

WET WIPES - benzethonium chloride swab
Delta Brands, 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.

Drug Facts

Active Ingredient

Benzethonium Chloride 0.3%

Purpose

Antibacterial

Uses

decreases bacteria on the 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

When using this product do not get into eyes.
If contact occurs, rinse thoroughly with water.

Stop use

Stop use and ask a doctor if irritation or rash develops and continues for more than 72 hours

Keep out of reach of children

Keep out of reach of children, for children under 2 years ask a doctor before use. for children use under adult supervision

Directions

Do not expose to direct sunlight, preferably place them in a cool place. Do not use on furniture. Do not flush down toilets, dispose in trash receptacles. Remove lid and open the seal Pull up the corner of the center sheet, twist it and thread through the dispenser split in the lid. Pull sheet out at an angle. When finished close lid flap to retain moisture. **Adults and children 2 years and over** - Use on hand and face to clean and refresh, allow skin to air dry. **Children under 2 years of age** - ask a doctor before use

Inactive Ingredients

Water, Propylene Glycol, Cocamidopropyl Betaine, PEG-7 Glyceryl Cocoate, Fragrance, Benzyl Alcohol, Methylchloroisothiazolinone, Methylisothiazolinone, Tetrasodium EDTA, PEG-40 Hydrogenated Castor Oil, Cetrimonium Chloride, Citric Acid, Aloe Vera Extract, Alphatocopherol Acetate (Vitamin E)

Package Label

WET WIPES

benzethonium chloride swab

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:20276-432 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|----------|
| BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP) | BENZETHONIUM CHLORIDE | 0.3 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |

| | |
|--|--|
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) | |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | |
| EDETATE SODIUM (UNII: MP1J8420LU) | |
| CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:20276-432-80 | 80 in 1 CANISTER | | |
| 2 | NDC:20276-432-40 | 40 in 1 CANISTER | | |
| 3 | NDC:20276-432-35 | 35 in 1 CANISTER | | |
| 4 | NDC:20276-432-30 | 30 in 1 CANISTER | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 04/29/2011 | |

Labeler - Delta Brands, Inc (102672008)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------------|---------|-----------|---------------------|
| Harbin Jinhua Enterprises Co., Ltd | | 529502405 | manufacture |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|---------------------|
| Huzhou Aupower Sanitary Commodity Co., Ltd | | 529722141 | manufacture |