## MYCOZYL AL- tolnaftate liquid PureTek Corporation

-----

Mycozyl 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**

Mycozyl AL™ Antifungal Liquid is supplied in a 1 fl oz / 30 mL glass bottle with a screw cap fitted with a brush applicator (NDC 59088-443-03)

## 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.

# Mycozyl AL™

Manufactured in the USA by: **PureTek Corporation**San Fernando, CA 91340
For questions or information call toll-free: **877-921-7873** 

## **Drug Facts** Active ingredient Purpose Tolnaftate 1%. .Antifungal

- 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.
   eliminates fungues 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

- clean the affected area and dry thoroughly
   apply a thin layer of the product over affected area twice daily (morning and night) paying special aftention 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.

## Other information

■ Store at 15 - 30°C (59 - 86°F) ■ avoid excessive heat ■ do not use if package is damaged

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-alpha-tocopheryl acetate.

List No. 44303JPA Rev.38289

NDC 59088-443-03

# Mycozyl 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 San Fernando, CA 91340 For questions or information call toll-free: 877-921-7873





## **MYCOZYL AL**

tolnaftate liquid

## **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59088-443
--------------	----------------	--------------------	---------------

**Route of Administration TOPICAL** 

## **Active Ingredient/Active Moiety**

ı	Ingredient Name	Basis of Strength	Strength
ı	TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	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)

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:59088- 443-03	30 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	06/09/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	06/09/2021	

# Labeler - PureTek Corporation (785961046)

Revised: 10/2024 PureTek Corporation