

**NOVONAIL SOLUTION- 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.*

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**Novonail Solution, Tolnaftate 1%**

Tolnaftate 1%

Antifungal

For effective treatment of most athlete's foot and ringworm. Relieves itching, scaling, cracking, burning, redness, soreness, 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.

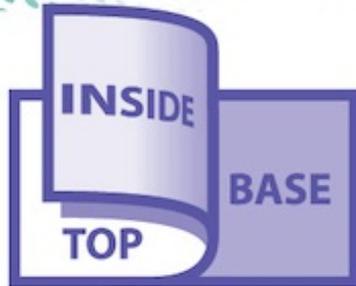
Aloe Barbadensis Leaf Extract, BHT, Carthamus Tinctorius (Safflower) Seed Oil, Hydrogenated Polyisobutene, Lavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Sesamum Indicum (Sesame) Seed Oil, Oryza Sativa (Rice) Bran Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Simmondsia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



<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Tolnaftate 1%.....	Anti-Fungal
<b>Uses</b>	
For effective treatment of most athlete's foot and ringworm.	
Relieves: • Itching • Scaling • Cracking	
• Burning • Redness • Soreness • Irritation	
• Discomfort. Helps prevent most athlete's foot (dermatophytosis) with daily use.	

0.45 FL OZ. (13.3 mL)

600 Peter Jefferson Parkway, Charlottesville VA, 22911  
NovoNail.com (800) 000-0000 Peel for Full Labeling



Multi-Layer Label

**INSIDE**

**300486**

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PROOF#

**01**

HD175

**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 the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions** • this product is not effective on the scalp or nails. 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 doctor. ▶

----- Indicates copy safe area

(No ink can extend beyond dotted lines)

**BASE**

**Directions (continued)** • supervise children in the use of this product. • For athlete's foot: pay special attention to spaces between toes; wear well-fitting, ventilated shoes; change shoes and socks at least once daily. • to prevent athlete's foot, apply once or twice daily (morning and/or night).

**Other information**

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

**Inactive ingredients** Aloe Barbadosis Leaf Extract, BUT Carthamus Tinctorius (Safflower) Seed Oil

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

## NOVONAIL SOLUTION

tolnaftate 1% liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72839-507
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TOLNAFTATE</b> (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>HYDROGENATED POLYBUTENE (1300 MW)</b> (UNII: 7D1YQ9Y5EZ)	
<b>ALMOND OIL</b> (UNII: 66YXD4DKO9)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL</b> (UNII: VIF565UC2G)	
<b>RICE BRAN OIL</b> (UNII: LZ06K1506A)	
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-507-01	13.3 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	03/11/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M005	03/11/2020	

**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(72839-507)

Revised: 7/2023

Derma Care Research Labs, LLC