

ISOPROPYL ALCOHOL- isopropyl alcohol solution
Fougera Pharmaceuticals Inc.

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.

Isopropyl Alcohol Antiseptic 75% Topical Solution

Drug Facts

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only USP grade ingredients in the preparation of the product, consistent with World Health Organization (WHO) recommendations.

The firm does not add other active or inactive ingredients.

Active ingredient(s)

Isopropyl alcohol 75% v/v

Purpose

Antiseptic

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame.

Do Not Use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep Out of Reach of Children

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

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.

- Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

- Store between 15° to 30°C (59° to 86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients

glycerin, hydrogen peroxide, purified water USP.

Package/Label Principal Display Panel - 60mL Bottle

NDC 0168-0907-60

E.FOUGERA & CO.

A division of Fougera Pharmaceuticals Inc.

Isopropyl Alcohol Antiseptic 75% Topical Solution

Hand Sanitizer

Non-sterile Solution

60 mL

NDC 0168-0907-60

**Isopropyl Alcohol
Antiseptic 75%
Topical Solution**

46267932A R04/2020 fougera®

**Hand Sanitizer
Non-sterile Solution**

E. FOUGERA & CO.
A division of Fougera Pharmaceuticals Inc.
Melville, New York 11747 **60 mL**

3 0168-0907-60 4

| Drug Facts | Purpose |
|---|----------------|
| Active ingredient[s] Isopropyl alcohol 75% v/v..... | Antiseptic |
| Use[s] Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. | |
| Warnings For external use only. Flammable. Keep away from heat or flame | |
| Do not use ■ in children less than 2 months of age ■ on open skin wounds | |
| When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. | |
| Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| Directions ■ Place enough product on hands to cover all surfaces. Rub hands together until dry. ■ Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other information ■ Store between 15° to 30°C (59° to 86°F) ■ Avoid freezing and excessive heat above 40°C (104°F) | |
| Inactive ingredients glycerin, hydrogen peroxide, purified water USP | |

ISOPROPYL ALCOHOL

isopropyl alcohol solution

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0168-0907 |
|---------------------|----------------|---------------------------|---------------|

| | |
|--------------------------------|---------|
| Route of Administration | TOPICAL |
|--------------------------------|---------|

| Active Ingredient/Active Moiety | | |
|---|--------------------------|-------------------|
| Ingredient Name | Basis of Strength | Strength |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 75 mL in 60 mL |

| Inactive Ingredients | |
|---|-----------------|
| Ingredient Name | Strength |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | |
| WATER (UNII: 059QF0K00R) | |

| Packaging | | | | |
|------------------|------------------|--|-----------------------------|---------------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0168-0907-60 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/15/2020 | |

| Marketing Information | | | |
|------------------------------|---|-----------------------------|---------------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 05/15/2020 | |

Labeler - Fougera Pharmaceuticals Inc. (043838424)

| Establishment | | | |
|------------------------------|----------------|---------------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Fougera Pharmaceuticals Inc. | | 174491316 | MANUFACTURE(0168-0907) |

Revised: 4/2020

Fougera Pharmaceuticals Inc.