

OPTI-NAIL 2-IN-1- tolnaftate liquid
Kramer Laboratories

Drug facts

Active ingredient	Purpose
Tolnaftate 1%	Anti-fungal

Uses

- proven effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- helps prevent most athlete's foot with daily use
- for effective relief of itching, burning and cracking.

Warnings

For external use only.

Do not use on children under 2 years of age unless directed by a doctor.

When using this product

- avoid contact with eyes.

Stop use and ask a doctor if

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

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

In case of accidental ingestion, contact a physician, emergency medical care facility or Poison Control Center immediately for advice.

Directions:

- Clean affected area with soap and warm water and dry thoroughly.
- Apply a thin layer of Maximum Strength Antifungal over affected area twice daily (morning and night) or as directed by a doctor.
- The brush applicator allows for easy application to skin around the nail.
- Wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.
- For athlete's foot pay special attention to spaces between the toes.

- For athlete's foot and ringworm, use daily for 4 weeks.
- For toe fungus, apply to skin around nails. If condition persists longer, consult a doctor.
- This product is not effective on the scalp or nails.
- Supervise children in the use of this product.

Other information

Store at room temperature 15°–30°C (59°–86°F).

Inactive ingredients

aloe vera (aloe barbadensis) gel, ascorbic acid (vitamin C), dimethicone, DMDM hydantoin, edetate disodium dihydrate, eucalyptol, glycerin, glyceryl stearate SE, lavender oil, mineral oil, olive oil, PEG-100 stearate, phenoxetol, propylene glycol, tea tree oil, titanium dioxide, alpha tocopheryl acetate (vitamin E), xanthan gum, water

PACKAGE LABEL

THE ONLY PRODUCT THAT

1. Improves Nail Appearance **AND**
2. Kills Fungus Around the Nail

NEW

Opti-Nail™ 2-in-1

FUNGAL NAIL REPAIR + ANTI-FUNGAL

1 Improves Nail Appearance Fungal Nail Repair Formula

Apply directly on nail

Visible Results Starting in Just **2 DAYS**

Net Wt 5mL
(.169 fl oz)

2 Kills Fungus Around Nail Maximum Strength Antifungal (1% Tolnaftate)

Apply to skin around nail

Clinically Proven to
Cure & Prevent

Fungal Infections*

Net Wt 5mL
(.169 fl oz)

INCLUDES:

1% Tolnaftate Antifungal Solution AND Fungal Nail Repair Formula

*restores skin health + cures most athlete's foot

Step 1

Apply Fungal Nail Repair Formula

Directly On Nail

Clinically Proven Formula that results In Healthier Looking Nails

- ✓ Visible Results Starting in **Just 2 Days**
- ✓ **Triple Action Formula** Lightens, Smooths, and Moisturizes
- ✓ Easy to Apply & Dries Quickly

Apply twice a day for 4 weeks, then use once daily as needed.

Fungal Nail Repair Formula Ingredients:

Ethyl lactate, glycerin, water, lactic acid, resacetophenone, citric acid (if needed for pH balance).

For External Use only. Apply only to nail surface.

Avoid contact with eyes and mucus membranes.

Do not use if you are allergic to any of the ingredients in this product.

Keep out of reach of children.

Diabetics should ask a doctor before use.

Sunburn Alert: may increase your skin's sensitivity to the sun and particularly the possibility of sunburn.

See package insert for full Opti-Nail 2-1 product instructions

Do not use if neck band is missing or broken

K0322

Fungal Nail Repair Formula does not treat, cure, or prevent fungal infections.

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Questions or Comments? Call 1-800-824-4894

Patent pending

Step 2

Apply Maximum Strength Antifungal

On Skin Around Nail

Clinically Proven to **Cure & Prevent** Fungal Infections

- ✓ Kills Fungus
- ✓ Stops Itching and Burning
- ✓ Restores Skin Health + Cures Most Athletes Foot

Maximum Strength Anti-Fungal not for nail or scalp fungus. Cures most athlete's foot.

