

CLARUS ANTIFUNGAL- tolnaftate cream
Clinical Therapeutic Solutions

CLARUS Antifungal

Drug Facts

Active Ingredient

Tolnaftate 1 %

Purpose

Anti-fungal

Uses:

For effective treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis). Relieves: Itching, Scaling, Cracking, Redness, Soreness, Burning, Irritation and prevents the reoccurrence of most athlete's foot with daily use.

Warnings

For external use only. Avoid contact with eyes.

Do not use

on children under 2 years of age unless directed by a physician.

Stop use and ask physician if:

- When using for athlete's foot or ringworm: if irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a physician.
- When using for prevention of athlete's foot: If irritation occurs, discontinue use and consult a physician.

If pregnant or breast-feeding,

ask a healthcare professional before use.

Keep out of reach of children

In the case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions:

For treatment of athlete's foot and ringworm:

To prevent athlete's foot:

- 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 physician.
- 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 physician. This product is not effective on scalp or nail infections.

- Clean the feet and dry thoroughly.
- Apply a thin layer of the product to the feet once or twice daily (morning and/or night).
- Supervise children in the use of this product.
- Pay special attention to spaces between the toes; wear well-fitting shoes, and change shoes and socks at least once daily.

Other information:

Store between 20 -25 C (68 -77 F) ⁰⁰⁰⁰

Inactive ingredients:

Aqua (Deionized Water), C12-15 Alkyl Benzoate, C13-14 Isoparaffin, Dimethyl Sulfone (MSM), Ethylhexylglycerin, Helianthus Annuus (Sunflower) Seed Oil, Laureth-7, Melaleuca Alternifolia (Tea Tree) Oil, Phenoxyethanol, Polyacrylamide, Polysorbate-20, Urea.

CLARUS ANTIFUNGAL CREAM Tolnaftate 1% MEDICAL STRENGTH ANTIFUNGAL CREAM IN A VEHICLE CONTAINING TEA TREE OIL AND UREA CLINICAL THERAPEUTIC SOLUTIONS NET WT. 1.5 oz (45g) PRFOESSIONAL Distributed by Clinical Therapeutic Solutions, PO Box 1257, Wall, NJ 07719 www.CTSRX.com

Product Label

CLARUS™

ANTIFUNGAL CREAM

Tolnaftate 1%

MEDICAL STRENGTH
ANTIFUNGAL CREAM

IN A VEHICLE CONTAINING
TEA TREE OIL AND UREA



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P R O F E S S I O N A L

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CLARUS ANTIFUNGAL

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44577-001
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 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
LAURETH-7 (UNII: Z95S6G8201)	
TEA TREE OIL (UNII: VIF565UC2G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
UREA (UNII: 8W8T17847W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44577-001-01	45 g in 1 TUBE; Type 0: Not a Combination Product	02/05/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	06/07/2012	

Labeler - Clinical Therapeutic Solutions (078402750)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(44577-001)

Revised: 11/2023

Clinical Therapeutic Solutions