

ELASKIN ANTISEPTIC HAND SANITIZER- isopropyl alcohol solution

Aleo BME, Inc.

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.

IPA 75% Antiseptic Topic Solution, Hand Sanitizer

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Isopropyl Alcohol 75% v/v. 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.

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

- 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.

Other information

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

Inactive ingredients

glycerin, hydrogen peroxide, sterile water

Package Label - Principal Display Panel

60 mL NDC: 74533-003-02

ElaSkin®
Isopropyl Alcohol Antiseptic
75% Topical Solution
Hand Sanitizer
Non-sterile Solution
2 FL OZ (60 mL)

6000142371

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State College, PA 16803
Questions? Contact support@aleobme.com

Drug Facts
Active Ingredient
Isopropyl alcohol 75% v/v.....
Use
Hand sanitizer to help reduce bacteria that pose 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.
When using this product Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly. • 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
• Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years when using this product to avoid swallowing.
Other Information
• Store between 15-30C • Avoid freezing and excessive heat above 40C
Inactive ingredients: Glycerin, hydrogen peroxide, sterile water

30mL NDC: 74533-003-01

ElaSkin®
Isopropyl Alcohol Antiseptic
75% Topical Solution
Hand Sanitizer
Non-sterile Solution
1 FL OZ (30 mL)

6000142372

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Drug Facts
Active Ingredient
Isopropyl alcohol 75% v/v.....
Purpose
Antiseptic
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 the product Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes with water thoroughly. • 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: Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 yrs of age when using the product to avoid swallowing.
Other information: • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients: Glycerin, hydrogen peroxide, sterile water

118mL NDC:74533-003-03

<p>ElaSkin® </p> <p>Isopropyl Alcohol Antiseptic 75% Topical Solution</p> <p>Hand Sanitizer</p> <p>4 FL OZ (118 mL)</p>  <p>8 60001 42373 0</p> <p>Made in USA ©2020 by Aleo BME Inc. State college, PA 16803 Questions? Contact support@aleobme.com</p>	<p>Drug Facts</p> <table border="1"><thead><tr><th>Active Ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Isopropyl alcohol 75% v/v.....</td><td>Antiseptic</td></tr></tbody></table>	Active Ingredient	Purpose	Isopropyl alcohol 75% v/v.....	Antiseptic
	Active Ingredient	Purpose			
	Isopropyl alcohol 75% v/v.....	Antiseptic			
	<p>Use Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p>				
	<p>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.</p>				
	<p>Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.</p>				
<p>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</p>					
<p>Other information • Non-sterile • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)</p>					
<p>Inactive ingredients Glycerin, hydrogen peroxide, sterile water</p>					

950 mL NDC: 74533-003-04



**Isopropyl Alcohol
Antiseptic 75% Topical
Solution**

**Hand Sanitizer
Refill**

32 FL OZ (950 mL)



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Drug Facts	
Active Ingredient	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic
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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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. 	
Other information	
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Inactive ingredients	
Glycerin, hydrogen peroxide, sterile water	

ELASKIN ANTISEPTIC HAND SANITIZER

isopropyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74533-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74533-003-02	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/02/2020	
2	NDC:74533-003-01	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/02/2020	
3	NDC:74533-003-03	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/04/2020	
4	NDC:74533-003-04	950 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/02/2020	

Labeler - Aleo BME, Inc. (079856690)

Establishment

Name	Address	ID/FEI	Business Operations
Aleo BME, Inc.		079856690	manufacture(74533-003)

Revised: 5/2020

Aleo BME, Inc.