

DERMATOOL FUNGAL NAIL TREATMENT- tolnaftate 1% liquid
Derma Care Research Labs, 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.

Tolnaftate 1%

Antifungal

Cures most Athlete's Foot (Tinea Pedis) and Ringworm (Tinea Corporis). Relieves itching, scaling, cracking, burning, redness, sores, and irritation and discomfort. Helps prevent most athlete's foot (dermatophytosis) with daily use.

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 (for athlete's foot and ringworm).

If swallowed, get medical help or contact a Poison Control Center right away.

For athlete's foot and ringworm: use daily for 4 weeks. Clean the affected area and dry thoroughly. Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. This product is not effective for the treatment of ringworm of the scalp or nails. 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. To prevent athlete's foot, apply once or twice daily (morning and/or night). Apply to skin around the nail and cuticle.

Carthamus Tinctorius (Safflower) Seed Oil, Hydrogenated Polyisobutene, Oryza Sativa (Rice) Bran Oil, Sesamum Indicum (Sesame) Seed Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Tocopheryl Acetate, Aloe Barbadensis Leaf Extract, Lavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Simmondsia Chinensis (Jojoba) Seed Oil, BHT.

Drug Facts

Active ingredient
Tolnaftate 1%.....

Purpose
Antifungal

Uses

• Cures most Athlete's Foot (Tinea Pedis) and Ringworm (Tinea Corporis)
• Relieves itching, scaling, cracking, burning, redness, soreness and irritation and discomfort. Helps prevent most athlete's foot (dermatophytosis) with daily use.

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 (for athlete's foot and ringworm).

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions • For athlete's foot and ringworm: use daily for 4 weeks.
• Clean the affected area and dry thoroughly • Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor • Supervise children in the use of this product • This product is not effective for the treatment of ringworm of the scalp or nails • 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 • To prevent athlete's foot, apply once or twice daily (morning and/or night) • Apply to skin around the nail and cuticle.

Other information

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

Inactive Ingredients
Carthamus Tinctorius (Safflower) Seed Oil, Hydrogenated Polyisobutene, Oryza Sativa (Rice) Bran Oil, Sesamum Indicum (Sesame) Seed Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Tocopheryl Acetate, Aloe Barbadensis Leaf Extract, Lavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Simmondsia Chinensis (Jojoba) Seed Oil, BHT

DERMATOOL®

FUNGAL NAIL TREATMENT

MEDICAL STRENGTH

Kills Fungus
Stops Itching & Burning
Restores Skin Health

ANTIFUNGAL SOLUTION
CLINICALLY PROVEN TO CURE &
PREVENT FUNGAL INFECTIONS

0.5 FL OZ (15mL)

FAST ACTING MEDICATED FORMULA

ELIMINATES FUNGUS THAT CAUSES FUNGAL NAILS

- Treats Toes & Fingers
- Deep Penetrating & Hydrating Action
- Easy to Apply Brush-on Liquid
- Helps Heal Damaged Nails

Questions?

support@dermatoolcare.com

DISTRIBUTED BY: Dermatool®
89 River St. #551
Hoboken, NJ 07030
www.dermatoolcare.com

Made in U.S.A with domestic & imported components

MADE IN USA

DERMATOOL FUNGAL NAIL TREATMENT

tolnaftate 1% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-510
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
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
ALMOND OIL (UNII: 66YXD4DKO9)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
RICE BRAN OIL (UNII: LZ06K1506A)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
JOJOBA OIL (UNII: 724GKU717M)	
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-510-01	1 in 1 CARTON	04/06/2023	
1		15 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		M005	04/06/2023	

Labeler - Derma Care Research Labs, LLC (116817470)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs, LLC		116817470	manufacture(72839-510)

Revised: 5/2023

Derma Care Research Labs, LLC