CREAMOL HAND SANITIZING WIPE- alcohol swab Laber Kimya AR-GE Sanayi Ticaret Levent KAHRIMAN

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.

CREAMOL HAND SANITIZING WIPE

Active Ingredient(s)

Alcohol 80% w/w. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Wipe hands; discard

Other information

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

Inactive ingredients

Aqua, Glycerin, Melaleuca Alternifolia Leaf Extract, Hypericum Perforatum Extract

Package Label - Principal Display Panel



CREAMOL HAND SANITIZING WIPE

alcohol swab

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77892-020 | |
| Route of Administration | TOPICAL | | | |

| Active Ingredient/Active Moiety | | | | |
|---------------------------------|--|-------------------|---------------|--|
| Ingredient Name | | Basis of Strength | Strength | |
| | ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 80 g in 100 g | |

Inactive Ingredients

| Ingredient Name | Strength | |
|---|----------|--|
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| HYPERICUM PERFORATUM WHO LE (UNII: XK4IUX8 MNB) | | |
| MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K) | | |
| WATER (UNII: 059QF0KO0R) | | |

| Packaging | | | | |
|-----------|--------------------|---|-----------------------------|---------------------------|
| l | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| ı | 1 NDC:77892-020-01 | 4 g in 1 POUCH; Type 0: Not a Combination Product | 11/18/2020 | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 11/18/2020 | | |
| | | | | |

Labeler - Laber Kimya AR-GE Sanayi Ticaret Levent KAHRIMAN (533149962)

| Establishment | | | | |
|--|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Laber Kimya AR-GE Sanayi Ticaret Levent KAHRIMAN | | 533149962 | manufacture(77892-020) | |

Revised: 11/2020 Laber Kimya AR-GE Sanayi Ticaret Levent KAHRIMAN