

ISOPROPYL ALCOHOL- isopropyl alcohol liquid CDMA

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.

Drug Facts Quality Choice 845.003/845AE

Active ingredients

Isopropyl alcohol 70%

Purpose

First aid antiseptic

Use

first aid to help prevent the risk of infection in:

- minor cuts
- scrapes
- burns

Warnings

For external use only. If taken internally serious gastric disturbances will result.

Flammable

- keep away from fire or flame, heat, spark, electrical

Ask a doctor

before use for deep or puncture wounds, animal bites or serious burns

When using this product

- do not get into eyes
- do not inhale
- do not apply over large areas of the body
- do not use longer than 1 week

Stop use

and ask a doctor if condition persists or gets worse

Keep out of reach of children

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

Caution

Fumes can be acutely irritating to skin, eyes and the respiratory system. Do not apply to irritated skin or if excessive irritation develops. Avoid getting into the eyes or on mucous membranes. Avoid inhaling this product.

Directions

- clean the affected area
- apply a small amount of this product on the area 1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

Other information

- does not contain, nor is intended as a substitute for grain or ethyl alcohol
- will product serious gastric disturbances if taken internally

Inactive ingredients

blue 1, glycerin, methyl salicylate, water, yellow 5

ADVERSE REACTIONS SECTION

Distributed by C.D.M.A, Inc

4.157 W 9 Mile Rd, Novi, MI 48375

www.qualitychoice.com Questions: 800-935-2362

principal display panel

QC

QUALITY

CHOICE

70%

Isopropyl

Alcohol

With Wintergreen

& Glycerin

First Aid Antiseptic

For Treatment of Minor

Cuts and Scrapes

WARNING

FLAMMABLE - Keep away from heat, spark, electrical, fire or flame

Use only in a well-ventilated area: fumes can be harmful.

CAUTION: Do not point at self or others; product will squirt when squeezed.

16 fl oz (473 mL)



ISOPROPYL ALCOHOL

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-153
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	924 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
WATER (UNII: 059QF0K00R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-153-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	03/08/2019	

Labeler - CDMA (011920774)**Registrant** - Vi-Jon, LLC (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(63868-153)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(63868-153)

