ISOPROPYL RUBBING ALCOHOL 50% WITH WINTERGREEN- isopropyl alcohol liquid
Universal Distribution Center LLC

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.

Isopropyl Rubbing Alcohol 50% with Wintergreen

Active Ingredients (by volume)

Isopropyl alcohol (50% conc.)

Purpose

First aid antiseptic

Uses

- first aid to help prevent the risk of infection in minor cuts, scrapes and burns

Warnings

For external use only; flammable, keep away from fire or flame, heat, spark, electrical

Ask a doctor before use if you have

- deep punctured wounds, animal bites or serious burns

When using this product

- do not get into eyes
- do not apply over large areas of the body
- do not use longer than one week unless directed by a doctor

Stop using this product if

- condition persists or gets worse

Keep this and all drugs out of the reach of children

In case of accidental ingestion, seek professional assistance or contact a Poison control center (1-800-222-1212) immediately

Directions

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

Other information

- store at room temperature
- does not contain, nor is intended as a substitute for grain or ethyl alcohol
- will produce serious gastric disturbances if taken internally

Inactive Ingredients

Water(Aqua), Methyl Salicylate, FD&C Blue #1, FD&C Yellow #5

PRINCIPAL DISPLAY PANEL

ISOPROPYL RUBBING ALCOHOL 50% WITH WINTERGREEN
FIRST AID ANTISEPTIC
12 FL.OZ (355 mL)

Isopropyl rubbing alcohol
50% by volume

Drug Facts

Active ingredients (by volume): ***Purpose***
Isopropyl alcohol
(50% conc.).....first aid antiseptic

Uses ■ first aid to help prevent the risk of infection in minor cuts, scrapes and burns

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Directions
■ clean effected area
■ apply small amount of this product on the area 1-3 times daily
■ May be covered with a sterile bandage
■ If bandaged, let dry first

Other information
■ store at room temperature
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Inactive Ingredient Water(Aqua),Methyl Salicylate, F D&C Blue #1,FD &C Yellow #5.

TAMPER EVIDENT: DO NOT USE IF THE UNDER CAP SAFETY FOIL IS BROKEN OR MISSING.

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Made in India

Distributed by: Universal Distribution Center
96 Distribution Boulevard • Edison, NJ 08817

ISOPROPYL RUBBING ALCOHOL 50% WITH WINTERGREEN
isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52000-051
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	50 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-051-01	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/20/2020	
2	NDC:52000-051-02	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/20/2020	
3	NDC:52000-051-03	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/20/2020	
4	NDC:52000-051-04	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/20/2020	
5	NDC:52000-051-05	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/20/2020	
6	NDC:52000-051-06	414 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/20/2020	
7	NDC:52000-051-07	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/20/2020	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations

Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52000-051)