

CLARUS AC ANTIFUNGAL SOLUTION- tolnaftate liquid

Clinical Therapeutic Solutions

CLARUS AC Antifungal Solution

Active ingredient

Tolnaftate 1%

Purpose

Topical Antifungal

Uses:

- Proven clinically effective in the treatment of most fungal infections including related/associated to tinea pedis (athlete's foot), tinea cruris (jock itch) and tinea corporis (ringworm).
- For effective relief of itching, scaling, cracking, burning, redness, soreness, irritation, discomfort associated to fungal infections.
- Prevents most tinea pedis (athlete's foot) with daily use.

Warnings:

For external use only.

Do not use

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

When using this product

- Avoid contact with the eyes.

Stop use and ask a doctor if

If irritation occurs or if there is no improvement within 4 weeks, 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) or as directed by a doctor.
- Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily. 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.
- This product is not effective on the scalp or nails.

Other information:

- Protect the product in this container from excessive heat and direct sun.

Inactive ingredients:

N-Acetylcysteine, Beeswax, Dimethyl Isosorbite, Helianthus Annuus (Sunflower) Oil, Lactic Acid, Tocopheryl Acetate (Vitamin E), Undecylenic Acid, Urea.

Questions?

(M-F) (9am-5pm EST) **732-894-9450**

Package Labeling:

NDC #12345-678-90

CLARUS[®] AC

ANTIFUNGAL / COSMETIC SOLUTION

NET WT. 1/2 oz (15g)



Tolnaftate 1%

In a vehicle containing cosmetic and penetrating ingredients

Available From Physicians

FRONT

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Tolnaftate 1%.....	Topical Antifungal

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Warnings: For external use only.

Do not use ■ on children under 2 years of age unless directed by a doctor. **When using this product** ■ Avoid contact with the eyes.

Stop use and ask a doctor if ■ If irritation occurs or if there is no improvement within 4 weeks, 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. **If pregnant or breast-feeding,** ask a health professional before use.

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Questions? 732-894-9450 (M-F) (9am-5pm EST)

REV 020221

BACK

CLARUS AC ANTIFUNGAL SOLUTION

tolnaftate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44577-128
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
ACETYLCYSTEINE (UNII: WYQ7N0BPYC)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
LACTIC ACID (UNII: 33X04XA5AT)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
UNDECYLENIC ACID (UNII: K3D86KJ24N)	
UREA (UNII: 8W8T17847W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44577-128-00	15 g in 1 TUBE; Type 0: Not a Combination Product	03/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	03/01/2021	

Labeler - Clinical Therapeutic Solutions (078402750)

Revised: 11/2023

Clinical Therapeutic Solutions