

**ANTI-FUNGAL CREAM- clotrimazole cream**  
**World Wide Services Limited Liability Company**

*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**

- **For external use only**
- **Do not use on children under 2 years of age unless directed by a doctor.**
- **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.

**Stop Use and ask a doctor if**

- Irritation occurs
- There is no improvement within 4 weeks (for athlete's foot or ringworm) or within 2 weeks (for jock itch).

## 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.

## Other Information

FootCure® Clotrimazole Anti-Fungal Cream is not manufactured or distributed by Bayer, owner of the registered trademark Lotrimin® AF.

## Questions

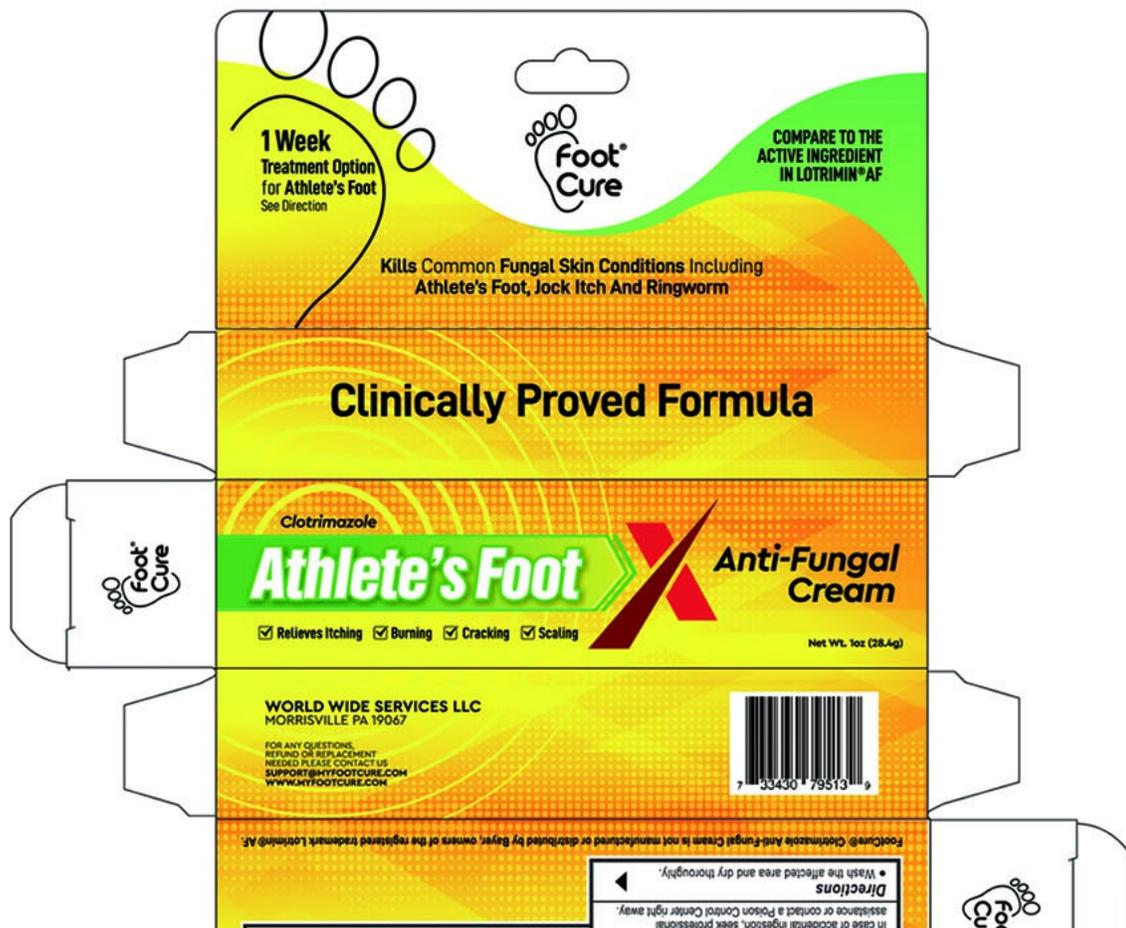
Adverse Event call 1 888 296 9067

For questions, refund or replacment needed please contact us support@myfootcure.com

www.myfootcure.com

## Packaging and Label

OUTER BOX



**DRUG FACTS**

**Active Ingredient** Clotrimazole USP 1% w/w ..... **Purpose** Antifungal Cream

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

**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 eyes.

**Stop use and ask a doctor if** There is no improvement within 4 weeks (for athlete's foot or ringworm) or within 2 weeks (for jock itch).

**Keep this and all drugs out of the reach of children.**

**Questions?** Adverse drug event call 1-888-296-9067

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

**Other information** Store at controlled room temperature 15°-30°C (59°-86°F). Close cap tightly after use. This product is not effective on the scalp or nails. If conditions persists longer, consult a doctor. For athlete's foot and ringworm, use daily for 4 weeks. For jock itch, use daily for 2 weeks. For athlete's foot and ringworm, use daily for 4 weeks. For the toes, wear well-fitting ventilated shoes, and change shoes and socks at least once daily. 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. Supervise children in the use of this product. Apply a thin layer over affected area twice daily (morning and night), or as directed by a doctor.

**DRUG FACTS (continued)**

**CLINICALLY PROVEN** RELIEVES ITCHING BURNING CRACKING SCALING

**Athlete's Foot** Anti-Fungal Cream

INNER TUBE

**Clotrimazole**

**Athlete's Foot** Anti-Fungal Cream

**Active ingredient** Clotrimazole USP 1% w/w ..... **Purpose** Antifungal Cream

**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** 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 eyes.

**Stop use and ask a doctor if** There is no improvement within 4 weeks (for athlete's foot or ringworm) or within 2 weeks (for jock itch).

**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.

**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.

See carton for complete adverse effects reporting information.

Distributed by: **WORLD WIDE SERVICES LLC MORRISVILLE PA 19067**

For any questions, refund or replacement needed please contact us [support@myfootcure.com](mailto:support@myfootcure.com) | [www.myfootcure.com](http://www.myfootcure.com)

Net wt. 1oz (28.4g)

## ANTI-FUNGAL CREAM

clotrimazole cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73538-001
<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)	

<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4HIY)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73538-001-01	1 in 1 BOX	01/09/2020	
1		28.4 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	01/08/2020	

**Labeler** - World Wide Services Limited Liability Company (117352480)

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