

## **HAND SANITIZER- alcohol gel**

### **GIA EVOLUTION 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 between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

purified water USP, glycerin, carbomer, triethanolamine.

# Package Label - Principal Display Panel

29.5 mL NDC: 77231-010-01

Cara principal

6 cm

6 cm



12 cm

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active Ingredient [s]</b> Ethyl alcohol 70% v/v . . . . . Antiseptic	<b>Purpose</b>	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<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>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>Warnings</b> For external use only. Flammable. Keep away from heat or flame.		<b>Other information</b> ■ Store between 15-30°C (59-86 °F) ■ Avoid freezing and excessive heat above 40°C (104 °F)	
<b>Do not use</b> ■ in children less than 2 months of age ■ on open skin wounds		<b>Inactive ingredients:</b> Purified water USP, Glycerin, Carbomer, Triethanolamine.	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.		<p style="text-align: right;">R00</p> <p><b>MANUFACTURED BY:</b> GIA EVOLUTION S.A. DE C.V. CARR AGUASCALIENTES - ZACATECAS KM 8.0 COL. LA PERLA, AGUASCALIENTES, AGS. C.P. 20110. MEXICO. <b>PRODUCT OF MEXICO</b></p>	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.			

6 cm

interior de etiqueta

Impresa sobre couche autoadherible blanco



C



K

59 mL NDC: 77231-010-02

Cara principal

6 cm

6 cm



12 cm

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active Ingredient [s]</b> Ethyl alcohol 70% v/v	<b>Purpose</b> Antiseptic	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<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>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>Warnings</b> For external use only. Flammable. Keep away from heat or flame.		<b>Other information</b> ■ Store between 15-30°C (59-86 °F) ■ Avoid freezing and excessive heat above 40°C (104 °F)	
<b>Do not use</b> ■ in children less than 2 months of age ■ on open skin wounds		<b>Inactive ingredients:</b> Purified water USP, Glycerin, Carbomer, Triethanolamine.	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.		ROO	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.			
<b>MANUFACTURED BY:</b> GIA EVOLUTION S.A. DE CV. CARR AGUASCALIENTES – ZACATECAS KM 8.0 COL. LA PERLA, AGUASCALIENTES, AGS. C.P. 20110. MEXICO. <b>PRODUCT OF MEXICO</b>			

6 cm

interior de etiqueta

Impresa sobre couche autoadherible blanco



C



K

237 mL NDC: 77231-010-03

15.6 cm

5 cm

8 10053 66022 5

**Gia**  
B-CARE

**Hand Sanitizer**  
CLEANER SKIN FOR THE ENTIRE FAMILY.  
NDC 77231-010-03

CONTAINS 70% ETHYL ALCOHOL

MANUFACTURED BY: GIA EVOLUTION S.A. DE CV. CARREAGUASCALIENTES - ZACATECAS KM 80. COL LA PERLA AGUASCALIENTES, AGS. C.P. 20110 MEXICO PRODUCT OF MEXICO

<b>Drug Facts</b>	
<b>Active Ingredient [s]</b> Ethyl alcohol 70% v/v	<b>Purpose</b> 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. Do not use ■ 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 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>Drug Facts (continued)</b> Keep out of reach of children 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 15-30°C (59-86 °F) ■ Avoid freezing and excessive heat above 40°C (104 °F)
<b>Inactive Ingredients:</b> Purified water USP, Glycerin, Carbomer, Triethanolamine.

R:00  
LOT:  
EXPIRATION DATE:

8 fl oz (237 mL)

Impresa sobre couche autoadherible blanco



C



K

500 mL NDC: 77231-010-04

15.6 cm

5 cm

8 10053 66023 2

**Gia**  
B-CARE

**Hand Sanitizer**  
CLEANER SKIN FOR THE ENTIRE FAMILY.  
NDC 77231-010-04

CONTAINS 70% ETHYL ALCOHOL

MANUFACTURED BY: GIA EVOLUTION S.A. DE CV. CARREAGUASCALIENTES - ZACATECAS KM 80. COL LA PERLA AGUASCALIENTES, AGS. C.P. 20110 MEXICO PRODUCT OF MEXICO

<b>Drug Facts</b>	
<b>Active Ingredient [s]</b> Ethyl alcohol 70% v/v	<b>Purpose</b> 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. Do not use ■ 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 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>Drug Facts (continued)</b> Keep out of reach of children 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 15-30°C (59-86 °F) ■ Avoid freezing and excessive heat above 40°C (104 °F)
<b>Inactive Ingredients:</b> Purified water USP, Glycerin, Carbomer, Triethanolamine.

