

ALCOHOL- isopropyl alcohol liquid
Blossom Pharmaceuticals

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.

Alcohol 70%

| Active Ingredient | Purpose |
|---------------------------|------------|
| Isopropyl Alcohol 70% v/v | Antiseptic |

PURPOSE

First aid to help prevent the risk of infection in:

- minor cuts
- scrapes
- burns

WARNINGS

- **For external use only**
- Flammable, keep away from fire or flame, heat, spark, electrical.
- Not for use with electrocautinary devices or procedures
- **Ask a doctor before use if you have** deep puncture wounds, animal bites or serious burns.
- **Stop use and ask a doctor if** condition persist or gets worse.

For rubbing and massaging:

- **Caution:** Do not apply to irritated skin or if excessive irritation develops
- Avoid getting into eyes or mucous membranes

INDICATIONS & USAGE

When using this product:

- do not get in eyes
- do not apply over large areas of the body
- do not use longer than 1 week unless directed by a doctor

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

DOSAGE & ADMINISTRATION

DIRECTIONS:

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

OTHER INFORMATION

- Store at room temperature: 15 deg C to 30 deg C 59 deg F to 86 deg F
- avoid excessive heat
- Does not contain, nor is it intended as a substitute for grain or ethyl alcohol
- Will produce serious gastric disturbances if taken internally

INACTIVE INGREDIENT

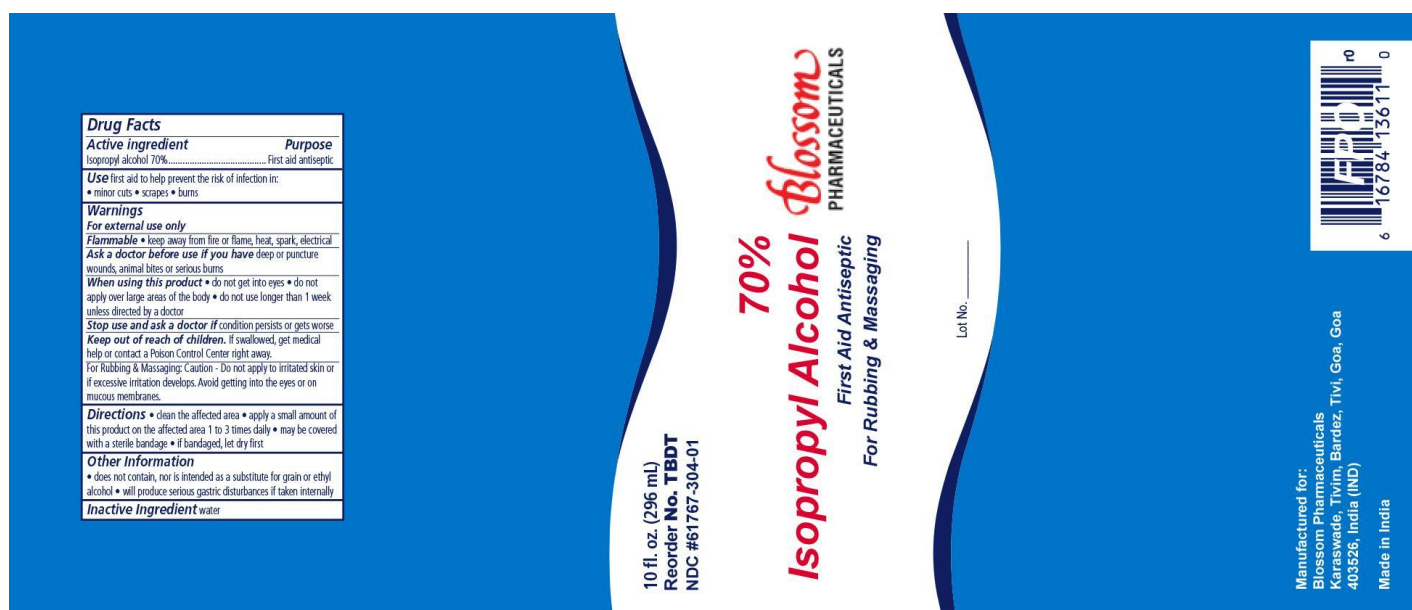
Inactive Ingredient

- Water

PRINCIPAL DISPLAY PANEL

DYNAREX 70% ISOPROPYL ALCOHOL

70 IPA BP.jpg



ALCOHOL

isopropyl alcohol liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61767-304 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 0.7 mL in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
| | |

WATER (UNII: 059QF0KO0R)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:61767-304-01 | 473 mL in 1 BOTTLE | | |
| 2 | NDC:61767-304-02 | 295 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 01/29/2014 | |

Labeler - Blossom Pharmaceuticals (677381470)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| Blossom Pharmaceuticals | | 677381470 | manufacture(61767-304) |

Revised: 1/2014

Blossom Pharmaceuticals