

CLARUS ANTIFUNGAL- tolnaftate cream
Clinical Therapeutic Solutions

CLARUS Antifungal Cream

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 the 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:

- 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.
- **To prevent athlete's foot:**
 - 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)

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.

Package Labeling:

<p style="text-align: center;">ANTIFUNGAL CREAM IN A VEHICLE CONTAINING TEA TREE OIL AND 20% UREA Tolnaftate 1% CLARUS ANTIFUNGAL CREAM</p>		1.5"							
<p>CLARUS™ Antifungal Cream</p> <table border="1"> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <td>Active ingredient</td> <td>Purpose</td> </tr> <tr> <td>Tolnaftate 1%.....</td> <td>Anti-fungal</td> </tr> </table> <p>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.</p> <p>Warnings: For external use only. Avoid contact with the eyes. Do not use on children under 2 years of age unless directed by a physician. Stop use and ask physician if:</p> <ul style="list-style-type: none"> • 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 the prevention of athlete's foot: If irritation occurs, discontinue use and consult a physician. If pregnant or breast-feeding, ask a 	Drug Facts		Active ingredient	Purpose	Tolnaftate 1%.....	Anti-fungal		<p>NDC 44577-001-01</p> <p>CLARUS ANTIFUNGAL CREAM</p> <p>Tolnaftate 1%</p> <p>IN A VEHICLE CONTAINING TEA TREE OIL AND 20% UREA</p>	
Drug Facts									
Active ingredient	Purpose								
Tolnaftate 1%.....	Anti-fungal								

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:**
- 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.
- To prevent athlete's foot:**
- 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)

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,



ANTIFUNGAL CREAM

Available From Physicians

Questions or Comments?
 Please visit www.BakoDx.com



NET WT. 3oz (85 g)

LOT:

EXP:

Distributed by:



A Part of **bako's** Integrated Physician Solution

PO Box 1257, Wall, NJ 07719

732.894.9450 • www.BakoDx.com

© 2014 Clinical Therapeutic Solutions

PROFESSIONAL

PROFESSIONAL

PROFESSIONAL

PROFESSIONAL

CLARUS ANTIFUNGAL

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44577-470
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 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:44577-470-00	1 in 1 BOX	03/11/2024	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	03/11/2024	

Labeler - Clinical Therapeutic Solutions (078402750)

Revised: 2/2024

Clinical Therapeutic Solutions