

MICOMITIN ANTIFUNGAL- 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.

Micomitin™
Antifungal Liquid
Tolnaftate 1%

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

Micomitin™ Antifungal Liquid is supplied in a 1 fl oz / 30 mL glass bottle with a screw cap fitted with a brush applicator (NDC 59088-640-03)

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.

Micomitin™ Antifungal Liquid

Manufactured in the USA by:

PureTek Corporation

Panorama City, CA 91402

For questions or information

call toll-free: **877-921-7873**

NDC 59088-640-03

Micomitin™ Antifungal Liquid

Tolnaftate 1%
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.

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Avoid excessive heat.

Keep this and all medication out of reach of children.

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Panorama City, CA 91402
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List No. 64003IAA Rev.38532



Drug Facts

| Active ingredient | Purpose |
|-------------------|------------|
| Tolnaftate 1% | Antifungal |

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List No. 64003IAA Rev.38533

MICOMITIN ANTIFUNGAL

tolnaftate liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59088-640 |
| 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:59088-640-03 | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/30/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333C | 08/30/2023 | |

Labeler - PureTek Corporation (785961046)

Revised: 8/2023

PureTek Corporation