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.

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

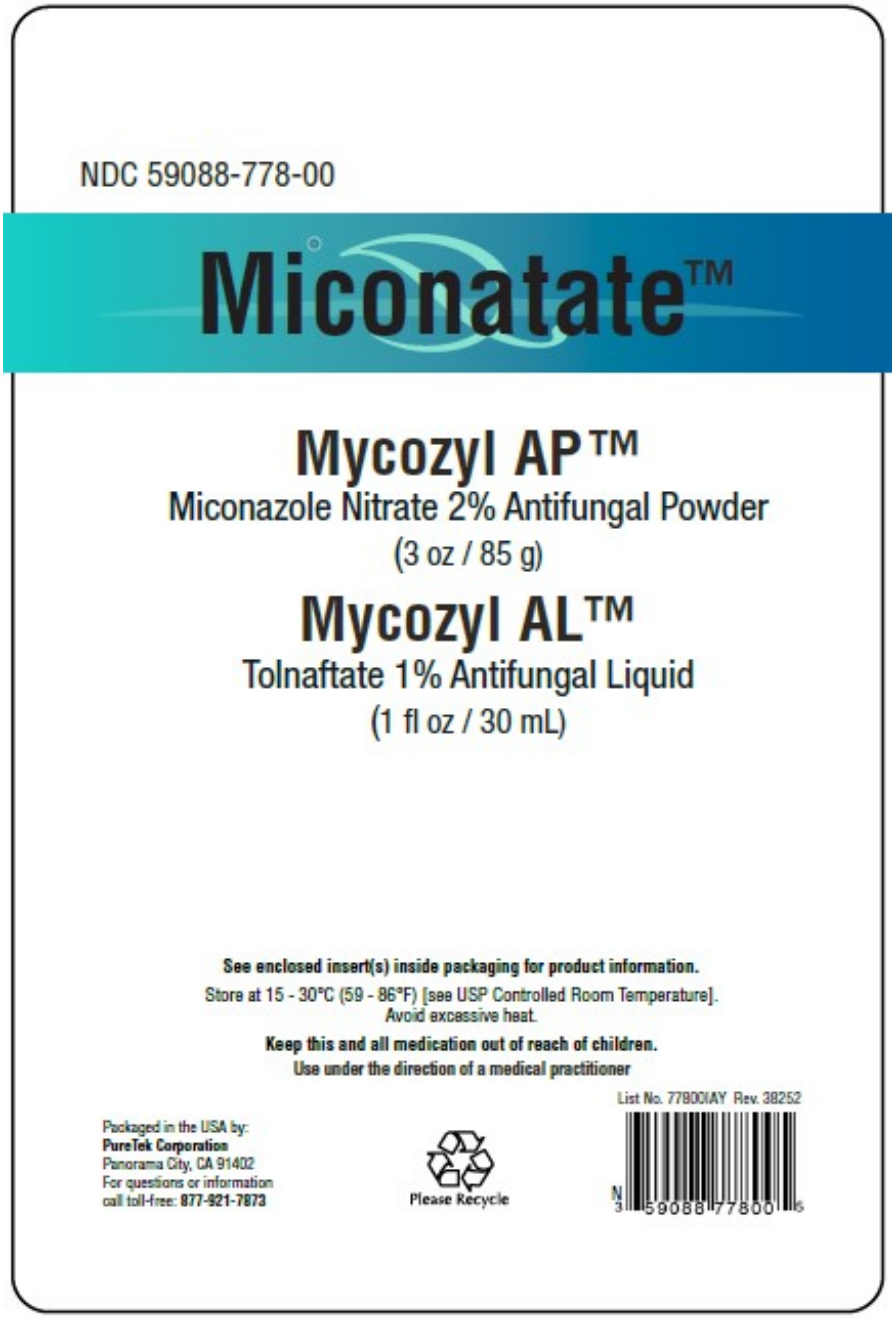
Mycozyl AL™ Antifungal Liquid is supplied in a 1 fl oz / 30 mL glass bottle with a screw cap fitted with a brush applicator (NDC 59088-443-03)

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**



MICONATATE

miconazole nitrate and tolnaftate kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59088-778

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59088-778-00	1 in 1 CARTON; Type 0: Not a Combination Product	09/02/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	0 BOTTLE, WITH APPLICATOR	1 mL in 30
Part 2	0 BOTTLE	1 g in 85

Part 1 of 2

MYCOZYL AL

tolnaftate liquid

Product Information

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

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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part333C	06/09/2021	

Part 2 of 2

MYCOZYL AP

miconazole nitrate powder

Product Information	
Item Code (Source)	NDC:59088-442
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 85 g

Inactive Ingredients	
Ingredient Name	**Strength**
LEVOMENOL (UNII: 24WE03BX2T)	
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GINGER (UNII: C5529G5JPQ)	
CANANGA ODORATA FLOWER (UNII: 76GTF6Z97M)	
XYLITOL (UNII: VCQ006KQ1E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
NYLON-12 (UNII: 446U8J075B)	
STARCH, CORN (UNII: O8232NY3SJ)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59088-442-07	85 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	12/08/2020	

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)

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