

**AQUA GEL- alcohol gel**  
**AD MEDIOS, 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.*

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**Active Ingredient(s)**

Alcohol 70% 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**

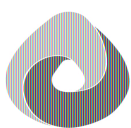


- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

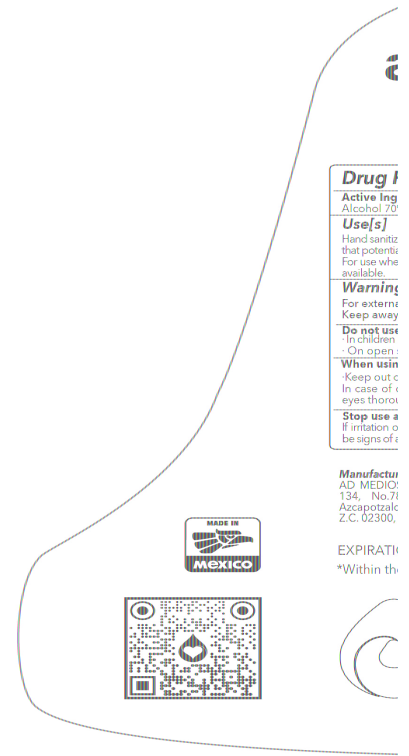
polyacrylic acid (Carbomer), triethanolamine (Trolamine), water

20 L NDC: 77739-001-01

20 L NDC: 77739-001-01

<p style="text-align: center;">aquaMEDIC</p>  <h1 style="text-align: center;">AquaGel™</h1> <h2 style="text-align: center;">HAND SANITIZER</h2> <p style="text-align: center;">TOTAL BALANCED Non-sterile solution</p> <ul style="list-style-type: none"><li> 70% ethyl alcohol</li><li> Methanol free*</li><li> Fragrance free</li></ul> <p style="text-align: center; border: 1px solid black; border-radius: 15px; padding: 5px;"><b>5.28 gal (20 L)</b></p>	<p><b>Drug Facts</b></p> <p><b>Active Ingredient(s).....Purpose</b> Alcohol 70% v/v.....Antiseptic</p> <p><b>Use[s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p><b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.</p> <p><b>Do not use</b> · In children less than 2 months of age. · On open skin wounds.</p> <p><b>When using this product</b> · Keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p><b>Stop use and ask a doctor</b> If irritation or rash occurs. These may be signs of a serious condition.</p> <p><b>Keep out of reach of children</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><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.</p> <p><b>Other information</b> · Store between 15-30°C (59-86°F) · Avoid freezing and excessive heat above 40°C (104°F)</p> <p><b>Inactive ingredients</b> Polyacrylic acid (Carbomer), triethanolamine (Trolamine), water.</p>	<p><b>Manufactured by:</b> AD MEDIOS S.A. de CV, Por 134, No.786, Industrial V, Azcapotzalco, Ciudad de México, Z.C. 02300, Mexico.</p> <p style="text-align: center;">PRODUCT OF MEXICO</p> <p style="text-align: center;"><b>aquaMEDIC</b></p> <p>*Within the percentage allowed (USP) (FEUM)</p> <div style="display: flex; justify-content: space-around;"></div> <p style="text-align: center;">H319</p> <div style="display: flex; justify-content: space-around;"></div> <p style="text-align: center;">EXPIRATION DATE AND BATCH NUMBER ON THE PACKAGE</p>  <p style="text-align: center;">7 506497 5001</p>
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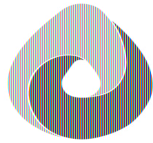
3780 mL NDC: 77739-001-02



