

DERMATIN ANTIFUNGAL- clotrimazole cream
Melaleuca, 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.

Dermatin Antifungal Cream Content of Label

Active ingredient

Clotrimazole 1%

Purpose

Antifungal

Uses

- Cures most athlete's foot, jock itch, and ringworm
- Relieves itching, burning, cracking, scaling, and discomfort accompanying these conditions

Warnings

For external use only

- When using this product avoid contact with the eyes

Do not use on children under 2 years of age unless directed by a doctor

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- clean the affected area and dry thoroughly
- apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by a physician
- children under 12 years of age should be supervised in the use of this product
- for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes; 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
- this product is not effective on scalp or nails

Other ingredients acrylates/C10-30 alkyl acrylates crosspolymer, benzyl alcohol, cetyl alcohol, deionized water, dimethicone, glyceryl stearate and PEG-100 stearate, propylene glycol, SD alcohol 40B, steareth-2, steareth-21, stearic acid, T36-C5[®] Melaleuca alternifolia (Tea Tree) leaf oil, triethanolamine.

Drug Facts (continued)

Directions ■ clean the affected area and dry thoroughly ■ apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by a physician ■ children under 12 years of age should be supervised in the use of this product ■ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes; 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 ■ this product is not effective on scalp or nails

Drug Facts (continued)

Other ingredients acrylates/C10-30 alkyl acrylates crosspolymer, benzyl alcohol, cetyl alcohol, deionized water, dimethicone, glyceryl stearate & PEG-100 stearate, propylene glycol, SD alcohol 40B, steareth-2, steareth-21, stearic acid, T3G-C5[®] Melaleuca alternifolia (Tea Tree) leaf oil, triethanolamine.



Dist. by: Melaleuca, Inc., Idaho Falls, ID 83402-6003
To order: 1-800-282-3000 • www.melaleuca.com
Product of USA #2370 01/11U **NOT FOR RESALE IN CANADA**



Drug Facts

Active ingredient	Purpose
Clotrimazole 1%	Antifungal

Uses ■ Cures most athlete's foot, jock itch, and ringworm ■ Relieves itching, burning, cracking, scaling, and discomfort accompanying these conditions

Warnings
For external use only ■ When using this product avoid contact with the eyes
Do not use on children under 2 years of age unless directed by a doctor
Stop use and ask a doctor if ■ irritation occurs ■ there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

PEEL HERE

DERMATIN ANTIFUNGAL

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-206
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 1G56KV7BUJ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-21 (UNII: 53J3F32P58)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TEA TREE OIL (UNII: VIF565UC2G)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-206-01	14 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	12/19/2011	

Labeler - Melaleuca, Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		139760102	manufacture

Revised: 2/2011

Melaleuca, Inc.