

## **UNDECYLENIC ACID - undecylenic acid liquid**

**CVS Pharmacy**

*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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### **drug facts**

#### **Section from Carton Label Follows :**

<b>Active ingredient</b>	<b>Purpose</b>
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.**

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

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**When using this product** avoid contact with the eyes

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**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

Carton

CVS  
pharmacy

Compare to the  
active ingredient  
in Fungi Nail<sup>®</sup>\*

# ANTI-FUNGAL LIQUID

MAXIMUM STRENGTH

- Maximum strength without prescription
- Proven clinically effective in the treatment of most finger & toe fungus



TREATS MOST FINGER & TOE FUNGUS

# 463589



CVS  
pharmacy

Compare to the  
active ingredient  
in Fungi Nail<sup>®</sup>\*

# ANTI-FUNGAL LIQUID

MAXIMUM STRENGTH

### WHEN TO USE:

CVS/pharmacy<sup>®</sup> Maximum Strength Anti-Fungal Liquid is for the effective treatment of most fungal infections of the skin. To use, simply apply CVS/pharmacy<sup>®</sup> Maximum Strength Anti-Fungal Liquid over the affected area.

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



Die# 28052-9

MAXIMUM STRENGTH

# ANTI-FUNGAL LIQUID

Compare to the  
active ingredient  
in Fungi Nail<sup>®</sup>\*

CVS  
pharmacy

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

### Drug Facts

Active ingredient	Purpose
Undecylenic acid 25% w/v	Antifungal

### Indications

- Treats most athlete's 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 athlete's foot.
- For athlete's 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.

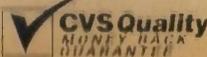
### Other Information

- This product should be stored at room temperature (59° - 86°F) (15° - 30°C) (50° - 86°F)
- Keep from freezing. If freezing occurs, warm to room temperature.

### Inactive Ingredients

Isopropyl Palmitate

\*This product is not manufactured or distributed by Kramer Laboratories, Inc. owner of the registered trademark Fungi Nail<sup>®</sup> Brand



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CVS  
pharmacy

Compare to the  
active ingredient  
in Fungi Nail<sup>®</sup>\*

# ANTI-FUNGAL LIQUID

MAXIMUM STRENGTH

- Maximum strength without prescription

- Proven clinically effective in the treatment of most finger & toe fungus

1 FL OZ (30 mL)

BXCVS124-02  
09/08  
DLI

# UNDECYLENIC ACID

undecylenic acid liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-132
<b>Route of Administration</b>	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:59779-132-15	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** - CVS Pharmacy (062312574)

**Registrant** - Pharma Pac, LLC (140807475)

## Establishment

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

Revised: 2/2011

CVS Pharmacy