

HAND SANITIZER- alcohol gel
Capace Medical, S.A. de C.V.

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.

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)

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.

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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, carbomer 940, trolamine, aloe vera, purified water USP

Package Label - Principal Display Panel



ALCOHOL ANTISEPTIC
75%
Topical Solution
GEL

HAND SANITIZER

0.17 FL OZ (5ml.)

Drugs Facts	
Active ingredient	Purpose
Ethyl alcohol 75%v/v	Antiseptic
Uses ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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.	
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Other Information ■ Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients Glycerin, Carbomer 940, Trolamine, Purified water, Aloe vera.	



MANUFACTURED BY:
CAPACE MEDICAL S.A. de C.V.
Guadalajara 1016 Col. Mitras sur
Monterrey, N.L. C.P. 64020

5 mL NDC: 78096-123-01

PACKAGE LABEL PRINCIPAL DISPLAY PANEL



ALCOHOL ANTISEPTIC
75%
Topical Solution
GEL

HAND SANITIZER

3.38 FL OZ. (100 mL)

100 mL NDC: 78096-123-02

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

Drugs Facts	
Active ingredient	Purpose
Ethyl alcohol 75%v/v	Antiseptic
Uses ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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Do not use ■ In children less than 2 months of age ■ On open skin wounds	
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Directions ■ Place enough product on hands to cover all surface. 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, Carbomer 940, Trolamine, Purified water, Aloe vera.	



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ALCOHOL ANTISEPTIC
 75%
 Topical Solution
 GEL

HAND SANITIZER

4.22 FL OZ (125 mL)

125 mL NDC: 78096-123-03

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

Drugs Facts	
Active ingredient	Purpose
Ethyl alcohol 75%v/v	Antiseptic
Uses ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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Flammable, Keep away from heat or flame	
Do not use	
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ALCOHOL ANTISEPTIC
75%
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GEL

HAND SANITIZER

8.45 FL OZ (250 mL)

250 mL NDC: 78096-123-04

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

Drugs Facts	
Active ingredient	Purpose
Ethyl alcohol 75%v/v	Antiseptic
Uses ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only.	
Flammable, Keep away from heat or flame	
Do not use	
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■ On open skin wounds	
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Inactive ingredients	
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ALCOHOL ANTISEPTIC
 75%
 Topical Solution
 GEL

HAND SANITIZER

11.15 FL OZ (330 mL)

330 mL NDC: 78096-123-05

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

Drugs Facts	
Active ingredient	Purpose
Ethyl alcohol 75%v/v	Antiseptic
Uses ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only.	
Flammable, Keep away from heat or flame	
Do not use	
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Directions	
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Other Information ■ Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients	
Glycerin, Carbomer 940, Trolamine, Purified water, Aloe vera.	



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ALCOHOL ANTISEPTIC
75%
Topical Solution
GEL

HAND SANITIZER

16.90 FL OZ (500 mL)

Drugs Facts	
Active ingredient	Purpose
Ethyl alcohol 75%v/v	Antiseptic
Uses ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only.	
Flammable, Keep away from heat or flame	
Do not use	
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Inactive ingredients	
Glycerin, Carbomer 940, Trolamine, Purified water, Aloe vera.	



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PACKAGE LABEL PRINCIPAL DISPLAY PANEL



ALCOHOL ANTISEPTIC
75%
Topical Solution
GEL

HAND SANITIZER

33.81 FL OZ (1000 mL)

Drugs Facts

Active ingredient	Purpose
Ethyl alcohol 75%v/v	Antiseptic

Uses ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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

- Place enough product on hands to cover all surface.
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, Carbomer 940, Trolamine, Purified water, Aloe vera.



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PACKAGE LABEL PRINCIPAL DISPLAY PANEL



ALCOHOL ANTISEPTIC
75%
Topical Solution
GEL

HAND SANITIZER

127.98 FL OZ (3785 mL)

3785 mL NDC: 78096-123-08

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

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Drugs Facts	
Active ingredient	Purpose
Ethyl alcohol 75%/v/v	Antiseptic
Uses ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only.	
Flammable, Keep away from heat or flame	
Do not use	
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ALCOHOL ANTISEPTIC
75%
Topical Solution
GEL

HAND SANITIZER

676.28 FL OZ (20000 mL)

20000 mL NDC: 78096-123-09

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

Drugs Facts	
Active ingredient	Purpose
Ethyl alcohol 75%/v/v	Antiseptic
Uses ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only.	
Flammable, Keep away from heat or flame	
Do not use	
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ALCOHOL ANTISEPTIC
75%
Topical Solution
GEL

HAND SANITIZER

6762.8 FL OZ (200000 mL)

200000 mL NDC: 78096-123-10

Package label principal

Drugs Facts	
Active ingredient	Purpose
Ethyl alcohol 75%v/v	Antiseptic
Uses ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only.	
Flammable, Keep away from heat or flame	
Do not use	
■ In children less than 2 months of age	
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ALCOHOL ANTISEPTIC
75%
Topical Solution
GEL

HAND SANITIZER

33814 FL OZ (1000000 mL)

Drugs Facts	
Active ingredient	Purpose
Ethyl alcohol 75%v/v	Antiseptic
Uses ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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Flammable, Keep away from heat or flame	
Do not use	
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■ On open skin wounds	
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Inactive ingredients	
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1000000 mL NDC: 78096-123-11

HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78096-123
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.75 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	0.25 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.25 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78096-123-01	5 mL in 1 PACKAGE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78096-123-02	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78096-123-03	125 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78096-123-04	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78096-123-05	330 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:78096-123-06	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:78096-123-07	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
8	NDC:78096-123-08	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
9	NDC:78096-123-09	20000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
10	NDC:78096-123-10	200000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
11	NDC:78096-123-11	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Capace Medical, S.A. de C.V. (812912385)

Registrant - Mario Hidalgo (080666336)

Establishment

Name	Address	ID/FEI	Business Operations
Capace Medical, S.A. de C.V.		812912385	manufacture(78096-123)