Step 2

Apply Maximum Strength Antifungal
On Skin Around Nail

Clinically Proven to Cure & Prevent Fungal Infections

- ✓ Kills Fungus
- ✓ Stops Itching and Burning
- ✓ Restores Skin Health + Cures Most Athletes Foot

Active ingredient	Purpose
Tolnaftate 1%	Antifungal

Uses ■ proven effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis) ■ helps prevent most athlete's foot with daily use ■ for effective relief of itching, burning and cracking.

Warnings
For external use only.
Do not use on children under 2 years of age unless directed by a doctor.
When using this product ■ avoid contact with eyes.
Stop use and ask a doctor if ■ irritation occurs ■ there is no improvement within 4 weeks.
KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. In case of accidental ingestion, contact a physician, emergency medical care facility or Poison Control Center immediately for advice.

Directions: ■ Clean affected area with soap and warm water and dry thoroughly. ■ Apply a thin layer of Maximum Strength Antifungal over affected area twice daily (morning and night) or as directed by a doctor.
■ The brush applicator allows for easy application to skin around the nail. ■ Wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.
■ For athlete's foot pay special attention to spaces between the toes.
■ For athlete's foot and ringworm, use daily for 4 weeks.
■ For toe fungus, apply to skin around nails. If condition persists longer, consult a doctor. ■ This product is not effective on the scalp or nails. ■ Supervise children in the use of this product.

Other information Store at room temperature 15°-30°C (59°-86°F). Protect from freezing. If freezing occurs warm to room temperature. Medicine may appear white to off white.

Inactive ingredients aloe vera (aloe barbadensis) leaf juice, ascorbic acid (Vitamin C), dimethicone, DMDM hydantoin, edetate disodium, eucalyptol, glycerin, glyceryl stearate SE, lavender oil, mineral oil, olive oil, PEG-100 stearate, phenoxyethanol, propylene glycol, tea tree oil, titanium dioxide, alpha tocopherol acetate, xanthan gum, water.

Maximum Strength Antifungal is not effective for nail or scalp fungus. Cures most athlete's foot.

THE ONLY PRODUCT THAT

1. Improves Nail Appearance AND
2. Kills Fungus Around the Nail

Opti-Nail[®]

2-in-1

FUNGAL NAIL REPAIR + ANTIFUNGAL

1

Improves Nail Appearance

Fungal Nail Repair Formula



Apply directly on nail

Visible Results Starting in Just 2 DAYS

Net Wt 5mL (169 fl oz)

2

Kills Fungus Around Nail

Maximum Strength Antifungal (1% Tolnaftate)



Apply to skin around nail

Clinically Proven to Cure & Prevent Fungal Infections*

Net Wt 5mL (169 fl oz)

INCLUDES:
1% Tolnaftate Antifungal Solution AND Fungal Nail Repair Formula

*restores skin health + cures most athlete's foot

Step 1

Apply Fungal Nail Repair Formula
Directly On Nail

Clinically Proven Formula that results In Healthier Looking Nails

- ✓ Visible Results Starting in Just 2 Days
- ✓ Triple Action Formula Lightens, Smooths, and Moisturizes
- ✓ Easy to Apply & Dries Quickly

Apply twice a day for 4 weeks, then use once daily as needed.

Fungal Nail Repair Formula Ingredients:
Ethyl lactate, glycerin, water, lactic acid, resacetophenone, aloe barbadensis leaf juice, lavender angustifolia oil, eucalyptol, citric acid (if needed for pH balance).

For External Use only. Apply only to nail surface. Solution looks clear. Avoid contact with eyes and mucus membranes. Do not use if you are allergic to any of the ingredients in this product. Keep out of reach of children. Diabetics should ask a doctor before use.
Sunburn Alert: may increase your skin's sensitivity to the sun and particularly the possibility of sunburn.

See package insert for full Opti-Nail 2-1 product instructions



Do not use if "SEALED FOR YOUR PROTECTION" stickers on the clear plastic package are destroyed or removed.

