

**CLOTRIMAZOIL ANTIFUNGAL- clotrimazole solution**  
**Pedifix, 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.*

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**ClotrimazOil Antifungal Solution**

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**Active Ingredient**

Clotrimazole 1%

**Purpose**

Antifungal

**Uses:**

For the cure of most:

- athlete's foot (tinea pedis)
- ringworm (tinea corporis)
- jock itch (tinea cruris)

For relief of:

- itching
- scaling
- cracking
- burning
- redness
- soreness
- irritation
- discomforts which may accompany these conditions.

**Warnings:**

**For external use only**

**Ask a doctor before use**

on children under 12 years of age

## **When Using This Product**

avoid contact with eyes

### **Stop Use and Ask Doctor If:**

- irritation occurs
- there is no improvement within 4 weeks (2weeks for jock itch).

### **KEEP OUT OF REACH OF CHILDREN.**

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

### **Inactive Ingredients:**

Aqua (Deionized Water), BHT, Carthamus Tinctorius (Safflower) Oil, Emu Oil, Eucalyptus Globulus Oil, Glycine Soja (Soybean) Oil, Lavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia (Tea Tree) Oil, Mentha Piperita (Peppermint) Oil, Olea Europaea (Olive) Fruit Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Rosa Canina (Rose Hips) Oil, Simmondsia Chinensis (Jojoba) Oil, Tocopheryl Acetate (Vitamin-E), Urea.

### **Directions:**

Read all package directions and warnings before using.

- Use only as directed.
- Clean the affected area with soap and warm water and dry thoroughly.
- Apply a thin layer over the affected area twice daily (morning and night) or as directed by a doctor.
- This product is not effective on the scalp or nails.
- Avoid applying to severely cracked or irritated areas.
- For athlete's foot: pay special attention to spaces between toes, wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.
- For athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks.
- Supervise children in the use of this product.
- Intended for use by normally healthy adults only.
- Persons under 12 years of age or those with sensitive or allergic skin should use only as directed by a doctor.

### **Other Information**

Apply to skin around affected areas. While not all finger and toe fungal infections are curable with OTC topical medications, if you see improvement within 4 weeks of use, you may continue to use until satisfactory results are obtained.

- You may report serious side effects to the phone number provided under Questions? Comments? on side panel.

### **Questions? Comments?**

Call 1-800-PEDIFIX (733-4349)

**ClotrimazOil Antifungal Solution CLOTRIMAZOLE 1%**

Exclusive Formula

Kills More Types of Fungus

No Touch, No Mess Brush-on Applicator

Manufactured in the USA for: PediFix, Inc. 301 Fields Lane Brewster, NY 10509 USA

Lot #:

Exp. Date:

Item #3490 REV321 ©2021 PediFix, Inc.

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ClotrimaZoil

Antifungal Treatment

1% CLOTRIMAZOLE

First Clotrimazole & Penetrating Essential Oils Formula

.5 Fl. oz (15 ml)

**ClotrimazOil Antifungal Solution .5oz/15ml (68927-3490-1)**



# CLOTRIMAZOLE ANTIFUNGAL

clotrimazole solution

## Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68927-3490 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength      |
|---|-------------------|---------------|
| <b>CLOTRIMAZOLE</b> (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65) | CLOTRIMAZOLE      | 10 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name                                    | Strength |
|--|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)                    |          |
| <b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K) |          |
| <b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)            |          |
| <b>EMU OIL</b> (UNII: 344821WD61)                  |          |
| <b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)           |          |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)              |          |

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|--|--|
| <b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)               |  |
| <b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)             |  |
| <b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)                  |  |
| <b>ALMOND OIL</b> (UNII: 66YXD4DKO9)                 |  |
| <b>JOJOBA OIL</b> (UNII: 724GKU717M)                 |  |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0) |  |
| <b>UREA</b> (UNII: 8W8T17847W)                       |  |

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| <b>Packaging</b> |                  |  |                      |                    |
|------------------|------------------|--|----------------------|--------------------|
| #                | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
| 1                | NDC:68927-3490-1 | 1 in 1 CARTON  | 02/07/2017           |                    |
| 1                |                  | 15 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

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| <b>Marketing Information</b> |  |                      |                    |
|------------------------------|--|----------------------|--------------------|
| Marketing Category           | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final          | part333C                                 | 06/19/2013           |                    |

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**Labeler** - Pedifix, Inc. (122271935)

**Establishment**

| Name        | Address | ID/FEI    | Business Operations     |
|-------------|---------|-----------|-------------------------|
| PURE SOURCE |         | 080354456 | manufacture(68927-3490) |

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|---------------|---------|-----------|---------------------|
| PEDIFIX, INC. |         | 122271935 | label(68927-3490)   |