

**HAND SANITIZER- alcohol gel**  
**Lc Farma, 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.*

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**Active Ingredient(s)**

Alcohol 70% 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**

water, carbomer, triethanolamine, glycerin

# Package Label - Principal Display Panel


500 mL NDC: 78523-010-01

# GEL

## Antiseptic Hand Rub

Topical Solution  
Non-sterile Solution

Kills  
**99%**  
of most common  
germs that may  
cause illness



# 70%

Alcohol Antiseptic  
Cont. Net. **500 ml**

Drug Facts	
<b>Active ingredient[s]</b> Ethyl alcohol 70% v/v	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b> • In children less than 2 months of age • On open skin wounds.	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> Carbopol, triethanolamine, glycerin, water.	

Made in México by: LC FARMA S.A. de C.V.  
Distributed by: CMA inc.

lot: \_\_\_\_\_  
Expiration: \_\_\_\_\_

# HAND SANITIZER

alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78523-010
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
TRIETHANOLAMINE HYDRIODIDE (UNII: DT98IT03JK)	
CARBOMER 934 (UNII: Z135WT9208)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78523-010-01	500 mL in 1 BOTTLE, DISPENSING; 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** - Lc Farma, S.A. de C.V. (951578633)

**Registrant** - Lc Farma, S.A. de C.V. (951578633)

## Establishment

Name	Address	ID/FEI	Business Operations
Lc Farma, S.A. de C.V.		951578633	manufacture(78523-010)

