MOIST WIPES- benzalkonium chloride lotion Shanghai Yinjing Medical Supplies 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.

Active ingredient

Benzalkonium chloride 0.1%

Purpose

Antibacterial

Use decreases bacteria on skin

Warnings

For external use only

Do not use

- -over large areas of the body
- -if you are allergic to any of the ingredients

When using this product avoid contact with eyes and face.

If contact occurs, flush thoroughly with water.

Stop use and ask a doctor if irritation or rash develops and

continues 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

- -for adults and children of 2 years and over
- -children under 2 years ask a doctor before using
- -allow to dry without wiping

Other information store at room temperature

Inactive ingredient

Water, Glycerin, Phenoxyethanol, Polysorbate 20, Aloe Barabdensis

Leaf Extract, Polyaminopropyl Biguianide, Disodium EDTA,

Fragrance, 2-Bromo-2 Nitroporpane 1,3 Diol, Tocopheryl Acetate



MOIST WIPES

benzalkonium chloride lotion

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55310-002 |
|--------------|----------------|--------------------|---------------|
|--------------|----------------|--------------------|---------------|

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength BENZALKO NIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM UNII:7N6JUD5X6Y) BENZALKONIUM CHLORIDE .1 g in 100 g

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| WATER (UNII: 059QF0KO0R) | | |
| POLYSORBATE 20 (UNII: 7T1F30 V5YH) | | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | | |
| POLYAMINO PRO PYL BIGUANIDE (UNII: 322U0 39 GMF) | | |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) | | |
| BRONOPOL (UNII: 6PU1E16C9W) | | |
| DISO DIUM EDTA-CO PPER (UNII: 6 V475AX0 6 U) | | |
| GLYCERIN (UNII: PDC6 A3C0 O X) | | |

.ALPHA.-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)

| l | Packaging | | | | | |
|---|--------------------|---|-----------------------------|---------------------------|--|--|
| l | # Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| ı | 1 NDC:55310-002-02 | 20 in 1 BAG | 06/15/2016 | | | |
| l | 1 NDC:55310-002-01 | .1 g in 1 PACKET; Type 0: Not a Combination Product | | | | |

| Marketing Infor | Marketing Information | | | | | |
|-------------------------|--|----------------------|--------------------|--|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | |
| OTC monograph not final | part333A | 06/15/2016 | | | | |
| | | | | | | |

Labeler - Shanghai Yinjing Medical Supplies Co., Ltd. (530501535)

Revised: 6/2016 Shanghai Yinjing Medical Supplies Co., Ltd.