

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.

Active Ingredient(s)

Alcohol 72% 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 and vitamin E

Package Label - Principal Display Panel

29.5 mL NDC: 77231-040-04

Cara principal

6 cm

6 cm



12 cm

<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredient [s]</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Ethyl alcohol 72% 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. 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. 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 72% v/v	Antiseptic	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</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 this 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, Triethanolamine, Vitamin E.</p>
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Ethyl alcohol 72% v/v	Antiseptic					

MANUFACTURED FOR: URGENT RESPONSE NETWORK, 6685 BETA DR., MAYFIELD VILLAGE, OH 44143. orders@urgentm.com PRODUCT OF MEXICO.

6 cm

interior de etiqueta

59 mL NDC: 77231-040-05

Cara principal

6 cm



6 cm

12 cm

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6 cm

237 mL NDC: 77231-040-07

15.6 cm



5 cm

Impresa sobre couche autoadherible blanco



500 mL NDC: 77231-040-08

15.6 cm

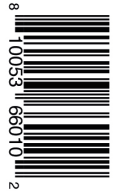
5 cm

 <p>8 100531 660131 3</p>	 <p>URGENT RN HAND SANITIZER ANTIBACTERIAL GEL NDC 77231-010-04</p>	<p>MANUFACTURED FOR: URGENT RESPONSE NETWORK, 6685 BETA DR., MAYFIELD VILLAGE, OH, 44143, orders@urgentm.com 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 72% v/v</td> <td>Antiseptic</td> </tr> </tbody> </table>	Active Ingredient [s]	Purpose	Ethyl alcohol 72% v/v	Antiseptic	<p>Drug Facts (continued)</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 72% v/v	Antiseptic							
<p>LOT: EXPIRATION DATE:</p>	<p>16.9 fl oz (500 mL)</p>	<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>	<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 this 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, Triethanolamine, Vitamin E.</p>					

946 mL NDC: 77231-040-09

15.6 cm

5 cm

 <p>8 100531 660101 2</p>	 <p>URGENT RN HAND SANITIZER ANTIBACTERIAL GEL NDC 77231-010-05</p>	<p>MANUFACTURED FOR: URGENT RESPONSE NETWORK, 6685 BETA DR., MAYFIELD VILLAGE, OH, 44143, orders@urgentm.com 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 72% v/v</td> <td>Antiseptic</td> </tr> </tbody> </table>	Active Ingredient [s]	Purpose	Ethyl alcohol 72% v/v	Antiseptic	<p>Drug Facts (continued)</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 72% v/v	Antiseptic							
<p>LOT: EXPIRATION DATE:</p>	<p>32 fl oz (946 mL)</p>	<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>	<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 this 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, Triethanolamine, Vitamin E.</p>					

3785 mL NDC: 77231-040-10

8.7 cm

11 cm

URGENT RN
HAND SANITIZER
ANTIBACTERIAL GEL
NDC 77231-010-06

72%
CONTAINS 72% ETHYL ALCOHOL

MANUFACTURED FOR: URGENT RESPONSE NETWORK, 6685 BETA DR., MAYFIELD VILLAGE, OH 44143. orders@urgentrn.com PRODUCT OF MEXICO.

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LOT:
EXPIRATION DATE: **1 gal (3.78 L)**

Impresa sobre couche autoadherible blanco



190 mL NDC: 77231-040-06

15.6 cm

5 cm

URGENT RN
HAND SANITIZER
ANTIBACTERIAL GEL
NDC 77231-020-01

72%
CONTAINS 72% ETHYL ALCOHOL

MANUFACTURED FOR: URGENT RESPONSE NETWORK, 6685 BETA DR., MAYFIELD VILLAGE, OH 44143. orders@urgentrn.com PRODUCT OF MEXICO.

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LOT:
EXPIRATION DATE: **6.4 fl oz (190 mL)**

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77231-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	1.5 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.5 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	1 g in 100 mL
WATER (UNII: 059QF0K00R)	
TOCOPHEROL (UNII: R0ZB2556P8)	0.02 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77231-040-10	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/2020	
2	NDC:77231-040-04	29.57 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/21/2020	
3	NDC:77231-040-05	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2020	
4	NDC:77231-040-07	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2020	
5	NDC:77231-040-08	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2020	
6	NDC:77231-040-09	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2020	
7	NDC:77231-040-06	190 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/21/2020	

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(77231-040) , pack(77231-040) , label(77231-040)