GTM GEL- isopropyl alcohol gel GTM Costa Rica Sociedad Anonima

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.

GTM Gel

DRUG FACTS

Active Ingredient

Isopropyl Alcohol 70%

Purpose

Antimicrobial

Use

To decrease bacteria on surfaces or on the skin. For use when soap and water are not available.

WARNINGS

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

When using this product

• Do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor

• If irritation or rash appears.

Keep out of reach of children

• If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• Place enough product on the Surface with a towel or hands and rub briskly until dry. Children under 6 years of age should be supervised when using this product

Other information

• Store below 86°F (30°C). May discolor certain fabrics or surfaces. Harmful to Wood finishes and plastics.

Inactive Ingredients

• Water, Tylose, Glycerin.

Package Labeling:



DRUG FACTS 2

Active Ingredient Purpose
Isopropyl Alcohol 70%......Antimicrobial

Use • To decrease bacteria on surfaces or on the skin. For use when soap and water are not available.

WARNINGS

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

When using this product • Do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor • If irritation or rash appears.

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

Directions • Place enough product on the Surface with a towel or hands and rub briskly until dry. Children under 6 years of age should be supervised when using this product.

Other information • Store below 86°F (30°C). May discolor certain fabrics or surfaces. Harmful to Wood finishes and plastics.

Inactive Ingredients • Water, Tylose, Glycerin.

Packaged and Distributed by GTM International Houston, Texas Tel. +1 713 993 0900

Manufactured by GTM Costa Rica S.A San Jose Costa Rica Tel. (+506) 2537-0010



GTM GEL

isopropyl alcohol gel

Product Type HUMAN OTC DRUG Item Code (Source) NDC:79859-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

reave ingredient/reave inforces			
Ingredient Name	Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
TYLOSEMA ESCULENTUM WHO LE (UNII: 5M1OL152FO)			
GLYCERIN (UNII: PDC6A3C0OX)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
#	Item Code	Package Description	Marketing Start Date	Marketing En

1 NDC:79859-001-00 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product 07/01/2020

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/01/2020	

Labeler - GTM Costa Rica Sociedad Anonima (853075281)

Revised: 8/2020 GTM Costa Rica Sociedad Anonima