AD 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.

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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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, polyacrylic acid (Carbomer), triethanolamine (trolamine), Water.

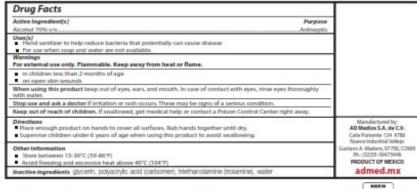
Package Label - Principal Display Panel

500 mL NDC: 77739-002-01









LOT No.: BEST BEFORE:



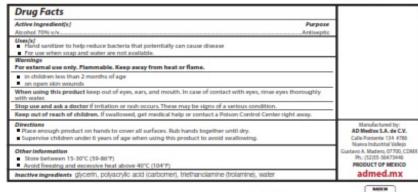
127.9 fl oz (3.785 L)



676.2 fl oz (20 L)







LOT No.: BEST BEFORE:



6762.80 fl oz (200 L)





8.45 fl oz (250ml)

250 mL NDC: 77739-002-06

AD GEL

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77739-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients					
Ingredient Name	Strength				
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.35 mL in 100 mL				
GLYCERIN (UNII: PDC6A3C0OX)	1.5 mL in 100 mL				
TROLAMINE (UNII: 9O3K93S3TK)	0.25 mL in 100 mL				
WATER (UNII: 059QF0KO0R)	27.9 mL in 100 mL				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:77739-002- 01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020			
2	NDC:77739-002- 02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020			
3	NDC:77739-002- 03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020			
4	NDC:77739-002- 04	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020			
5	NDC:77739-002- 05	200000 mL in 1 CONTAINER; Type 0: Not a Combination Product	06/02/2020			
6	NDC:77739-002- 06	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020			
	NDC-77720 002					

7 07	60 mL in 1 BOTTLE; Type 0: Not a Combina	tion Product 06/02/2020			
Marketing Information					
Marketing Catego	ry Application Number or Monogra	ph Citation Marketing Start Date I	Marketing End Date		
OTC monograph not fi	nal 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.		8 1458 1377	manufacture(77739-002)		

Revised: 12/2020 AD MEDIOS, S.A. de C.V.