

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

NDC 75990-5018-3


CERTUS
MEDICAL
Quality Brands. Superior Service.

Certus Antiseptic Towelette
First Aid Antiseptic

Contains: Benzalkonium Chloride 0.13%
■ For Single Use Only ■ Caution: Keep out of reach of children.

Sterile

Manufactured in China for: Certus Medical, Inc
PO Box 16247 Atlanta GA, 30321 USA
www.CertusMedical.com

 towelette
Lot:
Exp:

210032

| | |
|--|----------------------|
| Drug Facts | |
| Active Ingredients | Purpose |
| Benzalkonium Chloride, 0.13% w/w..... | First Aid Antiseptic |
| Use First aid antiseptic to help prevent the risk of infection in minor cuts, scrapes and burns | |
| Warnings | |
| For external use only | |
| Do Not Use ■ in the eyes or apply over large areas of the body ■ longer than 1 week unless directed by a doctor | |
| Ask a doctor in case of deep or puncture wounds, animal bites, or serious burns | |
| Stop use and ask a doctor if 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 ■ 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 | |
| Inactive Ingredient purified water, sodium bicarbonate | |

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 |
|---|-----------------------|-------------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.0013 mL in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC: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.