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Fungal Nail Repair Formula does not treat, cure, or prevent fungal infections.
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Questions or Comments? Call 1-800-824-4894
Patent pending

Opti-Nail™ 2-in-1 Fungal Nail Repair + Antifungal

Directions For Use

Always apply step 1 BEFORE Step 2

First clean affected areas with soap and water and dry thoroughly

Step 1

Apply Fungal Nail Repair Formula (Green side) to Nail Surface

Unscrew the green cap.

Using the applicator, apply a thin layer of solution directly on entire affected nail surface twice daily (morning and evening).

(Solution looks clear.)

Nail surface will appear wet after application. Avoid applying to skin around the nail.

After applying, recap tightly and allow treated nails(s) to dry for a few minutes before beginning Step 2.

Apply twice a day for 4 weeks, then use once daily as needed to maintain look.

For external use only. Avoid contact with skin. Apply only to nail surface. Avoid contact with eyes and mucous membranes. In case of contact with eyes, rinse cautiously with water for several minutes. May cause irritation if applied to skin. Discontinue use in the event of an allergic reaction or irritation. Do not use if you are allergic to any of the ingredients in the product. Keep out of reach of children. Avoid inhalation. Diabetics should ask doctor before use.

Sunburn Alert: This product contains alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use sunscreen, wear protective clothing, and limit sun exposure while using this product for a week afterwards. Product is flammable, do not use near an open flame.

Fungal Nail Repair Formula Ingredients: Ethyl lactate, glycerin, water, lactic acid, resacetophenone, citric acid (if needed for pH balance).

Fungal Nail Repair Formula does not treat, cure, or prevent fungal infections

Step 2

Apply Maximum Strength Antifungal (Blue side) to Skin Around Nail

Unscrew the blue cap.

Using the applicator, apply a thin layer of medicine to skin around nails twice daily (morning and evening).

(Medicine looks white to off-white.)

After applying, recap tightly and allow treated area to dry for a few minutes before putting on socks and shoes.

Apply twice a day for 4 weeks.

For external use only. Do not use on children under 2 years of age unless directed by a doctor. When using this product avoid contact with eyes. Stop use and ask a doctor if irritation occurs or if there is no improvement within 4 weeks. Keep out of reach of children. In case of accidental ingestion, contact a physician, emergency medical care facility or Poison Control Center immediately for advice.

Maximum Strength Antifungal: Active ingredient: Tolnaftate 1% Inactive ingredients: aloe vera (aloe barbadensis) gel, ascorbic acid (vitamin C), dimethicone, DMDM hydantoin, edetate disodium dihydrate, eucalyptol, glycerin, glyceryl stearate SE, lavender oil, mineral oil, olive oil, PEG-100 stearate, phenoxetol, propylene glycol, tea tree oil, titanium dioxide, tocopheryl acetate (vitamin E), xanthan gum, water

Maximum Strength Antifungal is not effective for nail or scalp fungus. Cures most athlete's foot.

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Questions or Comments? Call 1-800-824-4894

Patent pending

Store at room temperature 15°–30°C (59°–86°F)

K0322

Opti-Nail® 2-in-1 Fungal Nail Repair + Antifungal

Directions For Use

Always apply Step 1 BEFORE Step 2

First clean affected areas with soap and water and dry thoroughly

Step 1

Apply Fungal Nail Repair Formula (Green side) to Nail Surface

Remove nail polish before applying Opti-Nail®
Unscrew the green cap.

Using the applicator, apply a thin layer of solution directly on entire affected nail surface twice daily (morning and evening).

(Solution looks clear.)

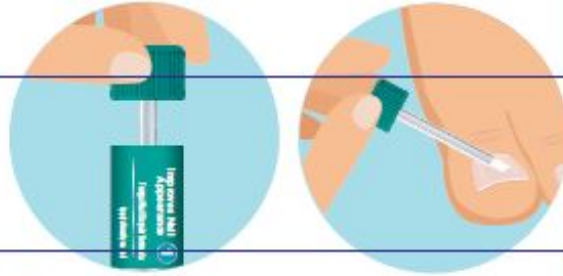
Nail surface will appear wet after application. Avoid applying to skin around the nail.