3780 mL NDC: 77739-001-02

**1L NDC: 77739-001-04**

aquaMEDIC

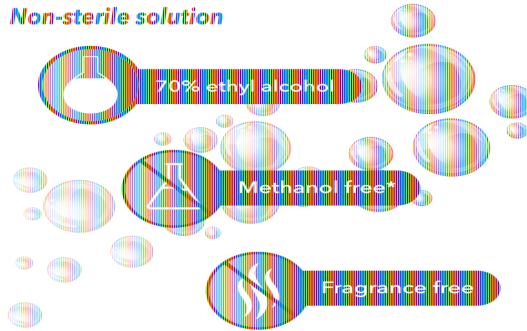


# AquaGel™

## HAND SANITIZER

TOTAL BALANCED

Non-sterile solution



33.81 fl oz (1,000 ml)

### Drug Facts

**Active Ingredient[s].....Purpose**  
Alcohol 70% v/v.....Antiseptic

#### Use[s]

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.

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

#### Inactive ingredients

Polyacrylic acid (Carbomer), triethanolamine (Trolamine), water.

500 mL NDC: 77739-001-05

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# AquaGel™

## HAND SANITIZER

TOTAL BALANCED  
Non-sterile solution



70% ethyl alcohol



Methanol free\*



Fragrance free

**16.91 fl oz (500 ml)**

**Drug Facts**

**Active Ingredient(s).....Purpose**  
Alcohol 70% v/v.....Antiseptic

**Use[s]**  
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.

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

**Inactive ingredients**  
Polyacrylic acid (Carbomer), triethanolamine (Trolamine), water.

**Manufactur**  
AD MEDIO  
134, No.7E  
Azcapotzal  
Z.C. 02300, I

PROD

**aqu**

\*Within the  
(USP) (FEUM)



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


EXPIRATIC  
NUMBER



7 5064

500 mL NDC: 77739-001-05

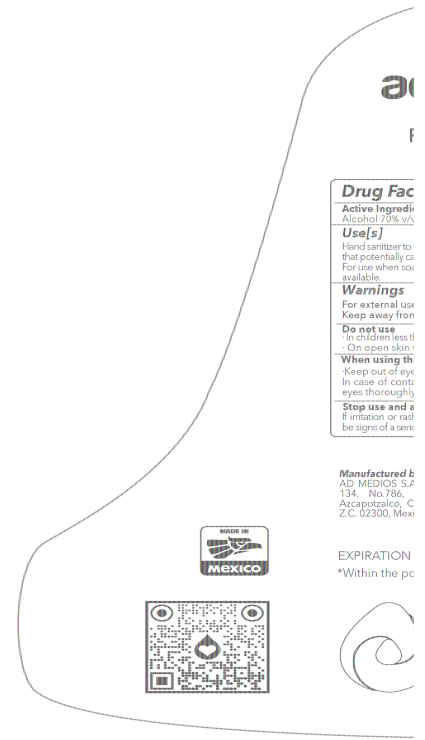
250 mL NDC: 77739-001-06

<p>aquaMEDIC</p>  <p><b>AquaGel™</b> <b>HAND SANITIZER</b></p> <p>TOTAL BALANCED Non-sterile solution</p>  <p>70% ethyl alcohol</p>  <p>Methanol free*</p>  <p>Fragrance free</p> <p><b>8.45 fl oz (250 ml)</b></p>	<p><b>Drug Facts</b></p> <p><b>Active Ingredient[s].....Purpose</b> Alcohol 70% v/v.....Antiseptic</p> <p><b>Use[s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p><b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.</p> <p><b>Do not use</b> - In children less than 2 months of age. - On open skin wounds.</p> <p><b>When using this product</b> Keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p><b>Stop use and ask a doctor</b> If irritation or rash occurs. There may be signs of a serious condition.</p>	<p><b>Keep out of reach of children</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> - Place enough product on to cover all surfaces. - Rub hands together until dry. - Supervise children under 6 of age when using this product to avoid swallowing.</p> <p><b>Other information</b> - Store between 15-30°C (59-86°F) - Avoid freezing and excessive heat above 40°C (104°F)</p> <p><b>Inactive ingredients</b> Polyacrylic acid (Carbopol), triethanolamine (Trolamine),</p>
	<p><b>Manufactured by:</b> AD MEDIOS S.A. de CV, Poniente 134, No.786, Industrial Vallejo, Azcapotzalco, Ciudad de Mexico, Z.C. 02300, Mexico.</p> <p>PRODUCT OF MEXICO</p> <p>EXPIRATION DATE AND BATCH NUMBER ON THE PACKAGING *Within the percentage allowed in (USP) (FEUM)</p>	   

