MYCOZYL AL- tolnaftate liquid
PURETEK CORPORATION

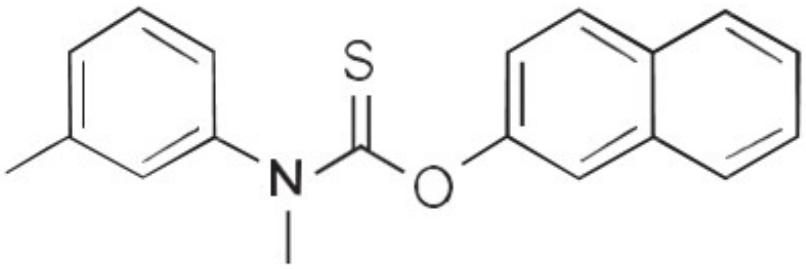
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Mycozyl AL

DESCRIPTION:

Each gram of **Mycozyl AL™** contains 10 mg of tolnaftate in a vehicle consisting of: 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.

Chemically, tolnaftate molecular formula is C19H17NOS and molecular weight 314.5 and is represented by the
following structure formula:



CLINICAL PHARMACOLOGY:

Tolnaftate has antifungal properties.

Pharmacokinetics:

Tolnaftate is only given topically, and there are no documented reports on its pharmacokinetics and systemic metabolism.

INDICATIONS AND USAGE:

Mycozyl AL™ is effective in the treatment of most skin infections such as athlete's foot (tinea pedis) and ringworm (tinea corporis). **Mycozyl AL™** has been designed to reach skin areas around and under the nails while it relives burning, cracking, scaling and discomfort which accompany these conditions. **Mycozyl AL™** is an antifungal that works by preventing and eliminating the growth of fungus on fingers, toes and around

the nails. It eliminates and helps stop the spread of fungal infections on cuticles around nail edges and under the nail tips where reachable with applicator brush. **Mycozyl AL™** cures and prevents fungal infections from coming back with daily use.

CONTRAINDICATIONS:

Tolnaftate topically applied is not likely to affect drugs taken or injected, but many drugs can interact with each other.

PRECAUTIONS:

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Avoid contact with eyes, lips and mucous membranes.

WARNINGS:

For External Use Only. Not For Ophthalmic Use

General:

Do not start, stop, or change the dosage of any medicine before checking with your doctor, health care provider or pharmacist first.

Carcinogenesis, Mutagenesis, and Impairment of Fertility:

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of Tolnaftate.

Pregnancy:

Teratogenic effects - There is currently no published human data available on the teratogenic and fetotoxic effects of tolnaftate.

Nursing Mothers:

Before using this medication while breastfeeding, it is recommended to consult with a healthcare professional.

Pediatric Use:

Safety and effectiveness have not been established in pediatric patients less than 2 years of age.

ADVERSE REACTIONS:

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.

OVERDOSAGE:

(See PRECAUTIONS).

DOSAGE AND ADMINISTRATION:

• Clean the affected area with soap and warm water and dry thoroughly
• Apply a thin layer of 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
• The brush applicator allows for easy application on skin around the nail and cuticle areas.
• 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.
• Supervise children in the use of this product.

Use under the direction of a licensed medical practitioner.
Call your doctor about side effects. To report side effects, call **PureTek Corporation** at
1-877-921-7873 or FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch.**

HOW SUPPLIED:

