ISOPROPYL RUBBING ALCOHOL 99% WITH WINTERGREEN- is opropyl alcohol liquid Home Smart Products

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.

HEALTH SMART ISOPROPYL RUBBING ALCOHOL 99% WITH WINTERGREEN

Active ingredient (by volume)

Isopropyl alcohol (99% 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, laneth-75, FD&C Blue #1, FD&C Yellow #5

PRINCIPAL DISPLAY PANEL

HEALTH SMART ISOPROPYL RUBBING ALCOHOL 99% WITH WINTERGREEN TOPICAL ANTIMICROBIAL

12 FL.OZ (354 mL)





Drug Facts

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Inactive Ingredient: Water, Methyl Salicylate, Laneth-75, FD&C Blue #1, FD&C Yellow #5

MADE IN INDIA • DISTRIBUTED BY: HOME SMART PRODUCTS • ALLEN PARK, MI



ISOPROPYL RUBBING ALCOHOL 99% WITH WINTERGREEN

isopropyl alcohol liquid

l	Product Information				
l	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52862-026	

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -	ISOPROPYL ALCOHOL	99 mL		

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
METHYL SALICYLATE (UNII: LAV5U5022Y)				
PEG-75 LANOLIN (UNII: 09179 O X7TB)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
1220 1220 1100 (0121230 11221 113)				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:52862-026- 03	119 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020		
2	NDC:52862-026- 04	178 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020		
3	NDC:52862-026- 06	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020		
4	NDC:52862-026- 09	295 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020		

NDC:52862-026- 10	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
NDC:52862-026- 11	414 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
7 NDC:52862-026- 12	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/18/2020		

Labeler - Home Smart Products (161872676)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment			
Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52862-026)

Revised: 6/2020 Home Smart Products