AMERICAN REDCROSS 91% ISOPROPYL RUBBING ALCOHOL 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 RED CROSS 91% ISOPROPYL RUBBING ALCOHOL WITH WINTERGREEN

Active ingredient (by volume)

Isopropyl alcohol (70% 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

PRINCIPAL DISPLAY PANEL



AMERICAN REDCROSS 91% ISOPROPYL RUBBING ALCOHOL WITH WINTERGREEN

isopropyl alcohol liquid

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51628-4237 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|--|----------------------|--------------------|
| Ingredient Name | Basis of Strength | Strength |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 91 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 |
| ١, | NDC:51628- | 355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a | 00/11/2020 | |

| 1 | 4237-1 | Combination Product | UO/ 11/2U2U | |
|---|----------------------|--|-------------|--|
| 2 | NDC:51628- 4237-2 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/11/2020 | |
| 3 | NDC:51628- 4237-4 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/11/2020 | |

| Marketing Information | | | |
|-------------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 08/11/2020 | |
| illiai | | | |

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(51628-4237) |

Revised: 4/2022 MY IMPORTS USA LLC