CERTUS ANTISEPTIC TOWELETTE - benzalkonium chloride swab Certus Medical, Inc.

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.

Certus Antiseptic Towelette 210032 Drug Facts and Label

Drug Facts Box OTC Active Ingredient Section

Benzalkonium Chloride 0.13% w/w

Drug Facts Box OTC Purpose Section

First Aid Antiseptic

Drug Facts Box OTC Indications & Usage Section

First aid antiseptic to help prevent the risk of infection in minor cuts, scrapes and burns

Drug Facts Box OTC Warnings Section

For external use only

Drug Facts Box OTC Do Not Use Section

in the eyes or apply over large areas of the body longer than 1 week unless directed by a doctor

Drug Facts Box OTC Ask Doctor Section

in case of deep or puncture wounds, animal bites, or serious burns

Drug Facts Box OTC Stop Use Section

and ask a doctor if the condition persists or gets worse

Drug Facts Box OTC Keep Out Of Reach Of Children Section

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

Drug Facts Box OTC Dosage & Administration Section

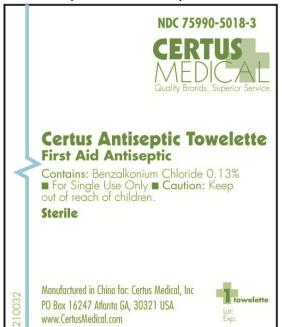
clean the affected area apply a small amount of this product on the area 1 to 3 times daily may be covered with a sterile bandage when dry

Drug Facts Box OTC Inactive Ingredient Section

purified water, sodium bicarbonate

Certus Antiseptic Towelette 210032 pouch

210032.jpg Certus Antiseptic Towelette pouch





ABW 3-23

CERTUS ANTISEPTIC TOWELETTE

benzalkonium chloride swab

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75990-5018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.0013 mL in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
SODIUM BICARBONATE (UNII: 8 MDF5 V39 QO)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NI	DC:75990-5018-3	1.4 mL in 1 POUCH		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	05/01/2011			

Labeler - Certus Medical, Inc. (966433653)

Revised: 4/2011 Certus Medical, Inc.