

**HAND SANITIZER- alcohol gel**  
**LABORATORIOS BREMER, S.A.**

*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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**Hand Sanitizer**

Drug Facts

**Active Ingredient(s)**

Alcohol 62% 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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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**

Carbomer, Triethanolamine, Water

**Package Label - Principal Display Panel**

**Alcohol Antiseptic 62%  
Topical Solution**

**Hand Sanitizer**  
**60 mL / 2 fl oz**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 62% 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	
<b>Do not use</b> • 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 eyes 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> • 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 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
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Product of Mexico | Made By LABORATORIOS BREMER, S.A. Garcia, Nuevo Leon 66000

60 mL NDC: 60854-162-02

<b>HAND SANITIZER</b>			
alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60854-162
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>	<b>Strength</b>	
	CARBOMER 940 (UNII: 4Q93RCW27E)		
	TROLAMINE (UNII: 9O3K93S3TK)		
	WATER (UNII: 059QF0KO0R)		
<b>Packaging</b>			
		<b>Marketing Start</b>	<b>Marketing End</b>

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60854-162-02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
2	NDC:60854-162-04	130 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
3	NDC:60854-162-08	220 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
4	NDC:60854-162-17	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
5	NDC:60854-162-34	1000 mL in 1 BOTTLE, DISPENSING; 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** - LABORATORIOS BREMER, S.A. (811585264)

### Establishment

Name	Address	ID/FEI	Business Operations
LABORATORIOS BREMER, S.A.		811585264	manufacture(60854-162)

Revised: 4/2020

LABORATORIOS BREMER, S.A.