

TM-TOLNAFTATE LR- tolnaftate liquid
Singular Dreamer Ltd.dba True Marker

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.

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
- **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
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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.

Other information

- Store at 15 - 30°C (59 - 86°F)
- avoid excessive heat
- do not use if package is damaged

Inactive ingredients

a-Bisabolol, Allantoin, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Cetearyl Alcohol, Curcuma Longa (Turmeric) Extract, Dimethyl Isosorbide, Ethylhexylglycerin, Glyceryl Stearate, Helianthus Annuus (Sunflower) Oil, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Isopropyl Alcohol, Melaleuca Alternifolia (Tea Tree) Oil, Phenoxyethanol, Polysorbate 60, Sodium Hydroxide, Thymus Vulgaris (Thyme) Extract, Zingiber Officinalis (Ginger) Extract.

Product label

TM -Tolnaftate LR
Tolnaftate 1% Liquid
Antifungal

NDC 83035-1262-4

Net Wt. 1.5 fl oz / 45 mL

Drug Facts

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Tolnaftate 1%	Antifungal

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Manufactured for:
Singular Dreamer, Ltd dba
True Marker
Glendale, CA 91205

TM-TOLNAFTATE LR

tolnaftate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83035-1262
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BISABOLOL OXIDE A (UNII: 16AE65F94Y)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
TURMERIC (UNII: 856YO1Z64F)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
THYME (UNII: CW657OBU4N)	
GINGER (UNII: C5529G5JPQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83035-1262-4	1 in 1 CARTON	06/26/2023	
1		45 mL 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	06/01/2023	

Labeler - Singular Dreamer Ltd.dba True Marker (129504103)**Registrant** - Singular Dreamer Ltd.dba True Marker (129504103)

