

## **ANTIBACTERIAL ALCOHOL WIPES- alcohol cloth**

### **Urigel**

*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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### **Antibacterial Alcohol wipes 80U**

#### **Active Ingredient(s)**

EthylAlcohol 80%. Purpose: Antibacterial

#### **Purpose**

Antibacterial, Hand Sanitizer

#### **Use**

For handwashing to decrease bacteria on skin.

#### **Warnings**

For external use only. Flammable. Keep away from heat or flame

#### **Do not use**

- on children less than 2 months of age
- on open skin wounds
- over large areas of the body or if you are allergic to any of these ingredients.

When using this product avoid contact with eyes. If contact occurs, 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.

#### **Directions**

- To use, pull out wipe and reseal container to maintain moisture.
- Unfold cloth and rub thoroughly over all surfaces of both hands. Use only once and dispose of wipe in a trash receptacle.
- Do not flush.
- Rub hands together briskly to dry.


#### **Other information**

- Store between 59-86 °F (15-30 °C)
- Avoid freezing and excessive heat
- Dispose of contents/container responsibly




#### **Inactive ingredients**

Water, Glycerin.


# Principal Display Panel 450 units



7 81159 03087 1



# ANTIBACTERIAL ALCOHOL WIPES



**DELTA**  
CLINICAL SOLUTIONS  
BETTER HEALTH THROUGH RESEARCH

**KILLS 99.9%  
OF GERMS**

70.547 OZ (2.0 Kg)

**450  
WIPES**

**Safe of  
Hands**

7.5 x 5.9 IN (19 x 15 cm)

**Drug Facts**

Active Ingredient	Purpose
Ethylalcohol 70%	Antibacterial

**Uses**

- For handwashing to decrease bacteria on skin.

**Warnings**

For external use only

Flammable, keep away from heat or flame.

**Do not use**

- on children less than 2 months of age
- on open skin wounds
- over large areas of the body or if you are allergic to any of these ingredients.

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or redness occurs. This may be a sign of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- To use, pull out wipe and reseal container to maintain moisture.
- Unfold cloth and rub thoroughly over all surfaces of both hands. Use only once and dispose of wipe in a trash receptacle.
- Do not flush.
- Rub hands together briskly to dry.

**Other Information**

Store between 59-86 °F (15-30 °C)  
Avoid freezing and excessive heat  
Dispose of contents/container responsibly

**Inactive Ingredients**

Water, Glycerin

Produced and distributed by:  
Antisépticos de México, S.A. de C.V.  
Blvd. Ciro #1023 Col. Lomas del Mirador  
C.P. 37358 León, Guanajuato, México.

Made in Mexico

80 each Sanitizer Wipes

**URIGEL**  
Inc

ANTIBACTERIAL  
**ALCOHOL WIPES**

**KILLS 99.9% OF GERMS**  
13.05 OZ (370 g)

**80 WIPES**

**SAFE FOR HANDS**  
7.5 x 5.9 IN (19 x 15 cm)

**ANTIBACTERIALLY POWERED BY NATURE**

**ALCOHOL 80%**

**Drug Facts**

Active Ingredient(s)	Purpose
Ethylalcohol 70%	Antibacterial

**Uses**  
For handwashing to decrease bacteria on skin

**Warnings**  
**For external use only**  
Flammable. Keep away from heat or flame.

**Do not use**  
on children less than 2 months of age on open skin wounds over large areas of the body or if you are allergic to any of these ingredients.

**When using this product avoid contact with eyes.** If contact occurs, rinse eyes thoroughly with water.

**Stop use and ask a doctor if irritation or redness occurs.** This may be a sign of a serious condition.

**Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.**

**Directions**  
To use, pull out wipe and reseal container to maintain moisture. Unfold cloth and rub thoroughly over all surfaces of both hands. Use only once and dispose of wipe in a trash receptacle. Do not flush. Rub hands together briskly to dry.

**Other information**  
Store between 59-86 °F (15-30°C)  
Avoid freezing and excessive heat  
Dispose of contents/container responsibly

**Inactive Ingredients:**  
Water, Glycerin

**Manufactured by:**  
ANTIBIOTICOS DE MEXICO, S.A. DE CV  
Blvd. Olin 10219 Col. Lomas del Mirador  
C.P. 06702 Mexico City, Mexico  
Tel: 52-55-5252-2924

**24-hour attention: 1-800-285-2924**

**PRODUCT OF MEXICO**

**NOT FOR USE ON WOUNDS**  
Not for use on wounds - SCF  
Distribuidor en USA: URIGEL, INC.  
C/O American Supply, Inc. - Houston, TX  
C/O American Supply, Inc. - Houston, TX

