

UNDECYLENIC ACID- anti-fungal liquid maximum strength liquid
Hudson Health 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.

Comfortzone Antifungal Liquid Solution

Active ingredient

Undecylenic acid 25%w/w

Purpose

Antifungal

Uses

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

For relief of:

discomfort which may accompany these conditions

itching

burning

redness

irritation

scaling

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 warnings and directions. Use only as directed.**

- clean the affected area and dry thoroughly
- apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by a doctor
- supervise children in the use of this product
- 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
- for athlete's foot and ringworm, use daily for 4 weeks. If conditions persists longer, consult a doctor
- this product is not effective on the scalp or nails

Other information

- store at room temperature 15°-30°C (59° - 86°F)
- protect from freezing. If freezing occurs warm to room temperature
- keep tightly closed when not in use

Inactive ingredient

isopropyl palmitate

Questions?

Call 1-877-237-0194

Principal Display Panel

comfortzone

maximum strength

anti-fungal liquid

undecylenic acid

eliminates fungus on fingers, toes & around nails

- easy to apply applicator brush
- dries quickly
- non-oily, clear formula

- no unpleasant odor

NET 1 FL. OZ (30mL)



DO NOT USE IF NECKBAND IS BROKEN

Drug Facts
Active ingredient Purpose
 Undecylenic acid 25% w/w.....Antifungal

Uses For cure of most tinea pedis (athlete's foot) and tinea corporis (ringworm)
For relief of ■ discomforts which may accompany these conditions ■ itching ■ burning ■ redness ■ irritation ■ scaling ■ soreness

Warnings
For external use only.
If pregnant or breastfeeding consult a healthcare professional before use.
Do not use on children under 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 reach of children. If accidental ingestion occurs, get medical help or contact a Poison Control Center right away.

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comfort//zone™
 maximum strength
anti-fungal liquid
undecylenic acid

Eliminates and helps stop the spread of fungal infections on cuticles, around nail edges, and under nail tips where reachable with applicator brush. Topical antifungal treatment will not penetrate hard nail surfaces.

*This product is not manufactured or distributed by Kramer Laboratories, Inc., owner of the registered trademark Fungi Nail®.
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 Hudson, NY 12534
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Questions? Call 1-877-237-0194
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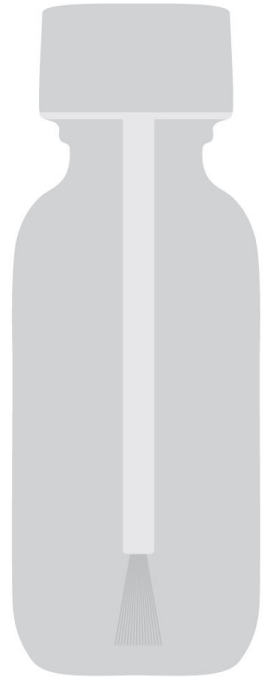


NDC 72446-004-01 Compare to the active ingredient in Fungi Nail®*

comfort//zone™
 maximum strength
anti-fungal liquid
undecylenic acid

eliminates fungus on fingers, toes & around nails

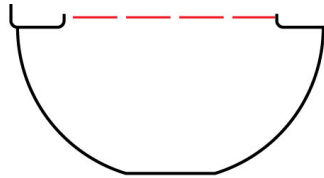
- easy to apply applicator brush
- dries quickly
- non-oily, clear formula
- no unpleasant odor



ACTUAL SIZE

NET 1 FL OZ (30 mL)

53-091AM-01



NDC 72446-004-01

DO NOT USE IF NECKBAND IS BROKEN

Active ingredient: Undecylenic acid (25% w/w)
Purpose: Antifungal **Uses:** For the cure of most tinea pedis (athlete's foot) and tinea corporis (ringworm)

maximum strength

anti-fungal liquid

undecylenic acid

eliminates fungus
on fingers, toes &
around nails

NET 1 FL OZ (30 mL)

Warnings: For external use only. If pregnant or breastfeeding consult a healthcare professional before use. Do not use on children under 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 irritation occurs or there is no improvement within 4 weeks. Keep out of reach of children. If accidental ingestion occurs, get medical help or contact a Poison Control Center right away. **Directions:** Read all warnings and directions. Use only as directed. Clean the affected area and dry thoroughly. Apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by a doctor. 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.

Inactive ingredient: isopropyl palmitate
Other information: Store at room temperature 15°-30°C (59°-86°F) Protect from freezing. If freezing occurs warm to room temperature. Keep tightly closed when not in use.

Questions? Call 1-877-237-0194
Retain outer packaging for complete Drug Facts information.

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Hudson, NY 12534
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50-091AM-01

UNDECYLENIC ACID

anti-fungal liquid maximum strength liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72446-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	7.5 g in 30 g

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72446-004-01	30 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	09/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	09/01/2018	

Labeler - Hudson Health LLC (081276171)

Revised: 7/2021

Hudson Health LLC