

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.

Flexitol®
Anti-Fungal Liquid

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 Barbados Leaf Juice, Butylated Hydroxytoluene, 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**

usainfo@flexitol.com

www.flexitol.com

PRINCIPAL DISPLAY PANEL - 30ml Bottle Carton

Flexitol®

**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

MAXIMUM STRENGTH
WITHOUT A PRESCRIPTION
FAST-DRYING

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Flexitol[®]

← Exp. Date Here

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APPROVED



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Drug Facts (continued)

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Boca Raton, Florida 33487

MANUFACTURED FOR:
LaCorium Health International Pty Ltd.,
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Bondi Junction, NSW 2022, Australia
Made in Australia

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Anti-Fungal
Liquid

Treats Fungus

APPROVED



Clinically Proven

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1 fl oz (30ml)

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0022-8



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

Inactive Ingredients

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: ZY81Z83HOX)	
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)