

TREATONIC TOENAIL FUNGUS TREATMENT KIT- toenail fungus treatment

100 KARMA INC

Initial Drug Listing - Treatonic Toenail Fungus Treatment Kit

25% Undecylenic Acid

1% Tolnaftate

Anti-fungal

- Helps Inhibit the growth of fungus.
- Improves the appearance of nails affected by fungus, including discoloration, thickening, splitting, crumbing, and brittleness.

For external use only

- on children under 2 years of age unless directed by a doctor.
- on diaper rash

when using this product:

avoid contact with eyes. Do not exceed the recommended daily dosage unless directed by a doctor.

Stop use and ask a doctor if

- irritation occurs
- this is no improvement within 4 weeks.

If pregnant or breast feeding, ask a health professional before use.

In case of accidental ingestion, seek medical advice immediately or contact a poison control center right away.

Directions (Treatment)

- Wash affected area and dry thoroughly.
- Apply a thin layer of the product over the affected area (around the nails and underneath nail tips) twice daily or directed by a doctor.
- Supervise children in the use of this product.

Directions (Patch)

- Clean & prepare the affected nail.
- Apply the antifungal solution to the affected nail.
- Apply the fungus nail patch. Firmly secure the patch to the sides of the toes or fingers, folding the remaining adhesive part to fully cover the toes/fingertips.
- Leave the patch on for 6-8 hours. Frequency: Use the patches consistently before bed.
- Maintain good foot hygiene.

Store at 20-25°C (68-77°F)

(Treatment) Isopropyl Myristate, Tea Tree Oil

(Patch) Water, Glycerin, Sodium Carboxymethyl Cellulose, Butylene Glycol, Urea



TREATONIC TOENAIL FUNGUS TREATMENT KIT

toenail fungus treatment kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85569-010
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85569-010-01	1 in 1 KIT; Type 0: Not a Combination Product	09/10/2025	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		1
Part 2		2

FUNGAL NAIL NIGHTTIME RENEWAL PATCHES

tolnaftate 1% patch

Product Information

Item Code (Source)	NDC:85569-009
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
UREA (UNII: 8W8T17847W)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	08/31/2025	

Part 2 of 2

TOENAIL FUNGUS TREATMENT

25% undecylenic acid liquid

Product Information

Item Code (Source)	NDC:85569-005
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	25 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TEA TREE OIL (UNII: VIF565UC2G)	

Marketing Information

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OTC Monograph Drug	M005	08/31/2025	

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Labeler - 100 KARMA INC (120186232)

Revised: 8/2025

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