

LUXURY ANTISEPTIC WITH WINTERGREEN- isopropyl alcohol solution
TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI

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.

Luxury 70% Isopropyl Alcohol- with Wintergreen

Active ingredient

Isopropyl Alcohol 70%

Purpose

First Aid Antiseptic

Uses

First aid to help prevent the risk of infection in:

- minor cuts
- scrapes
- burns

Warnings

For external use only.

If taken internally serious gastric

Flammable. Keep away from fire or flame, heat, spark, electrical.

Ask a doctor before use if you have deep 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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

Inactive ingredient

purified water, FD&C green #3, FD&C yellow #5, methyl salicylate

Principal Display Panel



LUXURY ANTISEPTIC WITH WINTERGREEN

isopropyl alcohol solution

| Product Information | | | | |
|--|---|---|-----------------------------|---------------------------|
| Product Type | | HUMAN OTC DRUG | Item Code (Source) | |
| Route of Administration | | TOPICAL | NDC:76772-036 | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | | | ISOPROPYL ALCOHOL | 70 mL in 100 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) | | | | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | | | | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:76772-036-35 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/10/2021 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | | 03/10/2021 | |

Labeler - TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

Registrant - TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|------------------------|
| TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI | | 533120570 | manufacture(76772-036) |

Revised: 1/2022

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