**SIRENOL ANTISEPTIC TOPICAL- alcohol gel**
**BM GLOBAL ELEKTRONIK GIDA SANAYI VE DIS 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.*

---

**Sirenol Antiseptic Topical Gel**

**Active Ingredient**

Alcohol 80%v/v

**Purpose**

Antiseptic

**Uses**

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,rines eyes thoroughly with water.

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

**Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

**Keep out of reach of children**

If swallowed, get medical help or contact a Poision Control Center right away.

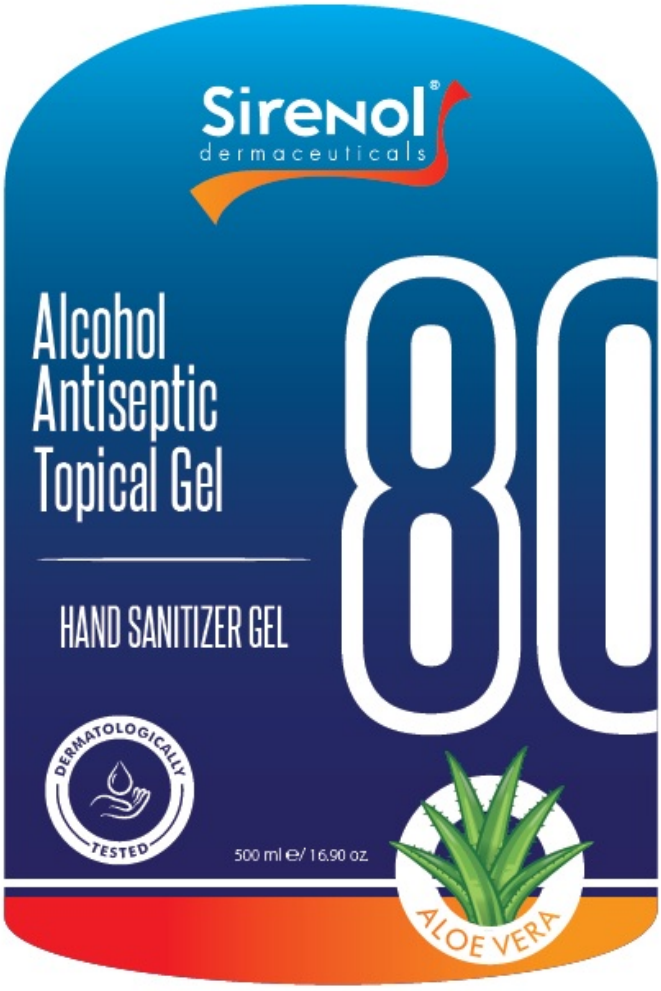
**Other Information (if applicable) :**

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above $40C^0$ ($104F^{\square 0}$)

**Inactive Ingredient**

Glycerin, Aloe Barbadensis Leaf Extract, Purified Water USP, Carbomer homopolymer, unspecified type

## Product label





# SIRENOL ANTISEPTIC TOPICAL

alcohol gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:80441-002 |
| **Route of Administration** | TOPICAL | | |

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

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **WATER** (UNII: 059QF0KO0R) | |

| | |
|---|---|
| **CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE** (UNII: 0A5MM307FC) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:80441-002-01 | 25 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/02/2020 | |
| **2** | NDC:80441-002-02 | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/02/2020 | |
| **3** | NDC:80441-002-03 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/02/2020 | |
| **4** | NDC:80441-002-04 | 150 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/02/2020 | |
| **5** | NDC:80441-002-05 | 200 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/02/2020 | |
| **6** | NDC:80441-002-06 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/02/2020 | |
| **7** | NDC:80441-002-07 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/02/2020 | |
| **8** | NDC:80441-002-08 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/02/2020 | |
| **9** | NDC:80441-002-09 | 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/02/2020 | |
| **10** | NDC:80441-002-10 | 5000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/02/2020 | |
| **11** | NDC:80441-002-11 | 10000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/02/2020 | |
| **12** | NDC:80441-002-12 | 6 in 1 PACKAGE | 09/02/2020 | |
| **12** | | 5 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product | | |
| **13** | NDC:80441-002-13 | 10 in 1 PACKAGE | 09/02/2020 | |
| **13** | | 5 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product | | |
| **14** | NDC:80441-002-14 | 20 in 1 PACKAGE | 09/02/2020 | |
| **14** | | 5 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product | | |
| **15** | NDC:80441-002-15 | 100 in 1 PACKAGE | 09/02/2020 | |
| **15** | | 5 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product | | |
| **16** | NDC:80441-002-16 | 1000 in 1 PACKAGE | 09/02/2020 | |
| **16** | | 5 mL in 1 NOT APPLICABLE; 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 | 09/02/2020 | |

**Labeler -** BM GLOBAL ELEKTRONIK GIDA SANAYI VE DIS TICARET LIMITED SIRKETI (355573134)

Revised: 9/2020 BM GLOBAL ELEKTRONIK GIDA SANAYI VE DIS TICARET LIMITED SIRKETI