FUNGI NAIL TOE AND FOOT- tolnaftate ointment
Kramer Laboratories

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.

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 areas with soap and warm water and dry thoroughly. ■ Apply a thin layer of Fungi-Nail® Anti-Fungal Ointment over affected area twice daily (morning and night) or as directed by a doctor. ■ 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. ■ To prevent athlete's foot, apply once or twice daily (morning and/or night). ■ For toe fungus, apply under nail and around cuticle area. 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 controlled room temperature 15°-30° C (59°-86° F) Protect from freezing. If freezing occurs warm to room temperature.

Inactive ingredients
Aloe Vera Leaf, Carbomer Homopolymer Type A (Allyl Pentaerythritol Crosslinked), Dimethicone 350, Eucalyptol, Lavender Oil, Glyceryl Monostearate, Olive Oil, Phenoxyethanol, Poloxamer 188, Purified Water USP, Sodium Hydroxide, Tea Tree Oil

PRINCIPAL DISPLAY PANEL

MAXIMUM STRENGTH

FUNGI-NAIL®
ANTI-FUNGAL

OINTMENT

CLINICALLY PROVEN TO
CURE AND PREVENT
FUNGAL INFECTIONS

TRIPLE ACTION FORMULA
 Kills Fungus
 Stops Itching & Burning
 Restores Skin Health
0.7 FL. OZ. (20 g)

Convenient and Easy to Apply

Deep Penetrating Medicine that Stays in Place

Not actual size.

Patent pending.

#1 Pharmacist Recommended

FUNGI-NAIL® ANTI-FUNGAL OINTMENT infused with 5 natural oils including tea tree, eucalyptol, aloe, olive and lavender

For best results treat around all toenails and in between toes.

Not for Nail or scalp fungus.

Cures most athlete's foot.

For more information about Fungi-Nail® and money back guarantee, visit us at funginail.com

Kramer Laboratories, Inc.
Bridgewater, NJ 08807
kramerlabs.com
funginail.com
1-800-824-4894

K1119

MAXIMUM STRENGTH

FUNGI-NAIL®
ANTI-FUNGAL
OINTMENT

KILLS FUNGUS • RESTORES SKIN

NET WT 0.7 FL. OZ. (20 G)

Distributed By:
KRAMER LABORATORIES

Kramer Laboratories, Inc. Bridgewater, NJ 08807 U.S.A.

kramerlabs.com
fungi-nail.com
1-800-824-4894

K0119

Distributed By:

KRAMER LABORATORIES

Kramer Laboratories, Inc. Bridgewater, NJ 08807 U.S.A.

kramerlabs.com
fungi-nail.com
1-800-824-4894

K0119

MAXIMUM STRENGTH

FUNGI-NAIL®

ANTI-FUNGAL

OINTMENT

KILLS FUNGUS • RESTORES SKIN

NET WT 0.7 FL. OZ. (20 g)

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 OUT OF 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 areas with soap and warm water and dry thoroughly. ■ Apply a thin layer of Fungi-Nail® Anti-Fungal Ointment over affected area twice daily (morning and night) or as directed by a doctor. ■ 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. ■ To prevent athlete's foot apply once or twice daily (morning and/or night) ■ For toe fungus, apply on skin around the nail and cuticle area. 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.

FUNGI NAIL TOE AND FOOT

tolnaftate ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55505-185
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 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Carbomer Homopolymer Type A (Allyl Pentaerythritol Crosslinked) (UNII: F68VH75CJC)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Dimethicone 350 (UNII: 2Y53S6ATLU)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Poloxamer 188 (UNII: LQA7B6G8JG)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Eucalyptol (UNII: RV6J6604TK)	
Lavender Oil (UNII: ZBP1YXW0H8)	
Olive Oil (UNII: 6UYK2W1W1E)	
Tea Tree Oil (UNII: VIF565UC2G)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55505-185-50	1 in 1 CARTON	06/01/2019	
1		20 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	11/15/2018	

Labeler - Kramer Laboratories (122720675)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmecuticals		001207208	manufacture(55505-185)

Revised: 12/2019

Kramer Laboratories