

GIA B-CARE- 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.

Gia B-Care 70% ethanol (carbomer)

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, Aminomethylpropanol.

Package Label - Principal Display Panel

190 mL NDC: 77231-080-01

15.6 cm

5 cm

	 <p>CONTAINS 70% ETHYL ALCOHOL</p> <p>B-CARE</p> <p>Hand Sanitizer</p> <p>CLEANER SKIN FOR THE ENTIRE FAMILY.</p> <p>NDC 77231-080-01</p> <p>6.4 fl oz (190 mL)</p>	<p>MANUFACTURED BY: GIA EVOLUTION S.A DE CV CARR AGUASCALIENTES - ZACATECAS KM 180 COL LA PERLA, AGUASCALIENTES, AGS CP. 20110 MEXICO PRODUCT OF MEXICO</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredient [s]</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Ethyl alcohol 70% v/v</td> <td>Antiseptic</td> </tr> </tbody> </table> <p>Use [s] 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.</p> <p>Do not use</p> <ul style="list-style-type: none"> in children less than 2 months of age on open skin wounds <p>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.</p> <p>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</p>	Active Ingredient [s]	Purpose	Ethyl alcohol 70% v/v	Antiseptic	<p>Drug Facts (continued) Keep out of reach of children. If swallowed, seek medical help or contact a Poison Control Center at once.</p> <p>Directions</p> <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 product to avoid swallowing. <p>Other information</p> <ul style="list-style-type: none"> Store between 15-30°C (59-86 °F) Avoid freezing and excessive heat above 40°C (104 °F) <p>Inactive ingredients: Purified water, USP Glycerin, Carbomer, Aminomethylpropanol.</p>
			Active Ingredient [s]	Purpose				
Ethyl alcohol 70% v/v	Antiseptic							
<p>R:00 LOT: EXPIRATION DATE:</p>								

Impresa sobre couche autoadherible blanco



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59 mL NDC: 77231-080-04



B-CARE

Hand Sanitizer

CLEANER SKIN FOR THE ENTIRE FAMILY.

NDC 77231-080-04

2 fl oz (59 mL)



8 10053 66066 9

CONTAINS 70% ETHYL ALCOHOL

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

Drug Facts		Drug Facts (continued)
Active Ingredient [s]	Purpose	Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.
Ethyl alcohol 70% v/v	Antiseptic	
Use [s]		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.
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		
Warnings		Other information <ul style="list-style-type: none"> Store between 15-30°C (59-86 °F) Avoid freezing and excessive heat above 40°C (104 °F)
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 thoroughly with water.		Inactive ingredients: Purified water USP, Glycerin, Carbomer, Aminomethylpropanol.
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.		

125 mL NDC: 77231-080-05



B-CARE

Hand Sanitizer

CLEANER SKIN FOR THE ENTIRE FAMILY.

NDC 77231-080-05

4.23 fl oz (125 mL)



8 10053 66065 2

CONTAINS 70% ETHYL ALCOHOL

R:00
LOT:
EXPIRATION DATE:

Drug Facts		Drug Facts (continued)
Active Ingredient [s]	Purpose	Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.
Ethyl alcohol 70% v/v	Antiseptic	
Use [s]		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.
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		
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GIA B-CARE
alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77231-080
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)	0.3 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.63 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.28 g in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77231-080-01	190 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77231-080-04	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
3	NDC:77231-080-05	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

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(77231-080) , pack(77231-080) , label(77231-080)