After applying, recap tightly and allow treated nail(s) to dry for a few minutes before beginning Step 2.

Apply twice a day for 4 weeks, then use once daily as needed to maintain look.

For external use only. Avoid contact with skin. Apply only to nail surface. Avoid contact with eyes and mucous membranes. In case of contact with eyes, rinse cautiously with water for several minutes. May cause irritation if applied to skin. Discontinue use in the event of an allergic reaction or irritation. Do not use if you are allergic to any of the ingredients in the product. Keep out of reach of children. Avoid inhalation. Diabetics should ask doctor before use. **Sunburn Alert:** This product contains alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use sunscreen, wear protective clothing, and limit sun exposure while using this product for a week afterwards. Product is flammable, do not use near an open flame.

Fungal Nail Repair Formula Ingredients: Ethyl lactate, glycerin, water, lactic acid, resacetophenone, aloe barbadensis leaf juice, lavandula angustifolia oil, eucalyptol, citric acid (if needed for pH balance). Fungal Nail Repair Formula does not treat, cure, or prevent fungal infections



Step 2

Apply Maximum Strength Antifungal (Blue side) to Skin Around Nail

Unscrew the blue cap.

Using the applicator, apply a thin layer of medicine to skin around nails twice daily (morning and evening).

(Medicine looks white to off-white.)

After applying, recap tightly and allow treated area to dry for a few minutes before putting on socks and shoes.

Apply twice a day for 4 weeks.

For external use only. Do not use on children under 2 years of age unless directed by a doctor. When using this product avoid contact with eyes. Stop use and ask a doctor if irritation occurs or if there is no improvement within 4 weeks. Keep out of reach of children. In case of accidental ingestion, contact a physician, emergency medical care facility or Poison Control Center immediately for advice.

Maximum Strength Antifungal: Active ingredient: Tolnaftate 1%. Inactive ingredients: aloe vera (aloe barbadensis) leaf juice, ascorbic acid (vitamin C), dimethicone, DMDM hydantoin, edetate disodium, eucalyptol, glycerin, glyceryl stearate SE, lavender oil, mineral oil, olive oil, PEG-100 stearate, phenoxyethanol, propylene glycol, tea tree oil, titanium dioxide, alpha tocopherol acetate, xanthan gum, water.

Maximum Strength Antifungal is not effective for nail or scalp fungus. Cures most athlete's foot.

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Questions or Comments? Call 1-800-824-4894
Patent pending

Store at room temperature 5°-30°C (59°-86°F). Protected from freezing. If freezing occurs warm to room temperature.

K03322

OPTI-NAIL 2-IN-1

tolnaftate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55505-219
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 mL

Inactive Ingredients

Ingredient Name	Strength
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Ascorbic Acid (UNII: PQ6CK8PD0R)	
Dimethicone (UNII: 92RU3N3Y1O)	
Dmdm Hydantoin (UNII: BYR0546TOW)	
Edetate Disodium (UNII: 7FLD91C86K)	
Eucalyptol (UNII: RV6J6604TK)	
Glycerin (UNII: PDC6A3C0OX)	
Glyceryl Stearate Se (UNII: FCZ5MH785I)	
Lavender Oil (UNII: ZBP1YXW0H8)	
Mineral Oil (UNII: T5L8T28FGP)	
Olive Oil (UNII: 6UYK2W1W1E)	
Peg-100 Stearate (UNII: YD01N1999R)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Tea Tree Oil (UNII: VIF565UC2G)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Xanthan Gum (UNII: TTV12P4NEE)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55505-219-67	5 mL in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product	01/20/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	01/20/2023	

Labeler - Kramer Laboratories (122720675)

Revised: 12/2023

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