ABUTOL ANTISEPTIC WET WIPES LEMON AND MINT SCENT- benzalkonium chloride cloth

Endeks Kimya Sanayi Ve Ticaret Anonim Sirketi

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.

Abutol ANTISEPTIC WET WIPES LEMON & MINT SCENT

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antiseptic

Uses

- hand wipes to decrease bacteria on the skin.
- recommended for repeated use.
- for use when soap and water are not available

Warnings

For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of eye contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if

- irritation or redness develop
- condition persists 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

- open resealable label. Pull out wipes. Close resealable label to prevent drying out wipe hands thoroughly with product and allow to dry
- dispose the wipe after use
- supervise children under 6 years of age when using this product to avoid swallowing
- do not flush

Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Aqua, Glycerin, Propylene glycol, Parfum, Polysorbate-20, Cocamidopropyl Betaine, Corn Oil, Lauryl Glucoside, Polyglyceryl-2 DipolyhydroxyStearate, Glyceryl Oleate, Dicaprylyl Carbonate, Tetrasodium EDTA, Phenoxyethanol, Benzoic Acid, Dehydroacetic acid.

PARIS

LEMON & MINT SCENT

SANITIZING WIPES

You may also report any serious side effects to PO Box 328, Wood Ridge, NJ 07075-328

ANTISEPTIC AGENT

- Sanitizing formula to help reduce cross-contamination and risk of infection.
- Leaves no stickiness or residue on hands.
- Hands feel smooth, soft and refreshed.

To Open Package

- Flip open dispensing lid
- Locate wipe at center of roll and thread through small opening in lid
- For best results dispense wipes at an angle
- Always close lid securely between uses to retain moisture

Made in TURKEY

TO DISPOSE WIPE: Place in a waste basket after use. **DO NOT FLUSH**

Lot Number and Exp Date on package

Packaging



benzalkonium chloride cloth

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78089-038 |
|--------------|----------------|--------------------|---------------|

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKONIUMUNII:7N6 JUD5X6Y) BENZALKO NIUM CHLO RIDE 0.13 g in 100 g

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX) | |
| CORN OIL (UNII: 8470G57WFM) | |
| LAURYL GLUCOSIDE (UNII: 76LN7P7UCU) | |
| POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12) | |
| GLYCERYL OLEATE (UNII: 4PC054V79P) | |
| DICAPRYLYL CARBONATE (UNII: 609 A3V1SUA) | |
| EDETATE SO DIUM (UNII: MP1J8420 LU) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| BENZOIC ACID (UNII: 8 SKN0 B0 MIM) | |
| DEHYDRO ACETIC ACID (UNII: 2KAG279R6R) | |

| Packaging | | | |
|--------------------|--|-----------------------------|---------------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:78089-038-01 | 72 in 1 PACKET | 08/29/2020 | |
| 1 | 4.11 g in 1 PACKAGE; Type 0: Not a Combination Product | | |

| Marketing Infor | mation | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 08/29/2020 | |
| | | | |

Labeler - Endeks Kimya Sanayi Ve Ticaret Anonim Sirketi (565678914)

| Establishment | | | |
|---------------|---------|--------|----------------------------|
| Name | Address | ID/FEI | Business Operations |

Revised: 8/2020

Endeks Kimya Sanayi Ve Ticaret Anonim Sirketi