

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 (methacrylic acid)

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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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

190 mL NDC: 77231-090-01



Impresa sobre couche autoadherible blanco



GIA B-CARE				
alcohol gel				
Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:77231-090
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	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			0.28 g in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)			0.397 mL in 100 mL	
METHACRYLIC ACID (UNII: 1CS02G8656)			6.5 g in 100 mL	
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77231-090-01	190 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 - 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(77231-090) , pack(77231-090) , label(77231-090)

Revised: 7/2020

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