

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.

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, Butyrospermum Parkii (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



DIABETIC ANTIFUNGAL

undecylenic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71521-391
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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: 6JVV35J00J)	
PROPANEDIOL (UNII: 5965N8W85T)	
PALMITIC ACID (UNII: 2V16EO95H1)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
STARCH, CORN (UNII: O8232NY3SJ)	
PENTAERYTHRITYL TETRAETHYLHEXANOATE (UNII: XJ7052W897)	
UREA (UNII: 8W8T17847W)	
CANDELILLA WAX (UNII: WL0328HX19)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
DOCOSANOL (UNII: 9G1OE216XY)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
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: 230OU9XXE4)	
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)	

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 Information

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

