

**HAND SANITIZER- alcohol gel**  
**Neonatural SA de CV**

*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.

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 below 100°F (43°C)

**Inactive ingredients**

water, glycerin, carbomer, triethanolamine

**Package Label - Principal Display Panel**

125 mL NDC: 78103-001-01

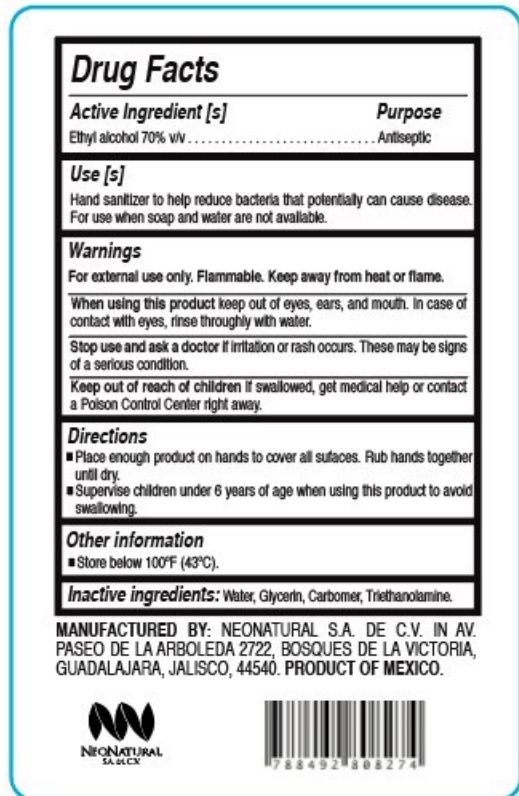


250 mL NDC: 78103-001-02

4.5 cm

4.5 cm

7 cm



500 mL NDC: 78103-001-03



1000 mL NDC: 78103-001-04

18.5 cm

14 cm

**Gel neo**  
Hands sanitizer  
70% ALCOHOL

Parabens & triclosan **FREE**

1000 mL (33.81 fl oz)

NEONATURAL S.A. DE C.V.

<b>Drug Facts</b>	
<b>Active Ingredient [s]</b>	<b>Purpose</b>
Ethyl alcohol 70% v/v	Antiseptic
<b>Use [s]</b>	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
Store below 100°F (43°C).	
<b>Inactive ingredients:</b> Water, Glycerin, Carbomer, Triethanolamine.	

MANUFACTURED BY: NEONATURAL S.A. DE C.V. IN AV. PASEO DE LA ARBOLEDA 2722, BOSQUES DE LA VICTORIA, GUADALAJARA, JALISCO, 44540. PRODUCT OF MEXICO.



5000 mL NDC: 78103-001-05

14 cm

10.5 cm

NEONATURAL S.A. DE C.V.

# Gel neo

**Hands sanitizer**  
**70% ALCOHOL**

Parabens & triclosan **FREE**

169.07 fl oz (5 L)

### Drug Facts

Active Ingredient [s]	Purpose
Ethyl alcohol 70% v/v	Antiseptic

### Use [s]

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.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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 surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

### Other information

- Store below 100°F (43°C).

**Inactive ingredients:** Water, Glycerin, Carbomer, Triethanolamine.

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20000 mL NDC: 78103-001-06

21.5 cm

14 cm

NEONATURAL S.A. DE C.V.

# Gel neo

**Hands sanitizer**  
**70% ALCOHOL**

Parabens & triclosan **FREE**

676.28 fl oz (20 L)

### Drug Facts

Active Ingredient [s]	Purpose
Ethyl alcohol 70% v/v	Antiseptic

### Use [s]

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.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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

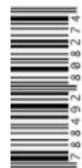
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

### Other information

- Store below 100°F (43°C).

**Inactive ingredients:** Water, Glycerin, Carbomer, Triethanolamine.

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3785 mL NDC: 78103-001-07

<b>HAND SANITIZER</b>			
alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78103-001
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
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)	2.4 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.27 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	1.03 g in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78103-001-01	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78103-001-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78103-001-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78103-001-04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78103-001-05	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:78103-001-06	20000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
7	NDC:78103-001-07	3785 mL in 1 BOTTLE; 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** - Neonatural SA de CV (951578100)

**Registrant** - Neonatural SA de CV (951578100)

## Establishment

Name	Address	ID/FEI	Business Operations
Neonatural SA de CV		951578100	manufacture(78103-001) , pack(78103-001) , label(78103-001)

Revised: 7/2020

Neonatural SA de CV