

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

For 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

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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 | Basis of Strength | Strength |
|--|-----------------------|----------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.08 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| WATER (UNII: 059QF0K00R) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| POLYAMINOPROPYL BIGUANIDE (UNII: DT9D8Z79ET) | |

Packaging

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

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| 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