dries in seconds.

Non-sterile Solution
Applicator is sterile if package is intact

Warnings

■ For external use only. ■ Flammable, keep away from fire or flame.

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 5%(v/v) Alcohol, purified water

inactive ingredients 0.70(v/v) Alcohol, purified water.

LOT: EXP:

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

CLEANSING TOWELETTE

benzalkonium chloride swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58488-005
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 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58488-005-01	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	04/11/2014	

Labeler - Tongzhou Ruihong Medical Products Factory (421312726)

Establishment			
Name	Address	ID/FEI	Business Operations
Tongzhou Ruihong Medical Products Factory		421312726	manufacture(58488-005)

Revised: 5/2016

Tongzhou Ruihong Medical Products Factory