

DERMATOOL FUNGAL NAIL TREATMENT- tolnaftate 1% liquid
Papalo Group LLC

Dermatool Antifungal

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

Purpose

Tolnaftate 1% 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

- Paraben Free
- Propylene Glycol Free
- Sulfate Free

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

**DERMATOOL FUNGAL NAIL TREATMENT**

tolnaftate 1% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84728-510
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:84728-510-01	1 in 1 CARTON	04/06/2023	
1		15 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
2	NDC:84728-510-02	2 in 1 BOX	01/31/2025	
2		15 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
3	NDC:84728-510-03	3 in 1 BOX	02/03/2025	
3		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 Drug	M005	04/06/2023	

Labeler - Papalo Group LLC (119324672)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs, LLC		116817470	manufacture(84728-510)

Revised: 1/2025

Papalo Group LLC