

RITE AID FUNGAL - undecylenic acid liquid

Rite Aid Corporation

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

Section from Carton Label Follows:

Active ingredient	Purpose
Undecylenic acid 25% w/v.....	Antifungal

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Undecylenic Acid 25% w/v.....	Antifungal

Uses

Treats most athletes foot (tinea pedis)
and ringworm (tinea corporis)

Section from **Warnings** section of Carton label follows:

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN

If accidental ingestion occurs,
immediately contact a physician,
emergency medical facility or Poison
Control Center for help.

Section from Directions portion of carton label follows:

Directions

- Using soap and water, clean 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.
- Use the brush applicator provided for easy application to the affected area
- For toe usage, change shoes and socks at least once daily and wear well fitting, ventilated shoes
- Pay particular attention to spaces between the toes for athletes foot
- For athletes foot and ringworm, use the product daily for 4 weeks. If condition persists longer, consult a physician
- This product is not effective on the scalp or nails
- Children must be supervised in the use of this product

From **Warnings** Section of Carton Label:

Warnings For external use only.

Ask a doctor before use on children under 2 years of age

When using this product avoid contact with the eyes

Stop use and consult a doctor if
- Irritation occurs - you do not notice improvement within 4 weeks

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From Inactive Ingredients section of Carton Label:

Inactive Ingredients Isopropyl Palmitate



DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

Drug Facts

Active ingredient **Purpose**
 Undecylenic acid 25% w/v.....Antifungal

Uses

- Treats most athletes foot (tinea pedis), and ringworm (tinea corporis).

Warnings

For external use only

Ask a doctor before use on children under 2 years of age

When using this product avoid contact with eyes

Stop use and consult a doctor if • irritation occurs • you do not notice improvement within 4 weeks

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. If accidental ingestion occurs, immediately contact a physician, emergency medical facility or Poison Control Center for help.

Directions

- Using soap and warm water, clean 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.
- Use the brush applicator provided for easy application to the affected area.
- For toe usage, change shoes and socks at least once daily and wear well fitting, ventilated shoes.
- Pay particular attention to spaces between the toes for athletes foot.
- For athletes foot and ringworm, use the product daily for 4 weeks. If condition persists longer, consult a physician.
- This product is not effective on the scalp or nails.
- Children must be supervised in the use of this product.

Other Information

- This product should be stored at room temperature 15° - 30°C (59° - 86°F)
- Keep from freezing. If freezing occurs, warm to room temperature.

Inactive Ingredient

Isopropyl Palmitate



Compare to the active ingredient in Fungi-Nail®*



Antifungal Liquid

Maximum Strength

*This product is not manufactured or distributed by Kramer Laboratories, Inc. owner of the registered trademark Fungi-Nail® Brand



IF YOU'RE NOT SATISFIED, WE'LL HAPPILY REFUND YOUR MONEY.

DISTRIBUTED BY:
 Rite Aid Corporation
 30 Hunter Lane, Camp Hill, PA 17011

Compare to the active ingredient in Fungi-Nail®*



Antifungal Liquid

Maximum Strength

Treats Most Finger & Toe Fungus

Maximum Strength Without A Prescription

Proven Clinically Effective In The Treatment Of Most Finger & Toe Fungus

1 FL OZ (30 mL)

Compare to the active ingredient in Fungi-Nail®*



Antifungal Liquid

Maximum Strength

WHEN TO USE:

Rite Aid® Maximum Strength Antifungal Liquid is for the effective treatment of most fungal infections of the skin.

Usage: Simply apply Rite Aid® Maximum Strength Antifungal Liquid over the affected area.

Non-prescription antifungal products do not work directly on the scalp or nails.

RITE AID FUNGAL

undecylenic acid liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11822-0250

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	288 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	712 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0250-1	1 in 1 CARTON		
1		30 mL in 1 BOTTLE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	06/01/2008	

Labeler - Rite Aid Corporation (014578892)

Registrant - Pharma Pac, LLC (140807475)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

Revised: 2/2011

Rite Aid Corporation