# MICOTRIN AL- tolnaftate liquid PureTek 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.

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**Mcotrin AL™** 

## **Tolnaftate 1% Antifungal Liquid**

## **Active ingredient**

Tolnaftate 1%

## **Purpose**

**Antifungal** 

#### Uses

- for the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis).
- relieves itching, burning, cracking, scaling, and discomfort which accompany these conditions.
- for the prevention of most Athlete's foot with daily use.
- eliminates fungus on fingers, toes, and around the nails.
- eliminates and helps stop the spread of fungal infections on cuticles around nail edges and under the nail tips where reachable with applicator brush.

## Warnings

# For external use only

#### Do not use on

children under 2 years of age unless directed by a doctor.

# When using this product

• do not get into eyes

# Stop use and ask a doctor

- for athlete's foot and ringworm if irritation occurs or there is no improvement within 4 weeks
- for prevention of athlete's foot if irritation occurs, discontinue use and consult a doctor

# 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)
  paying special attention to the edges of the nail, cuticles, and skin around the nails or
  as directed by a doctor
- supervise children in the use of this product
- 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
- if condition persists longer, consult a doctor.

## Use under the direction of a medical practitioner

#### Other information

- Store at 15 30°C (59° 86°F) [see USP Controlled Room Temperature].
- avoid excessive heat
- do not use if package is damaged

## **How Supplied**

**Micotrin AL™ Antifungal Liquid** is supplied in a 1 fl oz / 30 mL glass bottle with a screw cap fitted with a brush applicator (NDC 59088-477-03)

# Inactive ingredients

Apple Cider Vinegar, Argania Spinosa (Argan) Kernel Oil, Benzyl Alcohol, DMSO (Dimethyl Sulfoxide), Eucalyptus Globulus (Eucalyptus) Leaf Oil, Glycerin, Laureth-4, Lavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, PEG-8, DL-alphatocopheryl acetate.

## Micotrin AL™

Manufactured in the USA by:

**PureTek Corporation** 

Panorama City, CA 91402 For questions or information

call toll-free: **877-921-7873** 

#### Drug Facts

Active ingredient Purpose Tolnaftate 1%. .Antifungal

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List No. 47703IAA Rev.38351

NDC 59088-477-03

# Micotrin AL™

Tolnaftate 1% Antifungal Liquid Net Wt. 1 fl oz / 30 mL

Use under the direction of a medical practitioner FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

See enclosed insert(s) for full prescribing information.

Store at 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature]. Avoid excessive heat.

Keep this and all medication out of reach of children.

Manufactured in the USA by: PureTek Corporation Panorama City, CA 91402 call toll-free: 877-921-7873





## **MICOTRIN AL**

tolnaftate liquid

## **Product Information**

HUMAN OTC DRUG NDC:59088-477 **Product Type** Item Code (Source)

**Route of Administration TOPICAL** 

# **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength **TOLNAFTATE** TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV) 0.3 g in 30 mL

## **Inactive Ingredients**

Ingredient Name	Strength
ARGAN OIL (UNII: 4V59G5UW9X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	

**DIMETHYL SULFOXIDE (UNII: YOW8V9698H) EUCALYPTUS OIL (UNII: 2R040NI662)** 

GLYCERIN (UNII: PDC6A3C0OX)	
LAURETH-4 (UNII: 6HQ855798J)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
TEA TREE OIL (UNII: VIF565UC2G)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
APPLE CIDER VINEGAR (UNII: 0UE22Q87VC)	

ı	Packaging					
1	tem Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:59088- 477-03	30 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	10/25/2021			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	10/25/2021		

# Labeler - PureTek Corporation (785961046)

Revised: 1/2023 PureTek Corporation