

**HAND SANITIZER- alcohol cream**  
**ANTISEPTICOS DE MEXICO 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.*

-----

**URIGEL 80% ALCOHOL CREAM GEL**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Alcohol 80% 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

glycerin, hydrogen peroxide, purified water USP


## URIGEL 60ML 80% ALCOHOL CREAM GEL

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Ethyl Alcohol 80% .....	Antiseptic
<b>Use</b>	
For hand washing to decrease bacteria on the skin	
<b>Warnings</b>	
For external use only Flammable, keep away from fire and flame.	
<b>Do not use</b> in the eyes	
Stop use and ask a doctor if ■ irritation and redness develop. ■ condition persists for more than 72 hours. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
Wet hands thoroughly with product and allow to dry without wiping.	
<b>Other information</b>	
■ Store between 59-86°F (15-30°C) ■ Avoid freezing and excessive heat above 104°F (40°C)	
<b>Inactive ingredients</b>	
Glycerin, hydrogen peroxide, water, paraffin, carbopol 940	

**NOT TESTED ON ANIMALS**  
Distributed in USA by:  
Urigel, Inc  
1800 W. Beverly Blvd., Ste. 101  
Montebello, CA 90640  
1-800-255-3924

Product of Mexico  
Distributed in Mexico by:  
Antisépticos de México, S.A. DE C.V.  
Blvd.-Clío 10219, Col. Lomas del Mirador,  
C.P. 37358, León, Guanajuato, México  
Tel.: 477 103 55 47

LOT AND EXP.  
DATE ARE PRINTED  
ON THE BOTTLE




**CREAM ALCOHOL IN LOTION  
ANTIBACTERIAL AND ANTIVIRAL**

**Medical Degree 80%**

**MOISTURIZING**

**Dirt encapsulator for very  
frequent use**



**2.02 fl oz (0.063 qt) (60 ml)**

60 mL NDC: 76554-010-02

## URIGEL 250ML 80% ALCOHOL CREAM GEL

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Ethyl Alcohol 80%	Antiseptic
<b>Use</b>	
For hand washing to decrease bacteria on the skin	
<b>Warnings</b>	
For external use only Flammable, keep away from fire and flame.	
<b>Do not use</b> in the eyes	
Stop use and ask a doctor if <ul style="list-style-type: none"> <li>■ irritation and redness develop.</li> <li>■ condition persists for more than 72 hours.</li> </ul> Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
Wet hands thoroughly with product and allow to dry without wiping.	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>■ Store between 59-86°F (15-30°C)</li> <li>■ Avoid freezing and excessive heat above 104°F (40°C)</li> </ul>	
<b>Inactive ingredients</b>	
Glycerin, hydrogen peroxide, water, oleic acid, stearic acid	

**NOT TESTED ON ANIMALS**

Distributed in USA by:  
 Urigel, Inc  
 1800 W. Beverly Blvd., Ste. 101  
 Montebello, CA 90640  
 1-800-255-3924

Product of Mexico

Distributed in Mexico by:  
 Antisépticos de México, S.A. DE C.V.  
 Blvd. Clío 10219, Col. Lomas del Mirador,  
 C.P. 37358, León, Guanajuato, México  
 Tel.: 477 103 55 47

**LOT AND EXP.  
 DATE ARE PRINTED  
 ON THE BOTTLE**



85882478142



**CREAM ALCOHOL IN LOTION  
 ANTIBACTERIAL AND ANTIVIRAL**

**Medical Degree 80%**

**MOISTURIZING**

**Dirt encapsulator for very  
 frequent use**



**8.45 fl oz (0.264 qt) (250 ml)**

250ML NDC: 76554-010-03

**URIGEL 500ML 80% ALCOHOL CREAM GEL**

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Ethyl Alcohol 80% .....	Antiseptic
<b>Use</b>	
For hand washing to decrease bacteria on the skin	
<b>Warnings</b>	
For external use only Flammable, keep away from fire and flame.	
<b>Do not use</b> in the eyes	
Stop use and ask a doctor if <ul style="list-style-type: none"> <li>■ irritation and redness develop.</li> <li>■ condition persists for more than 72 hours.</li> </ul> Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
Wet hands thoroughly with product and allow to dry without wiping.	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>■ Store between 59-86°F (15-30°C)</li> <li>■ Avoid freezing and excessive heat above 104°F (40°C)</li> </ul>	
<b>Inactive ingredients</b>	
Glycerin, hydrogen peroxide, water, oleic acid, stearic acid	

**NOT TESTED ON ANIMALS**

Distributed in USA by:  
 Urigel, Inc  
 1800 W. Beverly Blvd., Ste. 101  
 Montebello, CA 90640  
 1-800-255-3924


Product of Mexico

Distributed in Mexico by:  
 Antisépticos de México, S.A. DE C.V.  
 Blvd. Clío 10219, Col. Lomas del Mirador,  
 C.P. 37358, León, Guanajuato, México  
 Tel.: 477 103 55 47