6092411001

80 Each NDC: 80924-110-01

100 Each Sanitizer Wipes

**URIGEL**  
Inc

ANTIBACTERIAL RESEALABLE BY DESIGN

# ANTIBACTERIAL ALCOHOL WIPES

**KILLS 99.9% OF GERMS**  
18.56 OZ (410 g)

**100 WIPES**

**SAFE FOR HANDS**  
7.5 x 5.9 IN (19 x 15 cm)

**ALCOHOL 80%**

Active Ingredient(s)	Purpose
Ethylalcohol 70%	Antibacterial

**Uses:**  
For handwashing to decrease bacteria on skin.

**Warnings:**  
**For external use only.**  
Flammable, keep away from heat or flame.

**Do not use:**  
on children less than 2 months of age on open skin wounds over large areas of the body or if you are allergic to any of these ingredients.

**When using this product avoid contact with eyes.** If contact occurs, rinse eyes thoroughly with water.

**Stop use and ask a doctor if irritation or redness occurs.** This may be a sign of a serious condition.

**Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.**

**Directions:**  
To use, pull out wipe and reseal container to maintain moisture. Unfold cloth and rub thoroughly over all surfaces of both hands. Use only once and dispose of wipe in a trash receptacle. Do not flush. Rub hands together briskly to dry.

**Other information:**  
Store between 59-86 °F (15-30 °C). Avoid freezing and excessive heat. Dispose of contents/container responsibly.

**Inactive Ingredients:**  
Water, Glycerin

**NOT LISTED ON ANIMAL DRUGS LIST (NADA) - SFDI**  
Distributed in USA by: URIGEL, INC.  
8010 Calle 107 No. 107, Lomas del Mirador, San Juan, P.R. 00926

**Distributed in Mexico by:**  
URIGEL, S. de C.V.  
8010 Calle 107 No. 107, Lomas del Mirador, San Juan, P.R. 00926

**24 hour attention 1-800-255-3924**

**PRODUCT OF MEXICO**

8500247870258

100 Each NDC:80924-110-02

450 Sanitizer Wipes

**URIGEL**  
Inc.

**ANTIBACTERIAL ALCOHOL WIPES**

**KILLS 99.9% OF GERMS**  
70.54 OZ (2 kg)

**450 WIPES**

**SAFE FOR HANDS**  
7.5 x 5.9 IN (19 x 15 cm)

**ANTIBACTERIAL POWERED BY MOISTURE**

**ALCOHOL 80%**

**Drug Facts**

<b>Active Ingredient(s)</b>	<b>Purpose</b>
Ethylalcohol 70%.....	Antibacterial
<b>Use</b>	
For handwashing to decrease bacteria on skin	
<b>Warnings</b>	
For external use only	
Flammable, keep away from heat or flame.	
Do not use	
on children less than 2 months of age on open skin wounds over large areas of the body or if you are allergic to any of these ingredients.	
When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or redness occurs. This may be a sign of a serious condition.	
Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
To use, pull out wipe and reseal container to maintain moisture	
Unfold cloth and rub thoroughly over all surfaces of both hands. Use only once and dispose of wipe in a trash receptacle. Do not flush.	
Rub hands together briskly to dry.	
<b>Other information</b>	
Store between 59-86 °F (15-30°C)	
Avoid freezing and excessive heat	
Dispose of contents/container responsibly	
<b>Inactive Ingredients:</b>	
Water, Glycerin	

**NOT TESTED ON ANIMALS**

**Distributed in Mexico by:**  
URIGEL, INC.  
Boulevard de la Industria 10219, Col. Lomas del Mirador,  
C.P. 06308, Tel. 477 103 55 47  
URIGEL, S de RL  
Calle de la Industria 10219, Col. Lomas del Mirador,  
C.P. 06308, Tel. 477 103 55 47

**24-hour attention 1-800-255-8924**

**PRODUCT OF MEXICO**

508047870265

450 Each NDC:80924-110-03

## ANTIBACTERIAL ALCOHOL WIPES

alcohol cloth

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80924-110
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80924-110-03	450 g in 1 CANISTER; Type 0: Not a Combination Product	10/30/2020	
2	NDC:80924-110-01	80 g in 1 CANISTER; Type 0: Not a Combination Product	10/01/2020	
3	NDC:80924-110-02	100 g in 1 CANISTER; Type 0: Not a Combination Product	10/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/01/2020	

**Labeler** - Urigel (117688244)

**Registrant** - Urigel Inc (117688244)

## Establishment

Name	Address	ID/FEI	Business Operations
Antisépticos de México, S.A. de C.V.		951576637	manufacture(80924-110)

Revised: 1/2021

Urigel