

FUNGAZOIL ADVANCED- clotrimazole 1% liquid

Pedifix

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.

FungaZoil Advanced

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 as doctor if irritation occurs, there is no improvement within 4 weeks (2 weeks for jock itch)

If swallowed, get medical help or contact a Poison control center immediately.

Active Ingredient

Clotrimazole 1%

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.

KEEP OUT OF REACH OF CHILDREN

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.

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.
- Super vise children in the use of this product.
- Intended for use by normally healthy adults only.
- Persons under 18 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.



Part# zBOX-P3492 Revision# ORGS14 Brand: PediFix Package Type: Carton Dimensions: 12.5313" x 8.625" Blister Position: N/A Printing Method: Offset Number of Colors: 4 File Name: 14106-zBOX-P3492 ORGS14.ai Companion Files: N/A Approval Date: 4-XX-2014 Linked Files: See at right Proof Required: Yes	4-Color Process Spot Color Pantone XXXX Pantone XXXX	 PediFix, Inc. • 281 Fields Lane • Brewster, NY 10509 PediFix Contact: MaryBeth Elkins PediFix Contact Phone: 845-278-3817 PediFix Contact Email: marybeth.elkins@pedifix.com Printer: Boutwell-Owens P3012 one bent-out-silo.tif Applying FungaZoil-silo.tif Fungus 1 Before-yellow.tif Fungus 1 After-sharpened.tif
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<h1>FUNGAZOIL ADVANCED</h1> <p>clotrimazole 1% liquid</p>			
<h2>Product Information</h2>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68927-3492
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0KO0R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
EMU OIL (UNII: 344821WD61)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
SOYBEAN OIL (UNII: 241ATL177A)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
TEA TREE OIL (UNII: VIF565UC2G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
ALMOND OIL (UNII: 66YXD4DKO9)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
JOJOBA OIL (UNII: 724GKU717M)	
UREA (UNII: 8W8T17847W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68927-3492-1	15 mL in 1 BOTTLE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	06/15/2014	

Labeler - Pedifix (122271935)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture(68927-3492)

Revised: 6/2014

Pedifix