BACTAKLEEN KLEEN WIPES- benzalkonium chloride liquid Excelsia Technologies Sdn Bhd

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.

BACTAKLEEN KLEEN WIPES

Active Ingredients

Benzalkonium chloride (0.08%)

Purpose

Antiseptic

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Uses

Fro sanitizing to decrease bacteria

Warnings

For external use only

Do not use if you are allergic to any of the ingredients

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water. avoid contact with broken skin

Stop use and ask a doctor if irritation or rash occurs. These may be sign of a serious condition.

Open the package, remove and wipe hands as needed.

Inactive Ingredients

Water. Polyaminopropyl Biguanide, Phenoxyethanol, Polysorbate 20, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate.

BACTAKLEEN KLEEN WIPES



pH Controlled

 ❖ Paraben FREE
 ❖ Formaldehyde FREE

 ♠ Alcohol FREE
 ↔ Dermatologically Tested





Drug Facts

Active ingredient
Benzalkonium Chloride (0,0)

Purpose

Warnings
For external use only.

Do not use

if you are allergic to any of the ingredients.
in children less than 2 months of age.
on open skin wounds.

When using this product avoid contact with eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a

Keep out of reach of children, If swallowed, get medical help or contact a Poisor Control Center (1-800-222-1222) right away.

Directions
• Open the package, remove wipe and wipe hands as needed.

Other information
- Store at room temperature.
- May discolor certain fabrics or surfaces.
- Avoid freezing and excessive heat above 104°F (40°C).

Inactive Ingredients
- Aqua, Polyaminopropyl Biguanide, Phenoxyethanol, Polysorbate 20, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate.

BACTAKLEEN KLEEN WIPES

benzalkonium chloride liquid

Product Information

Product Type

HUMAN OTC DRUG Item Code (Source) NDC:73215-110

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Ingredient Name

Basis of Strength Strength

BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM -UNII:7N6JUD5X6Y)

BENZALKONIUM **CHLORIDE**

0.08 g

Strength

Inactive Ingredients

POLYSORBATE 20 (UNII: 7T1F30V5YH)

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

ALOE VERA LEAF (UNII: ZY81Z83H0X)

WATER (UNII: 059QF0KO0R)

PHENO XYETHANOL (UNII: HIE492ZZ3T)

POLYAMINO PRO PYL BIGUANIDE (UNII: DT9 D8 Z79 ET)

Packaging

| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|------------------|---|-----------------------------|--------------------|
| ı | 1 | NDC:73215-110-01 | 100 in 1 POUCH; Type 0: Not a Combination Product | 07/28/2020 | |

Marketing Information

| l | Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|-------------------------|--|----------------------|--------------------|
| I | OTC monograph not final | part333E | 07/28/2020 | |

Labeler - Excelsia Technologies Sdn Bhd (659311797)

Registrant - Excelsia Technologies Sdn Bhd (659311797)

| Establishment | | | | | |
|---------------------------|---------|-----------|------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| MBH Cosmeceutical Sdh Bhd | | 659311739 | manufacture(73215-110) | | |

Revised: 7/2020 Excelsia Technologies Sdn Bhd