DISINFECTING WIPES- alcohol cloth NECM KIMYA AKARYAKIT URUNLERI MEDIKAL MALZEMELER SANAYI VE TICARET LIMITED 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.

BIORAD DERM DISINFECTING WIPES

Drug Facts

Active ingredient

Ethanol Alcohol 70%

Purpose

Antiseptic

Uses

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

Warnings

Flammable, keep away from fire/flame

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 contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and 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

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

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

Inactive ingredients

10mg glycerin, 10mg Butylene glycol, 10mg Perfume, ,365mg Aqua 10 mg Lanolin

Kills 99,99% of Germs

Import Company:

Hand Sanitizer, LLC

On Time Inventory

850 Kaliste Saloom Rd, Lafayette, La 70508.

www.handsanitizerllc.com

Manufactured: Necm Kimya Akaryakıt Ürünleri Medikal Malzemeler San. ve Tic. Ltd. Şti.

COUNTRY OF ORIGIN TURKEY

Open lid and pull out the first wipe.

Pull wipe apart at the perforated seam.

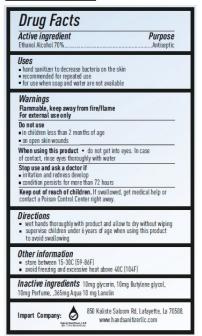
Keep container tighthy closed to keep wipes from drying out.

Do Not Flush

Packaging



DRUG FACTS LABEL



DISINFECTING WIPES

alcohol cloth

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79455-002 | |
| Route of Administration | TOPICAL | | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL | |
| | | | |

| Inactive Ingredients | | | |
|------------------------------------|----------|--|--|
| Ingredient Name | Strength | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | | | |
| WATER (UNII: 059QF0KO0R) | | | |
| LANOLIN (UNII: 7EV65EAW6H) | | | |

| Pa | Packaging | | | | |
|----|------------------|--|-----------------------------|---------------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:79455-002-01 | 1 in 1 PACKET | 07/13/2020 | | |
| 1 | | 5 mL in 1 PACKAGE; Type 0: Not a Combination Product | | | |
| 2 | NDC:79455-002-02 | 50 in 1 CONTAINER | 07/13/2020 | | |
| 2 | | 5 mL in 1 PACKAGE; Type 0: Not a Combination Product | | | |
| 3 | NDC:79455-002-03 | 70 in 1 CONTAINER | 07/13/2020 | | |
| 3 | | 5 mL in 1 PACKAGE; Type 0: Not a Combination Product | | | |
| 4 | NDC:79455-002-04 | 72 in 1 CONTAINER | 07/13/2020 | | |
| 4 | | 5 mL in 1 PACKAGE; Type 0: Not a Combination Product | | | |
| 5 | NDC:79455-002-05 | 80 in 1 CONTAINER | 07/13/2020 | | |
| 5 | | 5 mL in 1 PACKAGE; Type 0: Not a Combination Product | | | |
| 6 | NDC:79455-002-06 | 100 in 1 CONTAINER | 07/13/2020 | | |
| 6 | | 5 mL in 1 PACKAGE; Type 0: Not a Combination Product | | | |
| 7 | NDC:79455-002-07 | 120 in 1 CONTAINER | 07/13/2020 | | |
| 7 | | 5 mL in 1 PACKAGE; Type 0: Not a Combination Product | | | |
| 8 | NDC:79455-002-08 | 150 in 1 CONTAINER | 07/13/2020 | | |
| 8 | | 5 mL in 1 PACKAGE; Type 0: Not a Combination Product | | | |
| 9 | NDC:79455-002-09 | 200 in 1 PAIL | 07/13/2020 | | |
| 9 | | 5 mL in 1 PACKAGE; Type 0: Not a Combination Product | | | |
| 10 | NDC:79455-002-10 | 250 in 1 PAIL | 07/13/2020 | | |
| 10 | | 5 mL in 1 PACKAGE; Type 0: Not a Combination Product | | | |
| 11 | NDC:79455-002-11 | 350 in 1 PAIL | 07/13/2020 | | |
| 11 | | 5 mL in 1 PACKAGE; Type 0: Not a Combination Product | | | |
| 12 | NDC:79455-002-12 | 400 in 1 PAIL | 07/13/2020 | | |
| 12 | | 5 mL in 1 PACKAGE; Type 0: Not a Combination Product | | | |
| 13 | NDC:79455-002-13 | 750 in 1 PAIL | 07/13/2020 | | |
| 13 | | 5 mL in 1 PACKAGE; Type 0: Not a Combination Product | | | |
| 14 | NDC:79455-002-14 | 1000 in 1 PAIL | 07/13/2020 | | |
| 14 | | 5 mL in 1 PACKAGE; 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 | 07/13/2020 | | |
| | | | | |

Labeler - NECM KIMYA AKARYAKIT URUNLERI MEDIKAL MALZEMELER SANAYI VE TICARET LIMITED SIRKETI (355742649)

| Establishment | | | |
|--|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| NECM KIMYA AKARYAKIT URUNLERI MEDIKAL MALZEMELER SANAYI VE TICARET LIMITED SIRKETI | | 355742649 | manufacture(79455-002) |

Revised: 7/2020

NECM KIMYA AKARYAKIT URUNLERI MEDIKAL MALZEMELER SANAYI VE TICARET LIMITED SIRKETI