

CLARUS ANTIFUNGAL- tolnaftate solution

Clinical Therapeutic Solutions

CLARUS Antifungal

Drug Facts

Active Ingredient

Tolnaftate 1 %

Purpose

Anti-fungal

Uses:

For effective treatment of most athlete's foot and ringworm. Relieves:

Prevents the reoccurrence of most athlete's foot with daily use.

- Itching
- Scaling
- Cracking
- Redness
- Soreness
- Burning
- Irritation

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:

If condition persists longer, consult a physician. This product is not effective on scalp or nail infections.

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.

- 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.

Questions or Comments?

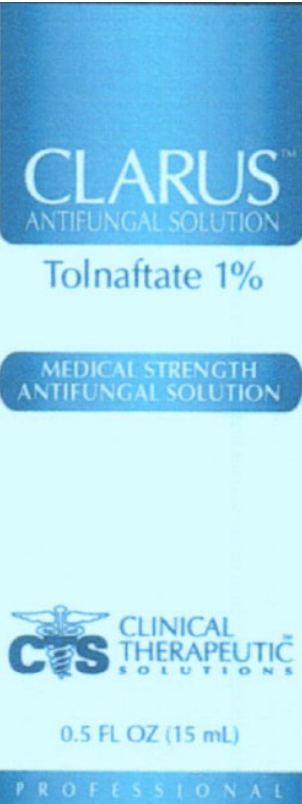

Please visit www.CTSRX.com

Inactive ingredients:

Amygdalus Dulcis (Sweet Almond) Oil, BHT, Helianthus Annuus (Sunflower) Seed Oil, Mentha Piperita (Peppermint) Oil, Sesamum Indicum (Sesame) Seed Oil, Tocopheryl Acetate (Vitamin E).

CLARUS ANTIFUNGAL SOLUTION Tolnaftate 1% MEDICAL STRENGTH ANTIFUNGAL SOLUTION CLINICAL THERAPEUTIC SOLUTIONS PO Box 1257, Wall, NJ 07719 0.5 FL OZ (15 mL)

Product Label

<p>Drug Facts</p> <p>Active ingredient Tolnaftate 1% Purpose Anti-fungal</p> <p>Uses: For effective treatment of most athlete's foot and ringworm. Relieves: <ul style="list-style-type: none"> ■ Itching ■ Scaling ■ Cracking ■ Redness ■ Soreness ■ Burning ■ Irritation Prevents the recurrence of most athlete's foot (dermatophytosis) 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: <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 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.</p> <p>Directions: For treatment of athlete's foot and ringworm: <ul style="list-style-type: none"> ■ 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: <ul style="list-style-type: none"> ■ 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. Inactive ingredients: Amygdalus Dulcis (Sweet Almond) Oil, BHT, Helianthus Annuus (Sunflower) Seed Oil, Mentha Piperita (Peppermint) Oil, Sesamum Indicum (Sesame) Seed Oil, Tocopheryl Acetate (Vitamin- E).</p>	<p>Directions: For treatment of athlete's foot and ringworm: <ul style="list-style-type: none"> ■ 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: <ul style="list-style-type: none"> ■ 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. <p style="text-align: center;">Question or Comments? Please visit www.CTSRX.com</p> </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: <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 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.</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>LOT:</p> <p>EXP:</p> </div> <p style="text-align: center;">Distributed by:  PO Box 1257, Wall, NJ 07719 www.CTSRX.com © 2012 Clinical Therapeutic Solutions</p>
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CLARUS ANTIFUNGAL

tolnaftate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44577-002
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
ALMOND OIL (UNII: 66YXD4DKO9)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SESAME OIL (UNII: QX10HY4QV)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44577-002-01	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/06/2017	

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(44577-002)

Revised: 11/2023

Clinical Therapeutic Solutions