

CLOTRIMAZOLE- clotrimazole 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.

Clotrimazole 1%

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)

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

Active ingredient

Clotrimazole 1%

Inactive ingredients

Aqua, BHT, safflower oil, emu oil, eucalyptus globulus oil, soybean oil, lavender oil, tea tree oil, peppermint oil, olive fruit oil, sweet almond oil, rose hip oil, jojoba oil, vitamin E, urea

Purpose

Anti-fungal

Keep out of reach of children

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 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-R3491 Revision# ORG414 Brand: Pedifix Package Type: Carton Dimensions: 12.5313" x 8.625" Blister Position: N/A Printing Method: Offset Number of Colors: 4 File Name: 14121-zBOX-R3491-ORG414.ai Companion Files: N/A Approval Date: 4-XX-2014 Linked Files: See at right Proof Required: Yes	4-Color Process Cyan Magenta Yellow Black Spot Color Pantone XXXX Pantone XXXX	Pedifix Footcare Products Pedifix, Inc. • 201 Fishers Lane • Inovator, NY 10569 Pedifix Contact: MaryBeth Elkins Pedifix Contact Phone: 845-278-3817 Pedifix Contact Email: marybeth.elkins@pedifix.com Printer: Boutwell-Owens
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<h1>CLOTRIMAZOLE</h1> <p>clotrimazole liquid</p>			
<h2>Product Information</h2>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68927-349 1
Route of Administration	TOPICAL		
<h2>Active Ingredient/Active Moiety</h2>			
	Ingredient Name	Basis of Strength	Strength
	CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARTHAMUS TINCTORIUS FLOWER OIL (UNII: SDQ136WIM5)	
EMU OIL (UNII: 344821WD61)	
EUCALYPTUS GLOBULUS WHOLE (UNII: S1P2XF3M3)	
SOYBEAN OIL (UNII: 241ATL177A)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
TEA TREE OIL (UNII: VIF565UC2G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
OLEA EUROPAEA FRUIT VOLATILE OIL (UNII: 8E7358CX1J)	
ALMOND OIL (UNII: 66YXD4DKO9)	
ROSA CANINA FLOWER OIL (UNII: DUY7M48IIT)	
JOJOBA OIL (UNII: 724GKU717M)	
UREA (UNII: 8W8T17847W)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68927-3491-1	15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/05/2014	

Labeler - Pedifix (122271935)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture(68927-3491)

Revised: 5/2014

Pedifix