ISOPROPYL RUBBING ALCOHOL 50% WITH WINTERGREEN- isopropyl alcohol liquid My Imports USA, 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.

American Redcross ISOPROPYL RUBBING ALCOHOL 50% WITH WINTERGREEN Active ingredient (by volume)

Isopropyl alcohol (50% concentrate)

Purpose

topical antimicrobial

Uses

- to decrease germs in minor cuts and scrapes
- helps relieve minor muscular aches due to exertion

Warnings

For external use only

- flammable, keep away from fire and flame
- will produce serious gastric disturbances if taken internally

Ask a doctor before use if you have deep puncture wounds or serious burns

When using this product

- do not get into eyes or mucous membranes
- use only in a well-ventilated area

Stop use and ask a doctor if condition persists or gets worse

Keep out of reach of children.

In case of an accidental ingestion, contact a Poison Control Center immediately

Directions

- apply to skin directly of with clean gauze, cotton or swab
- for rubbing apply liberally and rub with hands

Other information

- does not contain, nor is intended as a substitute for grain or ethyl alcohol
- keep bottle tightly closed

Inactive ingredient

Water, methyl salicylate, FD&C Blue #1, FD&C Yellow #5



ISOPROPYL RUBBING ALCOHOL 50% WITH WINTERGREEN

isopropyl alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51628-4233	
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:51628- 4233-1	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
2	NDC:51628-	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a	06/18/2020	

1	4233-2	Combination Product	UU/ 10/ 2U 2 U	
3	NDC:51628- 4233-3	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
art333A	06/18/2020			
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date		

Labeler - My Imports USA, LLC (195767988)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(51628-4233)	

Revised: 2/2022 My Imports USA, LLC