

**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

Email: service@treatonic.com



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	

Part 1 of 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: PDC6A3C00X)	
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

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

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OTC Monograph Drug	M005	09/10/2025	

Labeler - 100 KARMA INC (120186232)

Revised: 8/2025

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