250 mL NDC: 77739-001-06

5L NDC: 77739-001-12

5L NDC: 77739-001-12




**Drug Facts**  
**Active Ingredients**  
Alcohol 70% v/v  
**Use[s]**  
Hand sanitizer to  
that potentially ca  
For use when spe  
available.  
**Warnings**  
For external use  
Keep away from  
**Do not use**  
- In children less th  
- On open skin  
**When using th**  
- Keep out of eye  
In case of cont  
eyes thoroughly  
**Stop use and a**  
if irritation or rasi  
be signs of a seri

**Manufactured b**  
AD MEDIOS S.  
134, No. 786,  
Ascapotzalco, C  
Z.C. 02300, Mexi

**EXPIRATION**  
\*Within the pc

125 mL NDC: 77739-001-08

**aquaMEDIC**



# AquaGel™

## HAND SANITIZER



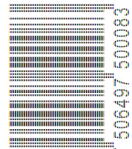
*TOTAL BALANCED*  
**Non-sterile solution**

70% ethyl alcohol

Methanol free\*

Fragrance free


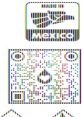

**4.23 fl oz (125 ml)**

<p><b>Drug Facts</b></p> <p><b>Active Ingredient[s].....Purpose</b> Alcohol 70% v/v.....Antiseptic</p> <p><b>Use[s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p><b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.</p> <p><b>Do not use</b> - In children less than 2 months of age. - On open skin wounds.</p> <p><b>When using this product</b> - Keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p><b>Stop use and ask a doctor</b> If irritation or rash occurs. These may be signs of a serious condition.</p> <p><b>Manufactured by:</b> AD MEDIOS S.A. de CV, Poniente 134, No.786, Industrial Vallejo, Azcapotzalco, Ciudad de Mexico, Z.C. 02300, Mexico.</p> <p style="text-align: center;">PRODUCT OF MEXICO</p> <p style="text-align: center;">EXPIRATION DATE AND BATCH NUMBER ON THE PACKAGE</p> <p style="text-align: center;">*Within the percentage allowed in (USP) (FEUM)</p>	<p><b>Keep out of reach of children</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><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.</p> <p><b>Other information</b> - Store between 15-30°C (59-86°F) - Avoid freezing and excessive heat above 40°C (104°F)</p> <p><b>Inactive ingredients</b> Polyacrylic acid (Carbomer), triethanolamine (Trolamine), water.</p> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">   </div> <div style="text-align: center;">  <p>7 506497 50083</p> </div> </div>
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125 mL NDC: 77739-001-08



60 mL NDC: 77739-001-09

<p>aquaMEDIC</p>  <p><b>AquaGel™</b> <b>HAND SANITIZER</b></p> <p>TOTAL BALANCED Non-sterile solution</p> <p>70% ethyl alcohol</p> <p>Methanol free*</p> <p>Fragrance free</p> <p><b>2.03 fl oz (60 ml)</b></p>	<p><b>Drug Facts</b></p> <p><b>Active ingredient[s].....Purpose</b> Alcohol 70% v/v.....Antiseptic</p> <p><b>Use[s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p><b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.</p> <p><b>Do not use</b> - In children less than 2 months of age. - On open skin wounds.</p> <p><b>When using this product</b> - Keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p><b>Stop use and ask a doctor</b> If irritation or rash occurs. These may be signs of a serious condition.</p> <p><b>Manufactured by:</b> AD MEDIOS S.A. de CV, Poniente 134, No.786, Industrial Vallejo, Azcapotzalco, Ciudad de Mexico, Z.C. 02300, Mexico.</p> <p><b>PRODUCT OF MEXICO</b></p> <p>EXPIRATION DATE AND BATCH NUMBER ON THE PACKAGE *Within the percentage allowed in (USP) (FEUM)</p>	<p><b>Keep out of reach of children</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><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.</p> <p><b>Other information</b> -Store between 15-30°C (59-86°F) -Avoid freezing and excessive heat above 40°C (104°F)</p> <p><b>Inactive ingredients</b> Polyacrylic acid (Carbomer), triethanolamine (Trolamine), water.</p>   <p>7 506497 500090</p>
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60 mL NDC: 77739-001-09

