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 2 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 (2 weeks 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 of CLORTIMAZOIL 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.
- Supervise children in the use of this product.
- Persons under 18 years of age or those with sensitive or allergic skin should use only as directed by a doctor.

Other Information
Apply CLOTRIMAZOIL 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 CLOTRIMAZOIL 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)
Monday–Friday, 9:00 AM to 5:00 PM Eastern Time

Clotrimazole Antifungal Solution CLOTRIMAZOLE 1%
DOCTOR RECOMMENDED
Broad Spectrum Antifungal Kills 6 Types of Fungus
Highly effective on infected surfaces, wherever reachable with the brush-on applicator.
Manufactured in the USA for: PediFix, Inc. 281 Fields Lane Brewster, NY 10509 USA
Lot #:
Exp. Date:
CLOTIRMAZOIL ANTIFUNGAL
clotrimazole solution

Product Information

Product Type: HUMAN OTC DRUG
Route of Administration: TOPICAL

Item Code (Source) NDC: 68927-3490

Active Ingredient/Active Moiety

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>CLOTIRMAZOILE (UNII: G07GZ97H65) (CLOTIRMAZOILE - UNII:G07GZ97H65)</td>
<td>CLOTIRMAZOILE</td>
<td>10 mg in 1 mL</td>
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## Inactive Ingredients

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<th>Ingredient Name</th>
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<td>WATER</td>
<td>(UNII: 059QF0KO0R)</td>
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<tr>
<td>BUTYLATED HYDROXYTOLUENE</td>
<td>(UNII: 1P9D0Z171K)</td>
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<tr>
<td>SAFFLOWER OIL</td>
<td>(UNII: 65UEH262IS)</td>
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<td>EMU OIL</td>
<td>(UNII: 344821WD61)</td>
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<td>EUCALYPTUS OIL</td>
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<td>SOYBEAN OIL</td>
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<td>LAVENDER OIL</td>
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<td>PEPPERMINT OIL</td>
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<td>OLIVE OIL</td>
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<td>ALMOND OIL</td>
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<tr>
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<td>(UNII: 9E8X80D2L0)</td>
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<td>UREA</td>
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## Packaging

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<td>1 in 1 CARTON</td>
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<td>1</td>
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<td>15 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
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## Marketing Information

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<td>OTC monograph final</td>
<td>part333C</td>
<td>06/19/2013</td>
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**Labeler** - Pedifix, Inc. (122271935)