MYCOZYL 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.

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

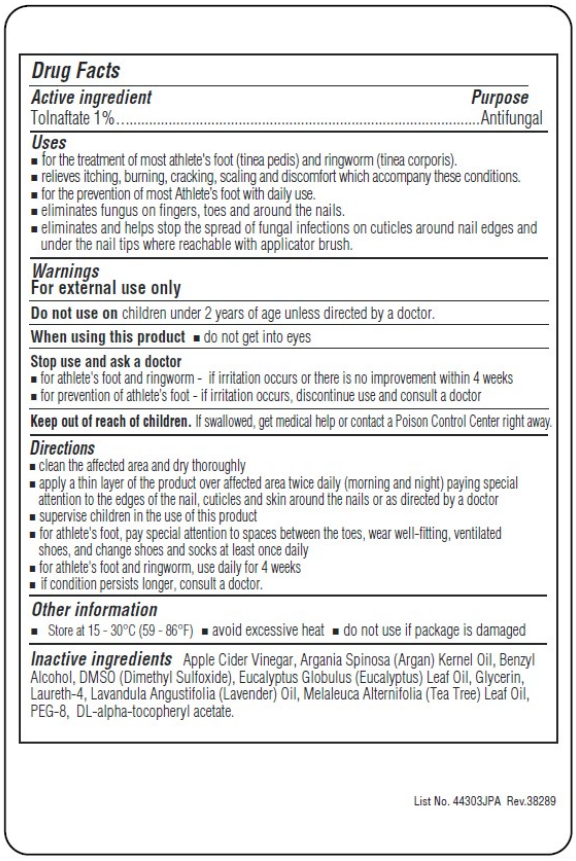
Mycozyl AL™Antifungal Liquid is supplied in a 1 fl oz / 30 mL glass bottle with a screw cap fitted with a brush applicator (NDC 59088-443-03)

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-alpha-tocopheryl 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

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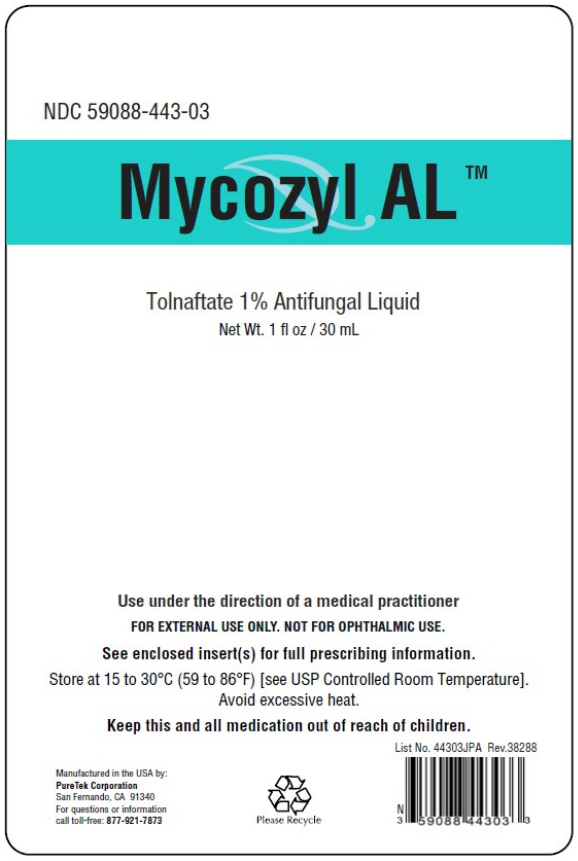
List No. 44303JPA Rev.38289



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.

List No. 44303JPA Rev.38288

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

Please Recycle

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		
Ingredient Name	**Basis of Strength**	**Strength**
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)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-443-03	30 mL in 1 BOTTLE, WITH 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 final	part333C	06/09/2021	

Labeler - PureTek Corporation (785961046)

Revised: 1/2023

PureTek Corporation