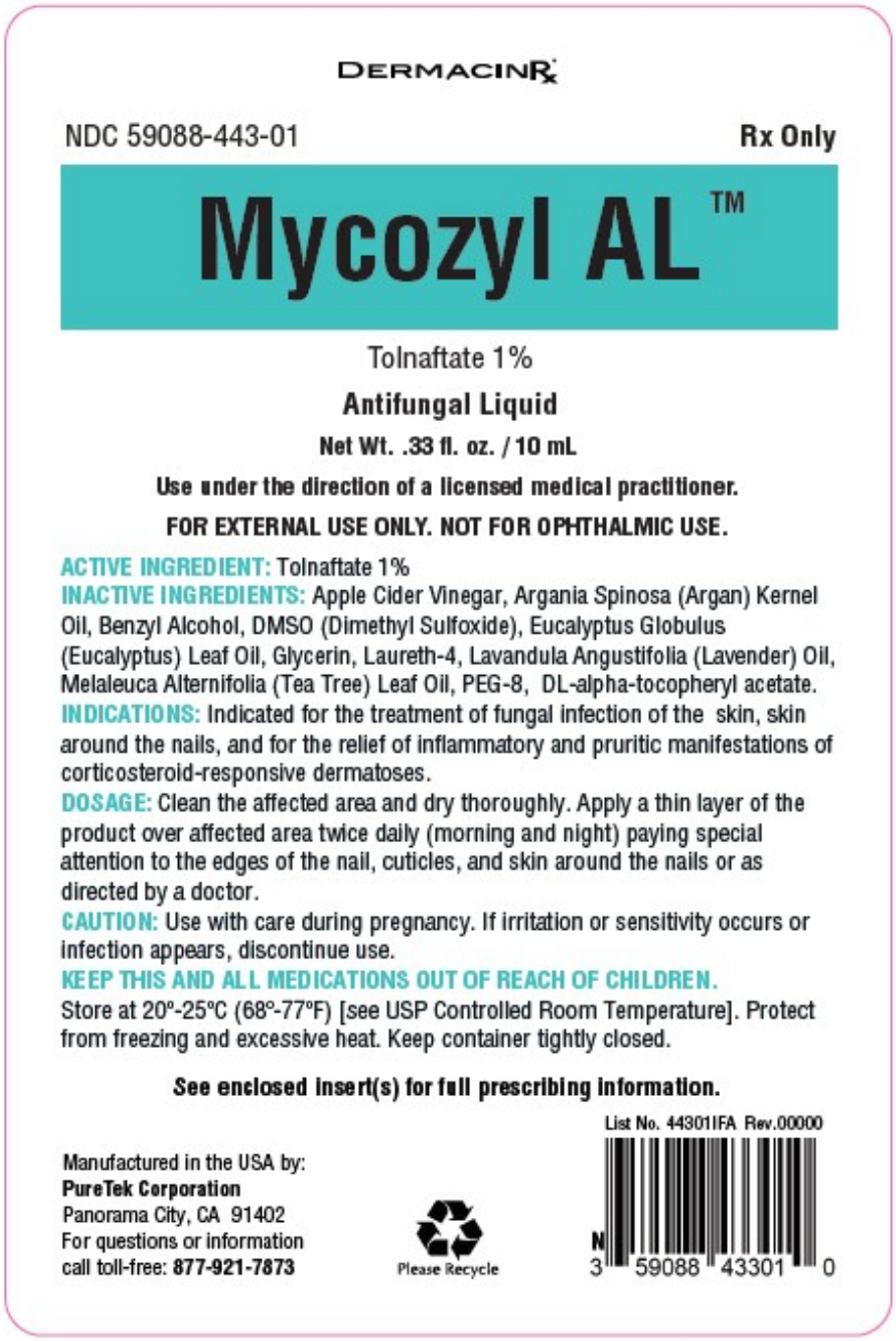
Mycozyl AL™ is supplied in:
10 mL glass bottle with a screw cap fitted with a brush applicator (NDC 59088-443-01).

Store at 20º-25ºC (68º-77ºF) [see USP Controlled Room Temperature]. Protect from freezing and excessive heat. Keep

container tightly closed.
Do not use if package is damaged. Keep out of reach of children.

Manufactured by:
PureTek Corporation
Panorama City, CA 91402
For questions or information
call toll-free: **877-921-7873**

Mycozyl AL™



MYCOZYL AL

tolnaftate liquid

Product Information			
Product Type	HUMAN PRESCRIPTION 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	0.1 g in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TEA TREE OIL (UNII: VIF565UC2G)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
LAURETH-4 (UNII: 6HQ855798J)	
APPLE CIDER VINEGAR (UNII: 0UE22Q87VC)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
ARGAN OIL (UNII: 4V59G5UW9X)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59088-443-01	10 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/17/2023	

Labeler - PURETEK CORPORATION (785961046)

Revised: 10/2023 PURETEK CORPORATION