R:00  
LOT:  
EXPIRATION DATE:

16.9 fl oz (500 mL)

Impresa sobre couche autoadherible blanco



C



K

946 mL NDC: 77231-010-05

15.6 cm

5 cm

8 10053 66024 9

**Gia**  
B-CARE

**CONTAINS 70% ETHYL ALCOHOL**

**Hand Sanitizer**  
CLEANER SKIN FOR THE ENTIRE FAMILY.  
NDC 77231-010-07  
33.8 fl oz (1 L)

MANUFACTURED BY: GIA EVOLUTION S.A. DE CV. CARR. AGUASCALIENTES - ZACATECAS KM 8.0. COL. LA PERLA, AGUASCALIENTES, AGS. C.P. 20110. MEXICO. PRODUCT OF MEXICO

<b>Drug Facts</b> <b>Active Ingredient [s]</b> Ethyl alcohol 70% v/v ..... Antiseptic <b>Purpose</b> Antiseptic	<b>Drug Facts (continued)</b> Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.
<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>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>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>Other information</b> Store between 15-30°C (59-86 °F) Avoid freezing and excessive heat above 40°C (104 °F)
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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>Inactive ingredients:</b> Purified water USP, Glycerin, Carbomer, Triethanolamine.

R:00  
LOT:  
EXPIRATION DATE:

Impresa sobre couche autoadherible blanco



3785 mL NDC: 77231-010-06

8.7 cm

11 cm

8 10053 66025 9

**Gia**  
B-CARE

**CONTAINS 70% ETHYL ALCOHOL**

**Hand Sanitizer**  
CLEANER SKIN FOR THE ENTIRE FAMILY.  
NDC 77231-010-06

MANUFACTURED BY: GIA EVOLUTION S.A. DE CV. CARR. AGUASCALIENTES - ZACATECAS KM 8.0. COL. LA PERLA, AGUASCALIENTES, AGS. C.P. 20110. MEXICO. PRODUCT OF MEXICO

<b>Drug Facts</b> <b>Active Ingredient [s]</b> Ethyl alcohol 70% v/v ..... Antiseptic <b>Purpose</b> Antiseptic	<b>Drug Facts (continued)</b> Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.
<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>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>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>Other information</b> Store between 15-30°C (59-86 °F) Avoid freezing and excessive heat above 40°C (104 °F)
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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>Inactive ingredients:</b> Purified water USP, Glycerin, Carbomer, Triethanolamine.

R:00  
LOT:  
EXPIRATION DATE:

1 gal (3.78 L)

Impresa sobre couche autoadherible blanco



20000 mL NDC: 77231-010-08

Alcohol Antiseptic 70%  
gel

Hand Sanitizer  
Non-sterile gel

(200 L)

Manufactured by:  
Gia Evolution S.A. de C.V.  
Carr. Aguascalientes-Zacatecas Km. 8.  
Aguascalientes, AGS. México. 20110  
+52 (449) 158 3500

1000000 mL NDC: 77231-010-07

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
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>	
<b>For external use only. Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b>	
<ul style="list-style-type: none"><li>▪ in children less than 2 months of age</li><li>▪ on open skin wounds</li></ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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>	
<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>	
<ul style="list-style-type: none"><li>▪ Store between 1-30C (59-86F)</li><li>▪ Avoid freezing and excessive heat above 40C (104F)</li></ul>	
<b>Inactive ingredients</b> glycerin, carbomer, triethanolamine, purified water USP	

Alcohol Antiseptic 70%  
gel

Hand Sanitizer  
Non-sterile gel

(1000 L)

Manufactured by:  
Gia Evolution S.A. de C.V.  
Carr. Aguascalientes-Zacatecas Km. 8.  
Aguascalientes, AGS. México. 20110  
+52 (449) 158 3500

20000000 mL NDC: 77231-010-09

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
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>	
<b>For external use only. Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b>	
<ul style="list-style-type: none"><li>▪ in children less than 2 months of age</li><li>▪ on open skin wounds</li></ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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>	
<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>	
<ul style="list-style-type: none"><li>▪ Store between 1-30C (59-86F)</li><li>▪ Avoid freezing and excessive heat above 40C (104F)</li></ul>	
<b>Inactive ingredients</b> glycerin, carbomer, triethanolamine, purified water USP	

