

FUNGICURE ANTI-FUNGAL LIQUID 25% - undecylenic acid liquid
Denison Pharmaceuticals LLC

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.

Fungicure Anti-Fungal Liquid 25%

Active Ingredient

Undecylenic acid 25% w/w

Purpose

Antifungal

Uses

For the cure of most

- ringworm (tinea corporitis) and athlete's foot (tinea pedis).

For relief of itching, scaling, cracking, burning, redness, soreness, irritation, and discomforts which may accompany these conditions.

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 ask a doctor if

- Irritation occurs
- There is no improvement within 4 weeks.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

Read all package directions and warnings before use.

Use only as directed.

Clean the affected area with soap and warm water and dry thoroughly.

Apply a thin layer of FUNGICURE Liquid over the affected area twice daily (morning and night), or as directed by a doctor.

This product is not effective on scalp or nails.

For ringworm and athlete's foot, use daily for 4 weeks.

For athlete's foot, pay special attention to spaces between toes; wear well fitting, ventilated shoes and change shoes and socks at least once daily.

If condition persists longer, consult a doctor.

Intended for use by normally healthy adults only.

Persons under 18 years of age or those with highly sensitive or allergic skin should use only as directed by a doctor.

Supervise children in the use of this product.

Other information

- FUNGICURE may be applied to exposed nail beds, cuticles, around nail edges and under nail tips where reachable with its applicator brush.
- This product is not intended to, nor will it, penetrate hard nail surfaces.
- While not all finger and toe fungal infections are curable with OTC topical medications, if you see improvement within 4 weeks of use, you may continue to use FUNGICURE until satisfactory results are obtained.
- You may report serious side effects to the phone number provided under *Questions?* below.

Inactive ingredients

Isopropyl palmitate

Questions? 1-800-792-2582

BONUS 33% FREE

MAXIMUM STRENGTH FUNGI CURE

ANTI-FUNGAL LIQUID

25% Undecylenic Acid

KILLS EXPOSED NAIL-BED FUNGUS

TOPICAL FORMULA
Net Contents: 1.33 FL. OZ. (40 mL)

No Varnish Area

Directions: Apply to affected nail(s) once daily. For best results, use on clean, dry nail(s). Avoid nail polish, nail treatments, nail art, and nail enhancers during treatment. For optimal results, avoid nail polish, nail treatments, nail art, and nail enhancers during treatment. For optimal results, avoid nail polish, nail treatments, nail art, and nail enhancers during treatment.

Warnings: Do not use if you are allergic to any of the ingredients. Do not use if you are pregnant or breastfeeding. Do not use if you have a known hypersensitivity to any of the ingredients. Do not use if you have a known hypersensitivity to any of the ingredients.

Caution: Keep out of reach of children. Store at room temperature. Do not use if the cap is loose or the seal is broken. Do not use if the cap is loose or the seal is broken.

Keep Out of Reach of Children When Not in Use.

© 2019 ALVAVIA, INC. ALL RIGHTS RESERVED. ALVAVIA, INC. IS A REGISTERED TRADEMARK OF ALVAVIA, INC. ALVAVIA, INC. IS A REGISTERED TRADEMARK OF ALVAVIA, INC. ALVAVIA, INC. IS A REGISTERED TRADEMARK OF ALVAVIA, INC.

ALVAVIA 2019 ALVAVIA, INC. 2019 ALVAVIA, INC. 2019 ALVAVIA, INC.

Dist.: ALVAVIA, INC. 2019 ALVAVIA, INC. 2019 ALVAVIA, INC.
Alvavia, Inc. 2019 ALVAVIA, INC. 2019 ALVAVIA, INC. 2019 ALVAVIA, INC.
Alvavia, Inc. 2019 ALVAVIA, INC. 2019 ALVAVIA, INC. 2019 ALVAVIA, INC.
Alvavia, Inc. 2019 ALVAVIA, INC. 2019 ALVAVIA, INC. 2019 ALVAVIA, INC.

DIE LINE
DOES NOT PRINT

BLEED LINE
DOES NOT PRINT

SAFE ZONE
DOES NOT PRINT

PMS 293
PMS 343

undecylenic acid liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0295-9810
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	250 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0295-9810-05	28 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	02/20/2019	
2	NDC:0295-9810-10	38 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	02/20/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	02/20/2019	

Labeler - Denison Pharmaceuticals LLC (001207208)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals LLC		001207208	manufacture(0295-9810)

Revised: 2/2019

Denison Pharmaceuticals LLC