FLEXITOL MEDICATED FOOT- tolnaftate cream
LaCorium Health International Pty Ltd

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.

Flexitol Medicated Foot Cream

Drug Facts

Active Ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- Clinically proven to prevent Athlete's Foot (Tinea Pedis) and Ringworm (Tinea Corporis) with daily use
- For effective relief of symptoms of Athlete's Foot, including itching, burning, cracking, scaling and discomfort associated with this condition.

Warnings

- Do not use on children under 2 years of age unless directed by a doctor
- For External Use Only
- Avoid contact with eyes
- If irritation occurs or if there is no improvement within 4 weeks (for Athlete's Foot) discontinue use and consult a doctor
- Do not use if seal on tube is punctured or is not visible. Keep out of reach of children.

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 doctor
- Supervise children in the use of this product
- For Athlete's Foot: pay special attention to the spaces between the toes; wear well fitting, ventilated shoes and change shoes and socks at least once daily.
- Use daily for 4 weeks. If condition persists longer consult a doctor.
- To prevent Athlete's Foot, apply once or twice daily (morning and/or night)
- This product is not effective on the scalp or nails
- Replace cap and tighten after each use.

Other Information

- **Store between 50°- 86°F in a dry place**

Inactive Ingredients

Aloe, Benzalkonium Chloride, Cetearyl Alcohol, Ceteth-20, Cetyl Alcohol, Glycerin, Lavandula, Angustifolia (Lavender) Oil, Menthol, Mineral Oil, Petrolatum, Polysorbate 60, Propylene Glycol, Sodium Phosphate, Tocopherol, Urea, Water

Questions or comments?

Call Toll Free **1-866-478-3338**
usainfo@flexitol.com
www.flexitol.com

USA DISTRIBUTOR:
LaCorium Health USA Inc.,
Boca Raton, Florida 33487

MANUFACTURED FOR:
LaCorium Health International Pty Ltd.,
Level 14, Tower 2,
101 Grafton Street,
Bondi Junction NSW 2022, Australia

PRINCIPAL DISPLAY PANEL - 56 g Tube Carton

Flexitol®

Medicated
Foot Cream

For treatment of
athlete's foot

Before

After 2 Weeks

APPROVED

AMERICAN
PODIATRIC
MEDICAL
ASSOCIATION

With Aloe & Vitamin E

DIABETIC FRIENDLY

Net Wt 2 oz (56 g)

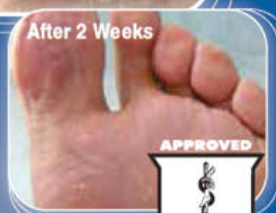
www.flexitol.com

Flexitol®

Flexitol®

Medicated Foot Cream

For treatment of athlete's foot



With Aloe & Vitamin E

DIABETIC FRIENDLY

Net Wt 2 oz (56 g)

- Clinically proven to prevent Athlete's Foot (Tinea Pedis) and Ringworm (Tinea Corporis)
- Effectively soothes and relieves symptoms of Athlete's Foot including itching, burning, cracking, scaling and discomfort associated with this condition
- Moisturizes and hydrates dry, cracked and flaky skin
- Cools irritated feet
- With Aloe & Vitamin E

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MADE IN AUSTRALIA

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AMERICAN PODIATRIC MEDICAL ASSOCIATION

With Aloe & Vitamin E

DIABETIC FRIENDLY

Net Wt 2 oz (56 g)

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Questions or comments?

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FLEXITOL MEDICATED FOOT

tolnaftate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43251-3340
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Tolnaftate (UNII: 06KB629TKV) (Tolnaftate - UNII:06KB629TKV)	Tolnaftate	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
Urea (UNII: 8W8T17847W)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Mineral Oil (UNII: T5L8T28FGP)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene glycol (UNII: 6DC9Q167V3)	
Petrolatum (UNII: 4T6H12BN9U)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Ceteth-20 (UNII: I835H2IHHX)	
Cetyl alcohol (UNII: 936JST6JCN)	
Menthol (UNII: L7T10EIP3A)	
Sodium phosphate (UNII: SE337SVY37)	
Benzalkonium chloride (UNII: F5UM2KM3W7)	
Tocopherol (UNII: R0ZB2556P8)	
Lavender Oil (UNII: ZBP1YXW0H8)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43251-3340-1	1 in 1 CARTON		
1		56 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333C	08/11/2012	

Labeler - LaCorium Health International Pty Ltd (758651624)

Establishment

Name	Address	ID/FEI	Business Operations
Jalco Pharmaceuticals Pty Ltd		757701409	MANUFACTURE(43251-3340) , PACK(43251-3340) , LABEL(43251-3340) , ANALYSIS(43251-3340)