Alcohol Antiseptic 70% gel

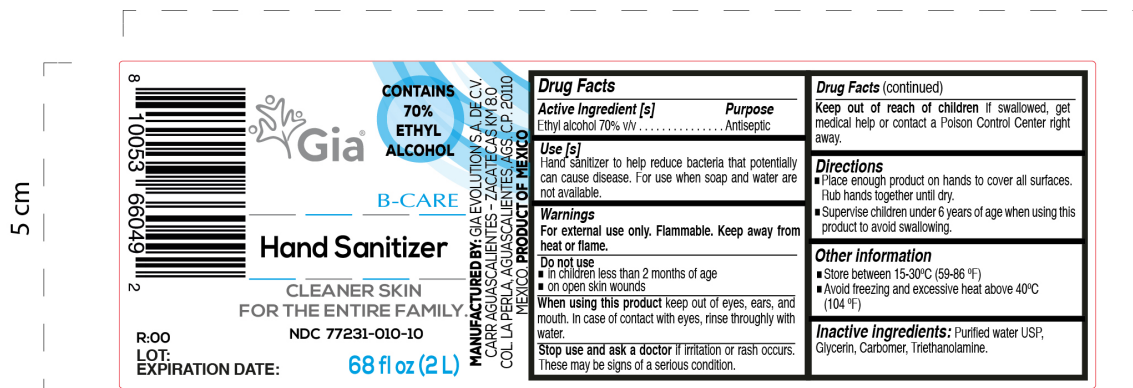
Hand Sanitizer Non-sterile gel

(20,000 L)

Manufactured by:  
 Gia Evolution S.A. de C.V.  
 Carr. Aguascalientes-Zacatecas Km. 8.  
 Aguascalientes, AGS. México. 20110  
 +52 (449) 158 3500

2000 mL NDC: 77231-010-10

14.9 cm



Impresa sobre couche autoadherible blanco




8000 mL NDC: 77231-010-11



14.9 cm

5 cm

 <p>8 10053 66050 1</p>	<p><b>CONTAINS 70% ETHYL ALCOHOL B-CARE</b></p> <p><b>Hand Sanitizer</b></p> <p>CLEANER SKIN FOR THE ENTIRE FAMILY. NDC 77231-010-11</p> <p><b>4-68 fl oz (2 L) (Net 272 fl oz/ 8L)</b></p>	<p><b>MANUFACTURED BY:</b> GIA EVOLUTION S.A. DE C.V. CARRAGUASCALIENTES - ZACATECAS KM 80 COLLA PERLA, AGUASCALIENTES, AGS. C.P. 20110 MEXICO. <b>PRODUCT OF MEXICO</b></p>	<p><b>Drug Facts</b></p> <table border="1"> <tr> <th>Active Ingredient [s]</th> <th>Purpose</th> </tr> <tr> <td>Ethyl alcohol 70% Wv</td> <td>Antiseptic</td> </tr> </table>	Active Ingredient [s]	Purpose	Ethyl alcohol 70% Wv	Antiseptic	<p><b>Drug Facts (continued)</b></p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>
	Active Ingredient [s]	Purpose						
Ethyl alcohol 70% Wv	Antiseptic							
			<p><b>Use [s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p><b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul> <p><b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.</p> <p><b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.</p>	<p><b>Directions</b></p> <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> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>Store between 15-30°C (59-86 °F)</li> <li>Avoid freezing and excessive heat above 40°C (104 °F)</li> </ul> <p><b>Inactive Ingredients:</b> Purified water USP, Glycerin, Carbomer, Triethanolamine.</p>				

Impresa sobre couche autoadherible blanco

HAND SANITIZER				
alcohol gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77231-010	
Route of Administration	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		
	CARBOMER 940 (UNII: 4Q93RCW27E)	0.4 g in 100 mL		
	GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL		
	TROLAMINE (UNII: 9O3K93S3TK)	0.35 g in 100 mL		
	WATER (UNII: 059QF0KO0R)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77231-010-06	3785.41 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77231-010-01	29.57 mL in 1 BOTTLE, UNIT-DOSE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77231-010-02	59.15 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77231-	236.59 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

4	010-03	250.35 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77231-010-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:77231-010-05	946.35 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:77231-010-08	200000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
8	NDC:77231-010-07	1000000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
9	NDC:77231-010-09	20000000 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
10	NDC:77231-010-10	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2020	
11	NDC:77231-010-11	8000 mL in 1 BOX; Type 0: Not a Combination Product	07/02/2020	

## Marketing Information

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

**Labeler** - GIA EVOLUTION SA DE CV (951577293)

**Registrant** - GIA EVOLUTION SA DE CV (951577293)

## Establishment

Name	Address	ID/FEI	Business Operations
GIA EVOLUTION SA DE CV		951577293	manufacture(77231-010) , pack(77231-010) , label(77231-010)

Revised: 7/2020

GIA EVOLUTION SA DE CV