

URIGEL NEUTRO HAND SANITIZER GEL 80% - alcohol gel

Antisépticos de México, S.A. de C.V.

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 3.75ML/1GAL 80% ALCOHOL SANITIZER GEL

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 hand washing to decrease bacteria on the skin

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

- Wet hands thoroughly with product and allow to dry without wiping

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Glycerin, hydrogen peroxide, water USP. paraffin, carbopol 940



ANTISEPTIC HAND SANITIZER

80% Ethyl Alcohol

Neutro

Non-Sterile Topical Solution



126.8 fl oz (3.96 qt) (3.75 L)

Drug Facts	
Active ingredient	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.	


NOT TESTED ON ANIMALS

Distributed in USA by:
 Urigel, Inc.
 1800 W. Beverly Blvd., Ste 101
 Montebello, CA 90640

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 No:
 Best Before:


 850024787005

URIGEL NEUTRO HAND SANITIZER GEL 80%

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76554-375
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.8 mL in 0.8 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
PARAFFIN (UNII: I9O0E3H2ZE)	
WATER (UNII: 059QF0K00R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76554-375-10	3750 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

Labeler - Antisépticos de México, S.A. de C.V. (951576637)

Registrant - Antisépticos de México, S.A. de C.V. (951576637)

Establishment

Name	Address	ID/FEI	Business Operations
Antisépticos de México, S.A. de C.V.		951576637	manufacture(76554-375)

Revised: 1/2021

Antisépticos de México, S.A. de C.V.