

IVGEL HAND SANITIZER- alcohol gel
Vago International Manufacturing SA de CV

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.

IVGEL Hand Sanitizer, 1000mL

IVGEL Drug Fact Chart

Active ingredients:

Ethyl Alcohol at 70%

Purpose

Antiseptic

Uses:

Hand Sanitizer to help reduce germs. For use when soap and water not available.

Warnings:

For external use only, Flammable. Keep away from open flame and sources of 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 of serious condition

Stop use and ask doctor:

If a 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:

Apply a small amount of product into hands and rub between both side of hands until dry. Supervise children under 6 years of age when using this product to avoid swallowing.

Other information:

Store below 110 °F (43 °C). Avoid freezing. May discolor certain fabrics or surface.

Inactive Ingredients:

Water, Glycerin, Carbopol, Trithanolamine

Package Labeling:

ivgel

Hand Sanitizer
Non Sterile Solution

- **Alcohol antiseptic 70%**
- **Topical solution**

Ingredients:

**Ethyl alcohol, Water, Glycerine,
Carbopol, Triethanolamine**

1000 ml (33.8 fl. oz.)

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Purpose: Antiseptic

Uses: Hand Sanitizer to help reduce germs.
For use when soap and water not available.

Warning: For external use only, Flammable. Keep away
from open flame and sources of 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 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: Apply a small amount of product into hands
and rub between both sides of hands until dry.
Supervise children under 6 years of age when
using this product to avoid swallowing.

Other information: Store below 110oF (43oC).
Avoid freezing. May discolor certain fabrics or surfaces.

Inactive Ingredients: Water, Glycerine, Carbopol,
Triethanolamine.

Bottled and packaged by:
WALCANTHUS PHARMACEUTICALS, INC.
10000 W. 10TH AVE., SUITE 1000
DENVER, CO 80202
Contact Us:
call@ivgel.com



IVGEL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74967-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74967-000-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/15/2020	

Labeler - Vago International Manufacturing SA de CV (589993745)

Revised: 5/2020

Vago International Manufacturing SA de CV