

## **UNDECYLENIC ACID- antifungal pen liquid**

**Family Dollar Services 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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### **Antifungal Nail Pen**

#### **Active ingredient**

Undecylenic acid 25%w/w

#### **Purpose**

Antifungal

#### **Uses**

For the cure of most tinea pedis (athlete's foot) and tinea corporis (ringworm)

#### **For relief of:**

itching  
burning  
redness  
irritation  
scaling  
discomfort which may accompany these conditions  
soreness

#### **Warnings**

For external use only.

#### **If pregnant or breastfeeding**

consult a healthcare professional before use.

#### **Do not use**

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

#### **When using this product**

avoid contact with eyes.

#### **Use only as directed**

by a doctor on persons with highly sensitive skin.

#### **Stop use and consult a doctor if**

- there is no improvement within 4 weeks
- irritation occurs

#### **Keep out of children.**

If accidental ingestion occurs, get medical help or contact a Poison Control Center right away.

### ***Directions***

**Read all warning and directions. Use only as directed.**

clean the affected area and dry thoroughly  
twist pen base with 3 clicks to saturate brush  
apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by the doctor  
the brush applicator allows for easy application under nails and surrounding cuticle area  
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. If condition persists longer, consult a doctor.  
this product is not effective on the scalp or nails

### ***Other information***

- store at room temperature 150 - 300C (590 - 860F)
- protect from freezing. if freezing occurs, warm to room temperature.
- keep tightly closed when not in use

### ***Inactive ingredient***

isopropyl palmitate

### ***Questions?***

Call 1-866-964-0939

### **Principal Display Panel**

**FAMILY WELLNESS**

**MAXIMUM STRENGTH**

Anti- Fungal Nail Pen

Undecylenic Acid 25%

Eliminates Fungus on Fingers, Toes and Around Nails

- Pre- filled with applicator brush
- Convenient and Easy to use
- Dries Quickly
- Non - oily, clean Formula

**0.05 FL. OZ (1.7 mL)**



## UNDECYLENIC ACID

antifungal pen liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-055
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	25 mg in 1.7 mL
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### Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-055-17	1.7 mL in 1 APPLICATOR; Type 0: Not a Combination Product	12/15/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	12/15/2017	

**Labeler** - Family Dollar Services Inc. (024472631)

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Family Dollar Services Inc.