

NU CALMAR- undecylenic acid cream
Nu Calmar 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.

DRUG FACTS

Active Ingredient

Undecylenic Acid 20%

Purpose

Anti-fungal

Uses:

Cures most Athlete's Foot, Jock Itch or Ringworm. **For effective relief of** itching, scaling, burning, redness, irritation, chafing associated with jock itch and itchy scaly skin between the toes.

Warning:

For external use only. Do not use on children under 2 years of age unless directed by a doctor. Avoid contact with the eyes. If irritation occurs or if there is no improvement within 2 weeks, discontinue use and consult a doctor.

Directions:

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 athlete's 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.

Inactive ingredients:

Shea butter, Coconut Oil, Lemon Oil, Jojoba wax, Tocopherol, Grape Seed Oil, Zinc Oxide, Glycerin (Vegetable)

Principal display panel

NU CALMAR

Absolute Soothing Cream

Natural Anti-Fungal Cream | Undecylenic Acid 20%
Cures most - Athlete's Foot - Jock Itch - Ringworm

5.072 oz / 150 ml

NU CALMAR All-natural anti-fungal cream

Calming, lightly scented all-natural anti-fungal cream. For effective relief of athlete's foot, jock itch, and ringworm. Soothes itching, scaling, burning, redness, irritation, chafing associated with jock itch and itchy, scaly skin between the toes.

BOTANICAL-BASED | VEGAN-FRIENDLY | SOAP-FREE | CRUELTY-FREE

Manufactured for: Nu Calmar Pty Ltd
Distributed by: Axcentia Pharmaceuticals
LLC, 306 Keystone Dr, Telford PA 18969 USA

Active Ingredient:
Undecylenic acid 20%



Inactive ingredients: Butyrospermum Parkii [Shea Butter] Fruit, Cocos Nucifera [Coconut Oil], Citrus Medica Limonum [Lemon] Peel Oil, Jojoba Wax, Tocopherol [Vitamin E], Vitis Vinifera [Grape] Seed Oil, Zinc Oxide.

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NU CALMAR

Absolute Soothing Cream
Natural Anti-Fungal Cream
Undecylenic Acid

Cures most - Athlete's Foot - Jock Itch - Ringworm

5.072 oz / 150 ml

Chemical-Free and Cruelty-Free

BOTANICAL-BASED
VEGAN-FRIENDLY

Calming, lightly scented
all-natural anti-fungal cream.
For effective relief of Athlete's
Foot, Jock Itch and Ringworm.

No Alcohol
No Aluminum
No Artificial Colors
No Parabens
No Petrolatum
No Phthalates
No Preservatives
No Propylene Glycol
No Triclosan
No Silicones
No Sulphates
No Synthetic Fragrances

Drug Facts

Active ingredient

Undecylenic Acid 20%.....

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Drug Facts (continued)

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Manufactured for:
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Distributed by:
Axcatria Pharmaceuticals, LLC
306 Keystone Dr, Telford,
PA 18969 USA

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undecylenic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73464-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	200 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SHEA BUTTER (UNII: K49155WL9Y)	

COCONUT OIL (UNII: Q9L0O73W7L)	
LEMON OIL (UNII: I9GRO824LL)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73464-001-01	150 mL in 1 JAR; Type 0: Not a Combination Product	01/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/29/2020	

Labeler - Nu Calmar Pty Ltd (745013724)

Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(73464-001)

Revised: 11/2022

Nu Calmar Pty Ltd