

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES FREESIA- benzalkonium chloride solution

ENCHANTE ACCESSORIES 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.

G0ABCW08

Active Ingredient

Benzalkonium Chloride 0.1%

Purpose

Antibacterial

Use

- To decrease bacteria on hands

WARNINGS

For external use only

Stop Use

Do not use if you are allergic to any ingredients listed

Discontinue use if irritation or redness occur. Consult a doctor if condition lasts for more than 72 hours

Do not get into eyes. Rinse thoroughly with water if contact occurs

keep out of reach of children

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Directions

For adults and children two years and over

Peel over reusable label and remove a wipe from the packet.

Wet hands thoroughly and air dry.

Place used wipes in to waste basket. Do not flush.

Inactive ingredients

Water, Glycerin, Ethylhexylglycerin, Freesia Refracta Extrac, Phenoxyethanol, Propylene Glycol, Fragrance



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benzalkonium chloride solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50563-226 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------------------|-----------------------|----------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 4.5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:50563-226-01 | 2 in 1 PACKAGE | 06/13/2020 | |

| | | | |
|------------------------------|---------------------------------------------------|-----------------------------|---------------------------|
| 1 | 30 in 1 PACKET; Type 0: Not a Combination Product | | |
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 06/13/2020 | |

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

| | | | |
|---------------------------------------------|----------------|---------------|----------------------------|
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| Zhejiang Ruolin Hygienic Products Co., Ltd. | | 415426870 | manufacture(50563-226) |

Revised: 6/2020

ENCHANTE ACCESSORIES INC.