

ANTISEPTIC TOWELETTE 01- benzalkonium chloride cloth
Cosmuses Cosmetics (Ningbo) Co., Ltd.

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.

antiseptic towelette

Drug Fact

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

First Aid Antiseptic

Uses

antiseptic cleansig of face, hands and body to decrease bacteria on skin without soap and water.

Warning

For external use only.

Do not use in the eyes. If this happens, rinse thoroughly with water.

Stop use and ask a doctor if irritation or redness develop and persists for more than 72 hours.

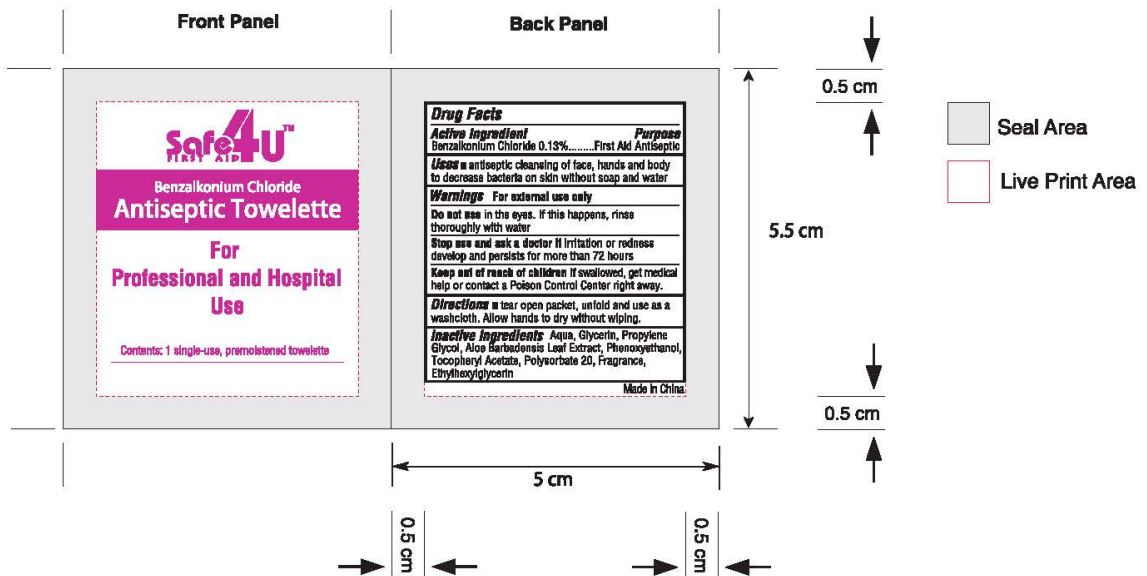
Keep out of reach of children if swallowed, get medical help or contact a poison control center right away.

Directions

Tear open packet, unfold and use as a washcloth. Allow hand to dry without wiping.

Inactive Ingredients

Aqua, Glycerin, Propylene Glycol, Aloe Barbadensis Leaf Extract, Phenoxyethanol, Tocopheryl Acetate, Polysorbate 20, Fragrance, Ethylhexylglycerin



benzalkonium chloride cloth

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:82953-004 |
| 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 g in 100 |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------------------------------|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| .ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) | |
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----|------------------|------------------------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:82953-004-01 | 10 in 1 BAG; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 10/13/2022 | |
| 2 | NDC:82953-004-02 | 15 in 1 BAG; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 10/13/2022 | |
| 3 | NDC:82953-004-03 | 20 in 1 BAG; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 10/13/2022 | |
| 4 | NDC:82953-004-04 | 30 in 1 BAG; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 10/13/2022 | |
| 5 | NDC:82953-004-05 | 50 in 1 BAG; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 10/13/2022 | |
| 6 | NDC:82953-004-06 | 100 in 1 BAG; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 10/13/2022 | |
| 7 | NDC:82953-004-07 | 1 in 1 BAG; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 10/13/2022 | |
| 8 | NDC:82953-004-08 | 10 in 1 JAR; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 10/13/2022 | |
| 9 | NDC:82953-004-09 | 20 in 1 JAR; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 10/13/2022 | |
| 10 | NDC:82953-004-10 | 30 in 1 JAR; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 10/13/2022 | |
| 11 | NDC:82953-004-11 | 50 in 1 JAR; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 10/13/2022 | |
| 12 | NDC:82953-004-12 | 60 in 1 JAR; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 10/13/2022 | |

| | | | | |
|-----------|------------------|---------------------------------------------------------------------------------|------------|--|
| 13 | NDC:82953-004-13 | 100 in 1 JAR; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 10/13/2022 | |
|-----------|------------------|---------------------------------------------------------------------------------|------------|--|

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph not final | part333A | 10/01/2022 | |

Labeler - Cosmuses Cosmetics (Ningbo) Co., Ltd. (725290934)

Registrant - Cosmuses Cosmetics (Ningbo) Co., Ltd. (725290934)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------------|---------|-----------|------------------------|
| Cosmuses Cosmetics (Ningbo) Co., Ltd. | | 725290934 | manufacture(82953-004) |

Revised: 10/2022

Cosmuses Cosmetics (Ningbo) Co., Ltd.