

SIRENOL ANTISEPTIC TOPICAL- alcohol solution
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 Solution

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.

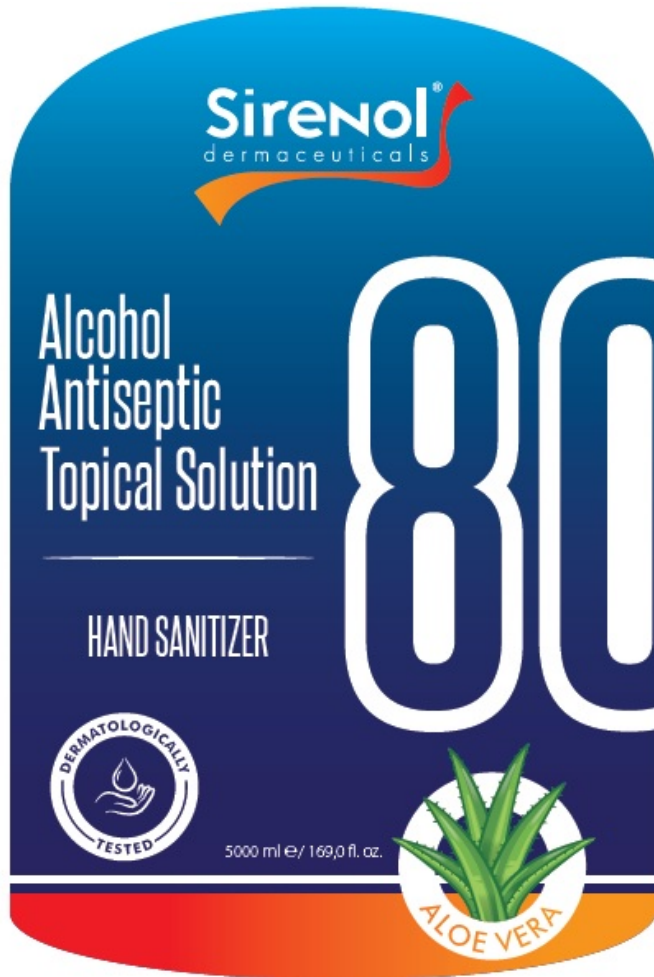
Other Information (if applicable) :

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C⁰ (104F⁰⁰)

Inactive Ingredient

Glycerin, Aloe Barbadosis Leaf Extract, Purified Water USP.

Product label



SIRENOL ANTISEPTIC TOPICAL

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80441-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80441-001-01	6 in 1 PACKAGE	09/02/2020	
1		5 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
2	NDC:80441-001-02	10 in 1 PACKAGE	09/02/2020	
2		5 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
3	NDC:80441-001-03	20 in 1 PACKAGE	09/02/2020	
3		5 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
4	NDC:80441-001-04	100 in 1 PACKAGE	09/02/2020	
4		5 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
5	NDC:80441-001-05	1000 in 1 PACKAGE	09/02/2020	
5		5 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
6	NDC:80441-001-06	60 in 1 BOTTLE	09/02/2020	
6		150 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
7	NDC:80441-001-07	80 in 1 BOTTLE	09/02/2020	
7		200 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
8	NDC:80441-001-08	100 in 1 BOTTLE	09/02/2020	
8		250 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
9	NDC:80441-001-09	25 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
10	NDC:80441-001-10	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
11	NDC:80441-001-11	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
12	NDC:80441-001-12	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
13	NDC:80441-001-13	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
14	NDC:80441-001-14	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
15	NDC:80441-001-15	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
16	NDC:80441-001-16	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
17	NDC:80441-001-17	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
18	NDC:80441-001-18	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
19	NDC:80441-001-19	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	

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

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