

UNDECYLENIC ACID - undecylenic acid liquid
Wal-Mart Stores 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.

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

Carton

Drug Facts (continued)

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 Ingredients
Isopropyl Palmitate

Questions?
Call: 1-888-287-1915



Satisfaction guaranteed - Or we'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, please call 1-888-287-1915.

Distributed by: Wal-Mart Stores, Inc., Bentonville, AR 72716.
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NEW!

equate®

Compare to Fungi Nail® Brand*

Maximum Strength

Anti-Fungal Liquid

Treats Most Finger and Toe Fungus

- Maximum strength without prescription
- Treats finger and toe fungus

Solution with brush applicator

NET WT
1 FL OZ (30 mL)

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Anti-Fungal Liquid

Treats Most Finger and Toe Fungus

- Maximum strength without prescription
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Solution with brush applicator

NET WT
1 FL OZ (30 mL)

Anti-Fungal Liquid

Maximum Strength

equate®

Do not use if 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
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UNDECYLENIC ACID

undecylenic acid liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-987	
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:49035-987-74	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 - Wal-Mart Stores Inc (051957769)

Registrant - Pharma Pac, LLC (140807475)

Establishment

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