200L NDC: 77739-001-10

**aquaMEDIC**



# AquaGel™

## HAND SANITIZER

*TOTAL BALANCED*  
Non-sterile solution

70% ethyl alcohol

Methanol free\*

Fragrance free

**52.83 gal (200 L)**

**Drug Facts**

**Active Ingredient(s).....Purpose**  
Alcohol 70% v/v.....Antiseptic

**Use[s]**  
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**  
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**Directions**  
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Rub hands together until dry.  
· Supervise children under 6 years of age when using this product to avoid swallowing.

**Other information**  
· Store between 15-30°C (59-86°F)  
· Avoid freezing and excessive heat above 40°C (104°F)

**Inactive ingredients**  
Polyacrylic acid (Carbomer), triethanolamine (Trolamine), water.

**Manufactured by:**  
AD MEDIOS S.A. de CV, Por 134, No.786, Industrial V Azcapotzalco, Ciudad de M Z.C. 02300, Mexico.

PRODUCT OF MEXICO

**aquaMEDIC**

\*Within the percentage allow (USP) (FEUM)



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EXPIRATION DATE AND BATCH NUMBER ON THE PACKAGE



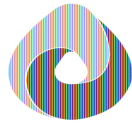
7 506497 50015

200L NDC: 77739-001-10

1000L 77739-001-11

1000L 77739-001-11

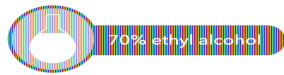
aquaMEDIC



# AquaGel™

## HAND SANITIZER

TOTAL BALANCED  
Non-sterile solution



264.17 gal (1,000 L)

### Drug Facts

**Active Ingredient[s].....Purpose**  
Alcohol 70% v/v.....Antiseptic

#### Use[s]

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.

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

#### Inactive ingredients

Polyacrylic acid (Carbomer), triethanolamine (Trolamine), water.

**Manufactured by:**  
AD MEDIOS S.A. de CV, Poni 134, No.786, Industrial Val Azcapotzalco, Ciudad de Mexico, Z.C. 02300, Mexico.

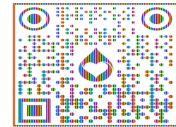
PRODUCT OF MEXICO

aquaMEDIC

\*Within the percentage allowed (USP) (FEUM)



H319



EXPIRATION DATE AND BATCH NUMBER ON THE PACKAGING



7 506497 50016

## AQUA GEL

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77739-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.03 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	28.97 mL in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77739-001-01	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
2	NDC:77739-001-02	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
3	NDC:77739-001-04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
4	NDC:77739-001-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
5	NDC:77739-001-06	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
6	NDC:77739-001-08	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
7	NDC:77739-001-09	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
8	NDC:77739-001-10	200000 mL in 1 CONTAINER; Type 0: Not a Combination Product	06/02/2020	
9	NDC:77739-001-11	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	06/02/2020	
10	NDC:77739-001-12	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/28/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/02/2020	

**Labeler** - AD MEDIOS, S.A. DE C.V. (814581377)

**Registrant** - AD MEDIOS, S.A. DE C.V. (814581377)

## Establishment

Name	Address	ID/FEI	Business Operations
AD MEDIOS S.A. DE C.V.		814581377	manufacture(77739-001)

Revised: 1/2021

AD MEDIOS, S.A. DE C.V.