FLEXITOL ANTI FUNGAL- undecylenic acid liquid 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.

 $\begin{aligned} & Flexitol_{\mathbb{R}} \\ & Anti-Fungal \ Liquid \end{aligned}$

Drug Facts

Active ingredient

Undecylenic Acid 25%

Purpose

Antifungal

Uses

For the treatment of: most Athlete's Foot (Tinea Pedis), Ringworm (Tinea Corporis). For relief of: itching, scaling, cracking, burning, redness, soreness, irritation and discomfort which may accompany these conditions.

Warnings

- For external use only
- Do not use on children under 2 years of age unless directed by a doctor
- Extremely flammable
- Keep away from fire or flame
- Avoid smoking during use and until product has dried
- Keep out of reach of children
- If swallowed, get medical help or contact a Poison Control Center right away
- Discontinue use and consult a doctor if irritation occurs or there is no improvement within 4 weeks

Directions

- Read all directions and warnings before use
- Clean affected area with soap and warm water and dry thoroughly
- Apply a thin layer of Flexitol Anti-Fungal Liquid over the affected area twice daily (morning and night) or as directed by a doctor
- 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.
- For Athlete's Foot and Ringworm use daily for 4 weeks. If condition persists longer, consult a doctor.
- Persons under 18 years of age or those with sensitive skin should use only as directed by a doctor
- Supervise children in the use of this product
- 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 Barbadensis Leaf Juice, Butylated Hydroxytoluebe, Eucalyptus Globulus Oil, Hydroxypropyl Methylcellulose, Isopropyl Alcohol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Tocopherol Acetate, Urea, Water

Comments or questions?

Call Toll Free 1-866-478-3338 us ainfo@flexitol.com www.flexitol.com

PRINCIPAL DISPLAY PANEL - 30ml Bottle Carton

 $Flexitol_{\mathbb{R}}$

Anti-Fungal Liquid

Treats Fungus

APPROVED
AMERICAN
PODIATRIC
MEDICAL
ASSOCIATION

Clinically Proven

Easy brush-on APPLICATOR

WITH UREA, ALOE VERA, VITAMIN E, TEA TREE & EUCALYPTUS OILS

NDC: 43251-3351

1 fl oz (30ml)

FAST-DRYING WITHOUT A PRESCRIPTION MAXIMUM STRENGTH

www.flexitol.com

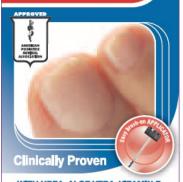
MAXIMUM STRENGTH WITHOUT A PRESCRIPTION FAST-DRYING

Flexitol.

Flexitol

Anti-Fungal Liquid

Treats Fungus



WITH UREA, ALOE VERA, VITAMIN E, **TEA TREE & EUCALYPTUS OILS** NDC: 43251-3351

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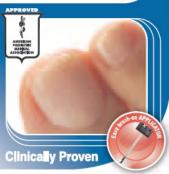
USA DISTRIBUTOR: LaCorium Health USA Inc., Boca Raton, Florida 33487 MANUFACTURED FOR: LaCorium Health International Pty Ltd.,

Level 14, Tower 2, 101 Grafton Street, Bondi Junction, NSW 2022, Australia Made in Australia

Flexitol

Anti-Fungal Liquid

Treats Fungus



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FLEXITOL ANTI FUNGAL

undecylenic acid liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:43251-3351

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Undecylenic acid (UNII: K3D86KJ24N) (Undecylenic acid - UNII:K3D86KJ24N)	Undecylenic acid	250 mg in 1 mL

Ingredient Name Strength Isopropyl Alcohol (UNII: ND2M416302) Water (UNII: 059QF0KO0R) Urea (UNII: 8W8T17847W) Eucalyptus Oil (UNII: 2R04ONI662) Hypromellose 2906 (4000 MPA.S) (UNII: 5EYA69XGAT) Tea Tree Oil (UNII: VIF565UC2G) Alpha.-Tocopherol Acetate, DL- (UNII: WR1WPI7EW8) Aloe Vera Leaf (UNII: ZY81Z83H0X) Butylated Hydroxytoluene (UNII: 1P9D0Z171K)

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:43251-3351-1	1 in 1 CARTON					
1		30 mL in 1 BOTTLE					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part333C	01/03/2009			

Labeler - LaCorium Health International Pty Ltd (758651624)