## DIABETIC ANTIFUNGAL- undecylenic acid cream Lavior 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.

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## **Active Ingredient**

Undecylenic Acid 10%.....Antifungal

## **Purpose**

**Antifungal** 

#### Uses

Cures most

- athlete's foot (tinea pedis)
- jock itch (tinea cruris)
- ringworm (tinea corporis)

Relieves itching, burning, cracking, and scaling.

# Warnings

For external use only. Avoid contact with eyes.

#### Do not use

on children under 2 years of age unless directed by a doctor

# Stop use and consult a doctor if

irritation occurs or if there is no improvement within 4 weeks (for athlete's foot or ringworm) or within 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**

- read all warnings and directions
- use only as directed
- wash the affected area and dry thoroughly

- apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor
- Supervise children in the use of this product
- for athletes' foot: pay special attention to 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; for jock itch, use daily for 2 weeks. If condition persists longer, consult a doctor.
- this product is not effective on the scalp or nails
- wash hands after each use

#### Other Information

store at room temperature

# **Inactive ingredients**

Water/Aqua/Eau, Propanediol, Inula Viscosa Flower/Leaf/Stem Extract, Urea, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Arachidyl Alcohol, Zea Mays (Corn) Starch, Behenyl Alcohol, Dimethicone, Pentaerythrityl Tetraethylhexanoate, Synthetic Beeswax, Glycerin, Phenoxyethanol, Euphorbia Cerifera (Candelilla) Wax/Candelilla Cera/Cire de Candelilla, Copernicia Cerifera (Carnauba) Wax/Cera Carnauba/Cire de Carnauba, Arachidyl Glucoside, Glyceryl Stearate SE, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, ButyrospermumParkii (Shea) Butter, Ethylhexylglycerin, Disodium EDTA, Xanthan Gum, Hydroxypropyl Bispalmitamide MEA, Polyglyceryl-2 Stearate, Glyceryl Stearate, Palmitic Acid, Stearyl Alcohol, Pentylene Glycol, Isomerized Safflower Acid, Caprylyl Glycol

### **Questions?**

Call toll free 1-844-474-2552 or visit www.lavior.com



#### **Drug Facts**

Active Ingredient Undecylenic Acid 10%....

Uses Cures most • athlete's foot (tinea pedis) • jock itch (tinea cruris) • ringworm (tinea corporis) Relieves itching, burning, cracking, and scaling.

Warnings For external use only. Avoid contact with eyes. Stop use and consult a doctor if irritation occurs of if there is no improvement within 4 weeks (for athlete's foot or ringworm or within 2 weeks (for jock itch).

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

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

Directions • read all warnings and directions • use only as directed • wash the affected area and dry throughly • apply a thin layer of the product over affected area and dry throughly • apply a thin layer of the product over affected area with ced ally (morning and night) or as directed by a doctor • supervise children in the use of this product • for adhletes from the special attention to speace between the toes, wear well-tilling, verificilled shoes, and change shoes and socks at least once daily for affects to tot and irrigovorum, use daily for wheels. In plock into a dealy of wheels, to plock in the used daily for 2 weeks. It condition preside longer, consult a doctor. • his product is not defective on the said or ratio. • week hands after each use

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Inactive Ingredients
Water/AugaPau, Proparatiol, hula Viscosa Flower/Leaf/Stem Editact, 
Urea, Melaleusa Alternifolia Float reol, Leaf (J. Arachidy) Alcond, Zea 
Mays (Com Starts, Deleten/Abord, Dimethoone, Perlararythrivi 
effactory incomparation, Symbiotic beasway, Glycam, Prenovelland, 
February incomparation, Stemans, Comparation, Prenovelland, 
Arachidy Glucoside, Glycary Stearate SE, Acryptales C10-90 Alloy Acrylato 
Cosperinga Certifica (Carnatula Wask) (Sheap Blatte, Ethimology) 
Biocolum EDIA, Xanthan Gum, Hydroxyproryl Bispalmitamide MEA, 
Polyphore-y 2-Stearate, Gylecys (Stearae, Parlimite, Aos, Steary) Alchord, 
Pentylene Glycol, Bomerized Satillower Acid, Caprylyl Glycol

The Prindermantion Stear Lyone and vono temperature.

Other information Store at room temp

Questions? Call toll free 1-844-474-2552 or visit www.lavior.com

NDC 71521-391-50













LAVIOR Antifungal Foot Ointment helps treat the most common fungal infections including tinea pedis (athlete's foot), tinea cruris (jock itch) and tinea corporis (ringworm). This antifungal cream helps relieve itching, scaling, cracking, redness, soreness, burning and irritation. It is specifically formulated for diabetic skin and contains ingredients to help repair damaged skin and promote healing of painful cracks and fissures.







Made in the USA

Manufactured for LAVIOR INC. Miami, FL 33180 info@lavior.com www.lavior.com

Manufactured in a cGMP facility



## DIABETIC **ANTIFUNGAL OINTMENT**

TREATS FUNGAL INFECTIONS

Specifically formulated for diabetics

Steroid-Free, Cortisone-Free, Paraben-Free, Fragrance-Free

10% Undecylenic Acid Antifungal

50 ml/ 1.7 fl.oz



#### LAVIOR DIABETES

We are dedicated to helping diabetics with our research and products, Our customers rely on LAVIOR to get solutions that restore skin's look and feel and improve the patient's quality of life.

LAVIOR Diabetes offers a clean remedy, without cortisone or steroid complications, that acts fast in diabetic skin.



SCAN FOR MORE INFORMATION



# **DIABETIC ANTIFUNGAL**

undecylenic acid cream

#### **Product Information**

**Route of Administration** 

**Product Type** HUMAN OTC DRUG **Item Code (Source)** 

NDC:71521-391

**Active Ingredient/Active Moiety** 

**Ingredient Name** 

TOPICAL

**Basis of Strength Strength** 

UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	10 g in 100 g
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Inactive Ingredients	
Ingredient Name	Strength
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
PROPANEDIOL (UNII: 5965N8W85T)	
PALMITIC ACID (UNII: 2V16EO95H1)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
STARCH, CORN (UNII: 08232NY3SJ)	
PENTAERYTHRITYL TETRAETHYLHEXANOATE (UNII: XJ7052W897)	
UREA (UNII: 8W8T17847W)	
CANDELILLA WAX (UNII: WL0328HX19)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
DOCOSANOL (UNII: 9G10E216XY)	
DIMETHICONE (UNII: 92RU3N3Y10)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DITTRICHIA VISCOSA WHOLE (UNII: 3SYW69FH88)	
SHEA BUTTER (UNII: K49155WL9Y)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
TEA TREE OIL (UNII: VIF565UC2G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYPROPYL BISPALMITAMIDE MONOETHANOLAMIDE (UNII: EVX7NC9YVE)	
ISOMERIZED SAFFLOWER ACID (UNII: 70S2158RCI)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:71521- 391-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/17/2021	

Marketing In	keting Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	03/17/2021		

# **Labeler -** Lavior Inc (080685327)

Revised: 5/2021 Lavior Inc