

NAILENE ANTIFUNGAL TREATMENT- tolnaftate liquid
Pacific World Corporation

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.

Nailene® Antifungal Treatment

Drug Facts

Active ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- Cures most fungal skin infections, including athlete's foot (tinea pedis) and ring worm (tinea corporis)
- Effectively relieves itching, burning, cracking and scaling accompanying such conditions

Warnings

For external use only.

Do not use

- near the mouth or eyes
- with known sensitivities to any listed ingredients
- on children under 2 years of age unless directed by a doctor

When using this product avoid eye contact. If accidental eye contact occurs, rinse thoroughly with water for 10-15 minutes.

Stop use and ask a doctor if rash or irritation occurs, or if no improvement is seen after four weeks.

If pregnant/breast-feeding, consult a health professional before using.

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

Directions

- Clean affected area with soap and warm water and dry thoroughly
- Apply a thin layer two times a day (mornings and evenings) to affected area especially the space between and around toes
- For athlete's foot, use daily for four weeks or as directed by a physician
- Allow solution to soak into skin or rub in to dry more quickly before putting on socks
- This product is not effective on scalp or nails.
- Following a proper foot hygiene regimen along with wearing well fitting, ventilated shoes and clean socks that are changed at least daily is helpful in preventing future infections

Other information

You may report questions or adverse reaction from using this product to 1(541)-476-3178, 8 am to 5 pm (M-F), PST.

Inactive ingredients

Water (Aqua), Caprylic/Capric Triglycerides, Isopropyl Palmitate, Polyquaternium 37, Propylene Glycol, Dicaprylate Dicaprate, PPG-1 Trideceth-6, Cocamidopropyl Betaine, Cocamidopropylamine Oxide, Phemerol Chloride, Cetrimonium Chloride, Allantoin, Didecyldimonium Chloride, Quaternium-15.

Imported & Distributed by:

UK/R.-U.: Pacific World Ltd.,

Stoke-on-Trent, Staffordshire. ST4 2 PJ

Australia: Creative Brands PTY LTD

30 Bando Road, Springvale, VIC 3171

South Africa: Indigo Cosmetics, Cape Town, 7460

New Zealand: BDM Grange, Auckland

PRINCIPAL DISPLAY PANEL - 18 mL Bottle Carton

new

61100

nailene®

**DOCTOR
FORMULATED**

**MAXIMUM STRENGTH
ANTIFUNGAL
TREATMENT**

Powered by
MYCOCIDE®

**For finger and
toe areas**

**No need to remove
nail polish or acrylics**

INCLUDES:

2 Extra-Coarse Nail Grinders

NET WT .6 FL OZ (18 mL) Antifungal Liquid

Glue

Glue

CONTENTS
1 Antifungal Treatment
.6 fl oz. (18 mL)
2 Extra-Coarse Nail Grinders

new

61100

nailene.



- Safe for Diabetes
- Recommended by Doctors
- Contains no harsh acids or alcohols
- Easy to apply, no noxious odor

MAXIMUM STRENGTH

ANTIFUNGAL TREATMENT



Powered by **MYCOCIDE®**

For finger and toe areas

No need to remove nail polish or acrylics

PATENTED PENETRATING DELIVERY SYSTEM



INCLUDES:

2 Extra-Coarse Nail Grinders
.6 FL OZ (18 mL) Antifungal Liquid



nailene.

MAXIMUM STRENGTH

ANTIFUNGAL TREATMENT

Powered by
MYCOCIDE

Drug Facts

Active ingredient	Purpose
Tolnaftate 1%	Antifungal

Uses ■ Cures athlete's foot (tinea pedis) and ringworm (tinea corporis)
 ■ For the effective relief of itching, burning, cracking and scaling feet
 ■ clinically proven to prevent athlete's foot (tinea pedis) 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. If contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if skin irritation occurs or if there is no improvement within 4 weeks

If pregnant/breast-feeding, ask a health professional before use

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

Directions ■ 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.

■ For athlete's foot: Pay attention to spaces between 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. If condition persists longer, consult a doctor. ■ This product is not effective on the scalp or nails

Other information You may report questions or adverse reaction from using this product to 1(541)-476-3178, 8 am to 5 pm (M-F), PST.

Inactive ingredients Water (Aqua), Caprylic/Capric Triglyceride, Isopropyl Palmitate, Polyquaternium-37, Propylene Glycol Dicaprylate/Dicaprate, Cocamidopropyl Betaine, Benzethonium Chloride, Cocamidopropylamine Oxide, Allantoin, PPG-1 Trideceth-6, Cetrimonium Chloride, Didecylidimonium Chloride, Quaternium-15, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate.

Directions:
 1. Clean fingers with soap and warm water and dry thoroughly.



2. Apply twice daily to affected area around and under the free edge of the nail.



3. Allow solution to soak into skin or rub in to dry more quickly.



Use on fingers and toes.

Manufactured for © Pacific World Corp., Aliso Viejo, CA 92655

Pacific World Corporation
 8409 Kerns Street, Suite 100
 San Diego, CA 92154

U.S. Patent Nos. 5,661,170; 5,827,870.
 Other patents pending

Imported & Distributed by:
 U.K.R.-U.: Pacific World Ltd.,
 Stone-on-trent, Staffordsh'rs, S74 2 P.J.
 Australia: Creative Brands PTY LTD
 30 Bando Road, Springvale, VIC 3171
 South Africa: Indigo Cosmetics, Cape Town, 7480
 New Zealand: BDM Grange, Auckland

Made in USA.

www.nailene.com

30-61100-003



Glue

NAILENE ANTIFUNGAL TREATMENT

tolnaftate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60193-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
POLYQUATERNIUM-37 (3000 MPAS) (UNII: HU373G0YSU)	
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)	
ALLANTOIN (UNII: 344S277G0Z)	
PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B)	
QUATERNIUM-15 (UNII: E40U03LEM0)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60193-102-02	1 in 1 CARTON		
1		18 mL in 1 BOTTLE, WITH APPLICATOR; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	--	----------------------	--------------------

Labeler - Pacific World Corporation (089693097)

Revised: 10/2014

Pacific World Corporation