#### MICONATATE- miconazole nitrate and tolnaftate 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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#### Miconatate™

Kit

Mycozyl AP™, Miconazole Nitrate 2%, Antifungal Powder (3 oz / 85 g) Mycozyl AL™, Tolnaftate 1%, Antifungal Liquid (1 fl oz / 30 mL)

# **Mycozyl AP**

## Active ingredient

Miconazole Nitrate 2%

## Purpose

Antifungal

#### Uses

- for the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis).
- relieves itching, burning, cracking, scaling, and discomfort which accompany these conditions.

#### 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 if

- for athlete's foot and ringworm irritation occurs or there is no improvement within 4 weeks
- for jock itch irritation occurs or there is no improvement within 2 weeks

# 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 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
- for jock itch, use daily for 2 weeks
- if condition persists longer, consult a doctor. This product is not effective on the scalp or nails.

# Other information

- protect from freezing
- avoid excessive heat
- do not use if package is damaged

#### Inactive ingredients

Aleurites Moluccana (Kukui) Seed Oil, Aloe Barbadensis (Aloe Vera) Leaf Juice Powder, Bisabolol, Carthamus Tinctorius (Safflower) Oleosomes, Fragrance, Nylon-12, Silica, Sodium Benzoate, Sodium Hyaluronate, Zea Mays (Corn) Starch, Zingiber Officinale (Ginger) Root Extract.

# Mycozylal AL

# **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**

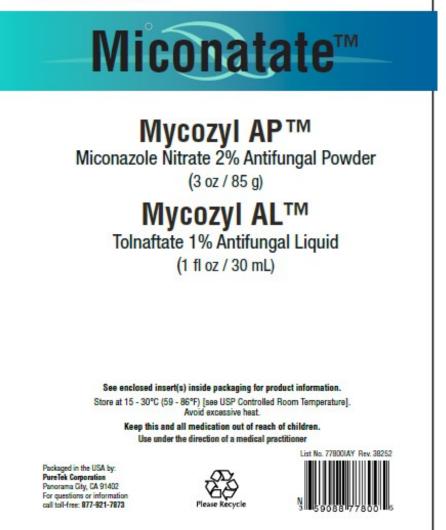
**Mycozyl AL**<sup>™</sup> **Antifungal Liquid** is supplied in a 1 fl oz / 30 mL glass bottle with a screw cap fitted with a brush applicator (NDC 59088-443-03)

# 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.

#### Miconatate™

Packaged in the USA by: **PureTek Corporation** Panorama City, CA 91402 For questions or information call toll-free: **877-921-7873**  NDC 59088-778-00



Μ	ICONATAT	Έ					
mi	conazole nitrat	e and tolna	ftate kit				
Product Information							
Product Type		HUMAN	I OTC DRUG	Item Coo	de (Source)	NDC:59088-778	
P	ackaging						
P #		Pa	ckage Descrip	tion	Marketing Start Date	Marketing End Date	
	ltem Code		<b>ckage Descrip</b> N; Type 0: Not a Co		-	-	
#	Item Code	1 in 1 CARTO	• •		Date	-	