**LOT AND EXP.  
 DATE ARE PRINTED  
 ON THE BOTTLE**



8500247878159




**CREAM ALCOHOL IN LOTION  
 ANTIBACTERIAL AND ANTIVIRAL**

**Medical Degree 80%**

**MOISTURIZING**

**Dirt encapsulator for very  
 frequent use**



**16.90 fl oz (0.528 qt) (500 ml)**

500ML NDC: 76554-010-04

**URIGEL 1000ML/1LTR 80% ALCOHOL CREAM GEL**



<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Ethyl Alcohol 80%	Antiseptic
<b>Use</b>	
For hand washing to decrease bacteria on the skin	
<b>Warnings</b>	
For external use only Flammable, keep away from fire and flame.	
<b>Do not use</b> in the eyes	
Stop use and ask a doctor if <ul style="list-style-type: none"> <li>■ irritation and redness develop.</li> <li>■ condition persists for more than 72 hours.</li> </ul> Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
Wet hands thoroughly with product and allow to dry without wiping.	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>■ Store between 59-86°F (15-30°C)</li> <li>■ Avoid freezing and excessive heat above 104°F (40°C)</li> </ul>	
<b>Inactive ingredients</b>	
Glycerin, hydrogen peroxide, water, oleic acid, stearic acid	


**NOT TESTED ON ANIMALS**

Distributed in USA by:  
 Urigel, Inc  
 1800 W. Beverly Blvd., Ste. 101  
 Montebello, CA 90640  
 1-800-255-3924

Product of Mexico

Distributed in Mexico by:  
 Antisépticos de México, S.A. DE C.V.  
 Blvd. Clío 10219, Col. Lomas del Mirador,  
 C.P. 37358, León, Guanajuato, México  
 Tel.: 477 103 55 47

LOT AND EXP.  
 DATE ARE PRINTED  
 ON THE BOTTLE





**CREAM ALCOHOL IN LOTION  
 ANTIBACTERIAL AND ANTIVIRAL**

**Medical Degree 80%**

**MOISTURIZING**

**Dirt encapsulator for very  
 frequent use**



**33.81 fl oz (1.05 qt) (1 L)**

1000ML/1LTR NDC: 76554-010-05

**URIGEL 3750ML/1GAL 80% ALCOHOL CREAM GEL**



**URIGEL**  
Inc

**CREAM ALCOHOL IN LOTION  
ANTIBACTERIAL AND ANTIVIRAL**

**Medical Degree 80%**

**MOISTURIZING**

**Dirt encapsulator for very  
frequent use**

**126.8 fl oz (3.96 qt) (3.75 L)**

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Ethyl Alcohol 80% .....	Antiseptic
<b>Use</b>	
For hand washing to decrease bacteria on the skin.	
<b>Warnings</b>	
For external use only	
Flammable, keep away from fire and flame.	
<b>Do not use</b> in the eyes	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> <li>■ irritation and redness develop.</li> <li>■ condition persists for more than 72 hours.</li> </ul>	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
Wet hands thoroughly with product and allow to dry without wiping.	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>■ Store between 59-86°F (15-30°C)</li> <li>■ Avoid freezing and excessive heat above 104°F (40°C)</li> </ul>	
<b>Inactive ingredients</b>	
Glycerin, hydrogen peroxide, water, oleic acid, stearic acid	


**NOT TESTED ON ANIMALS**

**Distributed in USA by:**  
Urigel, Inc  
1800 W. Beverly Blvd., Ste. 101  
Montebello, CA 90640  
1-800-255-3924

**Product of Mexico**

**Distributed in Mexico by:**  
Antisépticos de México, S.A. DE C.V.  
Blvd. Clio 10219, Col. Lomas del Mirador, C.P. 37358,  
León, Guanajuato, México  
Tel.: 477 103 55 47

**LOT AND EXP.  
DATE ARE PRINTED  
ON THE BOTTLE**



# HAND SANITIZER

alcohol cream

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76554-010
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
1,4-BUTANEDIOL MONOSTEARATE (UNII: OY671H06VI)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
OLEIC ACID OZONIDE (UNII: RQY857DOCC)	
PARAFFIN (UNII: I9O0E3H2ZE)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76554-010-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76554-010-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76554-010-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76554-010-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:76554-010-10	3750 mL in 1 BOTTLE, PUMP; 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** - ANTI SEPTICOS DE MEXICO SA DE CV (951576637)

**Registrant** - ANTI SEPTICOS DE MEXICO SA DE CV (951576637)

## Establishment

Name	Address	ID/FEI	Business Operations
ANTISEPTICOS DE MEXICO SA DE CV		951576637	manufacture(76554-010)

Revised: 1/2021

ANTISEPTICOS DE MEXICO SA DE CV