

**CLOTRIMAZOLE- clotrimazole cream**  
**TRIFECTA PHARMACEUTICALS USA LLC**

*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.*

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**Clotrimazole cream USP, 1%**

***Active ingredient***

Clotrimazole USP 1% w/w

***Purpose***

Antifungal Cream

**Keep this and all drugs out of the reach of children.** In case of accidental ingestion, seek professional assistance or contact a Poison Control Center right away.

***Uses***

Cures athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis). Relieves the itching, irritation, redness, scaling and discomfort which can accompany these conditions.

***Warnings***

- **Do not use on children under 2 years of age unless directed by a doctor.**
- **For external use only**
- **Avoid contact with eyes.**
- If irritation occurs or if there is no improvement within 4 weeks (for athlete's foot or ringworm) or within 2 weeks (for jock itch), discontinue use and consult a doctor.

***Directions***

- Wash the affected area and dry thoroughly.
- Apply a thin layer of this product over affected area twice daily (morning and night), or as directed by a doctor.
- Supervise children in the use of this product.
- For athlete's foot, pay special attention to the 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. For jock itch, use daily for 2 weeks.
- If conditions persists longer, consult a doctor.
- This product is not effective on the scalp or nails.

***Inactive Ingredients***

Dimethyl Sulfoxide, Ethylparaben, Glycerin, Glyceryl Stearate SE, Laureth-23, Light Mineral Oil, Petrolatum, Stearyl Alcohol, Water

## Other Information

- store at controlled room temperature 15°-30°C (59°- 86°F)
- Close cap tightly after use.

## Questions?


Adverse drug event call 1-888-296-9067

**Dist. By Trifecta Pharmaceuticals USA™**

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL 33301, USA

## Packaging



COMPARE TO THE ACTIVE INGREDIENT IN LOTRIMIN® AF  
NDC: 69396-001-20

**Cures Most Athlete's Foot**  
Relieves Itching, Burning, Cracking & Scaling

**Clotrimazole Cream**  
USP, 1%  
Net Wt. 1 oz. (28.4g)  
anti-fungal cream

**100% GUARANTEED**

Relieves Itching, Burning, Cracking & Scaling

**Clotrimazole Cream**  
USP, 1%  
anti-fungal cream

DRUG FACTS	DRUG FACTS (continued)
<p><b>Active ingredient</b> Clotrimazole USP 1% w/w</p> <p><b>Purpose</b> Antifungal Cream</p> <p><b>Use</b> Cures athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis). Relieves the itching, irritation, redness, scaling and discomfort which can accompany these conditions.</p> <p><b>Warnings</b></p> <ul style="list-style-type: none"> <li>Do not use on children under 2 years of age unless directed by a doctor.</li> <li>For external use only.</li> <li>Avoid contact with eyes.</li> <li>If irritation occurs or if there is no improvement within 4 weeks (for athlete's foot or ringworm) or within 2 weeks (for jock itch), discontinue use and consult a doctor.</li> <li>Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center right away.</li> </ul> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>Wash the affected area and dry thoroughly.</li> </ul>	<ul style="list-style-type: none"> <li>Apply a thin layer over affected area twice daily (morning and night), or as directed by a doctor.</li> <li>Supervise children in the use of this product.</li> <li>For athlete's foot, pay special attention to the spaces between the toes, wear well-fitting ventilated shoes, and change shoes and socks at least once daily.</li> <li>For athlete's foot and ringworm, use daily for 4 weeks. For jock itch, use daily for 2 weeks.</li> <li>If conditions persists longer, consult a doctor.</li> <li>This product is not effective on the scalp or nails.</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>Store at controlled room temperature 15°-30°C (59°-86°F).</li> <li>Close cap tightly after use.</li> </ul> <p><b>Inactive ingredients</b> Dimethyl Sulfoxide, Ethylparaben, Glycerin, Glyceryl Stearate SE, Laureth-23, Light Mineral Oil, Petrolatum, Stearyl Alcohol, Water.</p> <p><b>Questions?</b> Adverse drug event call 1-888-296-9067 Dist. By Trifecta Pharmaceuticals USA™ 101 NE Third Avenue, Suite 1500 Ft. Lauderdale, FL 33301, USA</p>

GLOBE® Clotrimazole Anti-Fungal Cream is not manufactured or distributed by Schering-Plough HealthCare Products, Inc., owners of the registered trademark Lotrimin® AF.

Lot No. . . . .  
Mfg. Date . . . . .  
Exp. Date . . . . .  
Product of PRC

# CLOTRIMAZOLE

clotrimazole cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69396-001
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
LAURETH-23 (UNII: N72LMW566G)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	

STEARYL ALCOHOL (UNII: 2KR89I4HIY)

WATER (UNII: 059QF0KO0R)

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-001-20	1 in 1 BOX	07/28/2015	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69396-001-05	1 in 1 BOX	08/23/2016	
2		15 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 final	part333C	03/10/2015	

**Labeler** - TRIFECTA PHARMACEUTICALS USA LLC (079424163)

**Registrant** - Trifecta Pharmaceuticals USA (079424163)

Revised: 11/2017

TRIFECTA PHARMACEUTICALS USA LLC