Quantity of					
Part #	Package	e Quantity		<b>Total Product Qua</b>	antity
Part 1 0 BOTT	ILE, WITH APPLICAT	OR	1 mL in 30		
Part 2 0 BOTT	art 2 0 BOTTLE				
Part 1 of	2				
ΜΥϹΟΖΥΙ	A 1				
tolnaftate liqu	lid				
Product Inf	ormation				
Item Code (S	ource)	NDC:59088-443			
Route of Adm	ninistration	TOPICAL			
Active Ingre	edient/Active	Moiety			
	Ingred	ient Name		<b>Basis of Strength</b>	n Strength
TOLNAFTATE (I				TOLNAFTATE	0.3 g in 30 mL
		(TOLNAFTATE - UNII:06KB62	.91KV)		
		(TOLNAFTATE - UNII:06KB62	.9160)		0.0 g 11 20 112
Inactive Ing	gredients	Ingredient Name	.91KV)		Strength
Inactive Ing	<b>jredients</b> (UNII: VIF565UC2G)		(9180)		
Inactive Ing TEA TREE OIL ( GLYCERIN (UNII	<b>gredients</b> (UNII: VIF565UC2G) : PDC6A3C0OX)	Ingredient Name	.91KV)		
Inactive Ing TEA TREE OIL ( GLYCERIN (UNII APPLE CIDER V	<b>Jredients</b> (UNII: VIF565UC2G) : PDC6A3C0OX) <b>'INEGAR</b> (UNII: 0UE	Ingredient Name	(9180)		
Inactive Ing TEA TREE OIL ( GLYCERIN (UNII APPLE CIDER V LAURETH-4 (UN	<b>Jredients</b> (UNII: VIF565UC2G) : PDC6A3C0OX) <b>'INEGAR</b> (UNII: 0UE	Ingredient Name 22Q87VC)	.91KV)		
Inactive Ing TEA TREE OIL ( GLYCERIN (UNII APPLE CIDER V LAURETH-4 (UN BENZYL ALCOF	<b>Jredients</b> (UNII: VIF565UC2G) : PDC6A3C0OX) <b>(INEGAR</b> (UNII: 0UE III: 6HQ855798J) <b>IOL</b> (UNII: LKG8494	Ingredient Name 22Q87VC)	(9180)		
Inactive Ing TEA TREE OIL ( GLYCERIN (UNII APPLE CIDER V LAURETH-4 (UN BENZYL ALCOH .ALPHATOCOI	<b>Jredients</b> (UNII: VIF565UC2G) : PDC6A3C0OX) <b>(INEGAR</b> (UNII: 0UE III: 6HQ855798J) <b>IOL</b> (UNII: LKG8494	Ingredient Name 22Q87VC) WBH) 5, <b>DL</b> - (UNII: WR1WPI7EW8)	(91KV)		
Inactive Ing TEA TREE OIL ( GLYCERIN (UNII APPLE CIDER V LAURETH-4 (UN BENZYL ALCOH .ALPHATOCOI DIMETHYL SUL	UNII: VIF565UC2G) DC6A3C0OX) INEGAR (UNII: 0UE) III: 6HQ855798J) OL (UNII: LKG8494 PHEROL ACETATE	Ingredient Name 22Q87VC) WBH) 5, DL- (UNII: WR1WPI7EW8) W8V9698H)	291 KV)		
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Inactive Ing TEA TREE OIL ( GLYCERIN (UNII APPLE CIDER V LAURETH-4 (UN BENZYL ALCOF .ALPHATOCOI DIMETHYL SUL EUCALYPTUS O LAVENDER OIL POLYETHYLENI ARGAN OIL (UNI PACKAGING # Item Code	gredients         (UNII: VIF565UC2G)         : PDC6A3C0OX)         'INEGAR (UNII: 0UE         III: 6HQ855798J)         HOL (UNII: LKG8494         PHEROL ACETATE         FOXIDE (UNII: YOV         DIL (UNII: 2R040NIE         (UNII: 2 BP1YXWOH         E GLYCOL 400 (UI         II: 4V59G5UW9X)	<b>Ingredient Name</b> 222Q87VC) 222Q87VC) 2008 2009 2009 2009 2009 2009 2009 2009			Strength
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Inactive Ing TEA TREE OIL ( GLYCERIN (UNII APPLE CIDER V LAURETH-4 (UN BENZYL ALCOF ALPHATOCOI DIMETHYL SUL EUCALYPTUS O LAVENDER OIL POLYETHYLENI ARGAN OIL (UN PACKAGING # Item Code 1 NDC:59088-	gredients         (UNII: VIF565UC2G)         : PDC6A3C0OX)         INEGAR (UNII: 0UE         III: 6HQ855798J)         HOL (UNII: LKG8494         PHEROL ACETATE         FOXIDE (UNII: YOV         DIL (UNII: 2R040NIE         (UNII: 2 BP1YXWOH         E GLYCOL 400 (UI         II: 4V59G5UW9X)         30 mL in 1 BOTT	Ingredient Name 22Q87VC) WBH) ; DL- (UNII: WR1WPI7EW8) W8V9698H) 62) 8) WII: B697894SGQ) ackage Description LE, WTH APPLICATOR; Type		Marketing Start	Strength
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ОТ	C monograph fina	al part333C		06/09/2021	L		
Ρ	art 2 of 2						
N	IYCOZYL A	Ρ					
	iconazole nitra						
		ce pomaei					
Ρ	roduct Infor	mation					
it.	Item Code (Source) NDC:59088-442						
	oute of Admini		TOPICAL				
R	bute of Admini	stration	TOPICAL				
		. /					
A	ctive Ingredi		-				
		_	edient Name			-	h Strength
M	CONAZOLE NITE	RATE (UNII: VW4	H1CYW1K) (MICONAZOLE - UNII:7N	INO0D7S5M)	MICONAZOL	E NITRAT	E 2 g in 85 g
In	active Ingre	dients					
	<b>j</b>		Ingredient Name				Strength
LE	VOMENOL (UNII:	24WE03BX2T)					<b>--</b>
			LOWER) OLEOSOMES (UNII: 956	50Q72309)			
sc	DIUM BENZOAT	<b>E</b> (UNII: 0J245F	E5EU)				
	NGER (UNII: C552						
			NII: 76GTF6Z97M)				
X	<b>LITOL</b> (UNII: VCQ	006KQ1E)					
SI		UNII: ETJ7Z6XB	U4)				
AL	OE VERA LEAF (	UNII: ZY81Z83H	10X)				
N١	(LON-12 (UNII: 44	6U8J075B)					
ST	STARCH, CORN (UNII: 08232NY3SJ)						
κι	JKUI NUT OIL (UI	NII: TP11QR7B8	R)				
H)	HYALURONATE SODIUM (UNII: YSE9PPT4TH)						
-							
Pa	ackaging						
#	ltem Code	Pae	kage Description	Marketin Dat			eting End Date
1	NDC:59088-442- 07	85 g in 1 BOTT Product	LE; Type 0: Not a Combination				
Μ	Marketing Information						
	Marketing Category	Applicat	tion Number or Monograph Citation		ing Start ate	Marl	keting End Date
01	C monograph fina	al part333C		12/08/2020	)		
	5	•					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part333C	09/02/2021			

# Labeler - PureTek Corporation (785961046)

Revised: 1/2023

PureTek Corporation