

URIGEL 80% HAND SANITIZER CREAM GEL- alcohol cream
URIGEL INC

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 SANITIZER 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 3ML 80% ALCOHOL SANITIZER CREAM GEL




3 mL NDC: 80924-002-01

URIGEL 60ML 80% HAND SANITIZER CREAM GEL

Drug Facts	
Active Ingredients	Purpose
Ethyl Alcohol 80%	Antiseptic
Use	
For hand washing to decrease bacteria on the skin	
Warnings	
For external use only Flammable, keep away from fire and flame.	
Do not use in the eyes	
Stop use and ask a doctor if <ul style="list-style-type: none"> 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.	
Directions	
Wet hands thoroughly with product and allow to dry without wiping.	
Other information	
<ul style="list-style-type: none"> Store between 59-86°F (15-30°C) Avoid freezing and excessive heat above 104°F (40°C) 	
Inactive ingredients	
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	



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**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)

60ML NDC:80924-002-02

URIGEL 250ML 80% ALCOHOL SANITIZER CREAM GEL

Drug Facts	
Active Ingredients	Purpose
Ethyl Alcohol 80%	Antiseptic
Use	
For hand washing to decrease bacteria on the skin	
Warnings	
For external use only Flammable, keep away from fire and flame.	
Do not use in the eyes	
Stop use and ask a doctor if <ul style="list-style-type: none"> ■ 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.	
Directions	
Wet hands thoroughly with product and allow to dry without wiping.	
Other information	
<ul style="list-style-type: none"> ■ Store between 59-86°F (15-30°C) ■ Avoid freezing and excessive heat above 104°F (40°C) 	
Inactive ingredients	
Glycerin, hydrogen peroxide, water, oleic acid, stearic acid	

NOT TESTED ON ANIMALS

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 Montebello, CA 90640
 1-800-255-3924

Product of Mexico

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 C.P. 37358, León, Guanajuato, México
 Tel.: 477 103 55 47

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



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**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: 80924-002-03

URIGEL 500ML 80% ALCOHOL SANITIZER CREAM GEL

Drug Facts	
Active Ingredients	Purpose
Ethyl Alcohol 80%	Antiseptic
Use	
For hand washing to decrease bacteria on the skin	
Warnings	
For external use only Flammable, keep away from fire and flame.	
Do not use in the eyes	
Stop use and ask a doctor if <ul style="list-style-type: none"> ■ 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.	
Directions	
Wet hands thoroughly with product and allow to dry without wiping.	
Other information	
<ul style="list-style-type: none"> ■ Store between 59-86°F (15-30°C) ■ Avoid freezing and excessive heat above 104°F (40°C) 	
Inactive ingredients	
Glycerin, hydrogen peroxide, water, oleic acid, stearic acid	


NOT TESTED ON ANIMALS

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**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: 80924-002-04

URIGEL 1000ML 80% ALCOHOL SANITIZER CREAM GEL

Drug Facts	
Active Ingredients	Purpose
Ethyl Alcohol 80%	Antiseptic
Use	
For hand washing to decrease bacteria on the skin	
Warnings	
For external use only Flammable, keep away from fire and flame.	
Do not use in the eyes	
Stop use and ask a doctor if <ul style="list-style-type: none"> ■ 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.	
Directions	
Wet hands thoroughly with product and allow to dry without wiping.	
Other information	
<ul style="list-style-type: none"> ■ Store between 59-86°F (15-30°C) ■ Avoid freezing and excessive heat above 104°F (40°C) 	
Inactive ingredients	
Glycerin, hydrogen peroxide, water, oleic acid, stearic acid	



NOT TESTED ON ANIMALS

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**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:80924-002-05

URIGEL 3750ML 80% ALCOHOL SANITIZER CREAM GEL



URIGEL
Inc

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**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)

Drug Facts	
Active Ingredients	Purpose
Ethyl Alcohol 80%	Antiseptic
Use	
For hand washing to decrease bacteria on the skin.	
Warnings	
For external use only	
Flammable, keep away from fire and flame.	
Do not use in the eyes	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> ■ 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.	
Directions	
Wet hands thoroughly with product and allow to dry without wiping.	
Other information	
<ul style="list-style-type: none"> ■ Store between 59-86°F (15-30°C) ■ Avoid freezing and excessive heat above 104°F (40°C) 	
Inactive ingredients	
Glycerin, hydrogen peroxide, water, oleic acid, stearic acid	


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3750ML/1GAL NDC: 80924-002-10

URIGEL 80% HAND SANITIZER CREAM GEL

alcohol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80924-002
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80924-002-01	3 mL in 1 PACKET; Type 0: Not a Combination Product	03/30/2020	
2	NDC:80924-002-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:80924-002-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:80924-002-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:80924-002-10	3750 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
6	NDC:80924-002-04	500 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 - URIGEL INC (117688244)

Registrant - URIGEL INC (117688244)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 1/2021

URIGEL INC