

CLOTRIMAZOLE- clotrimazole cream
TRIFECTA PHARMACEUTICALS USA LLC

Globe 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.**

Stop Use and ask a Doctor

Irritation occurs

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

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

Cetamacragol 1000, Cetostearyl alcohol, mineral oil, methylparaben, propylene glycol, propylparaben, purified water, white petrolatum.

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

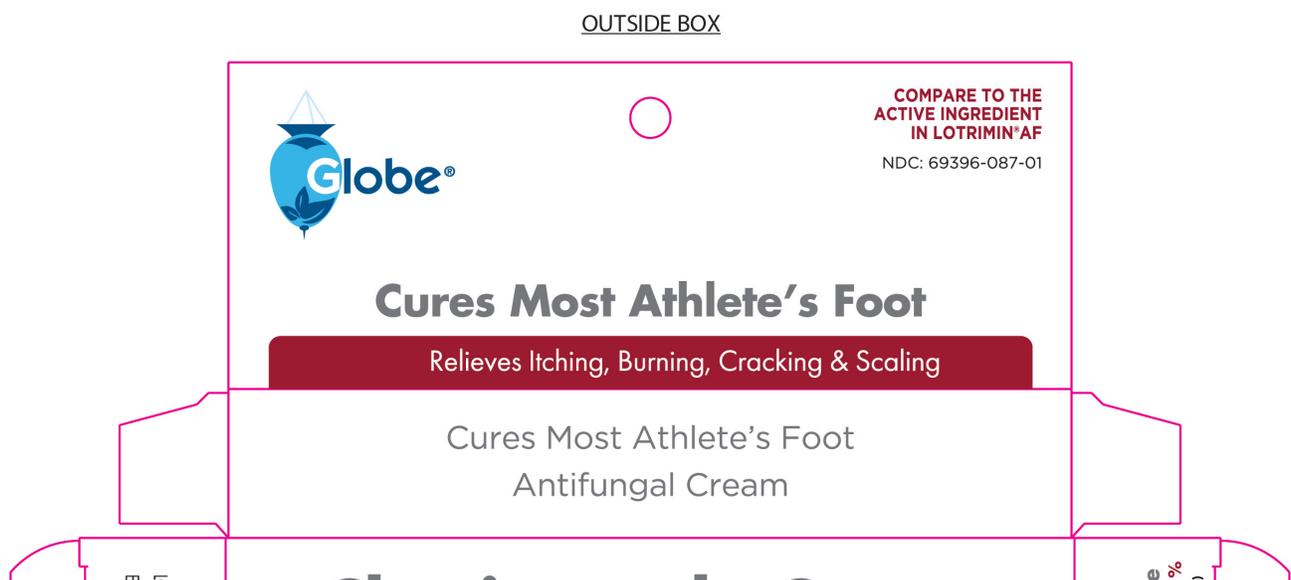
Ft. Lauderdale, FL 33301, USA

Made in India

www.trifecta-pharma.com

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

Packaging



Clotrimazole Cream

USP, 1%

Net Wt. 1 oz. (28.4g)

antifungal cream



Distributed by:
Trifecta Pharmaceuticals USA*
 101 NE Third Avenue, Suite 1500
 Ft. Lauderdale, FL 33301 USA
 Made in India
 www.trifecta-pharma.com



**100%
 GUARANTEED**

GO/DRUGS/910/L (MFG License No.)

X0010HEI17

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

<p>DRUG FACTS Clotrimazole USP 1% W/WAntifungal</p>	<p>Active Ingredient Clotrimazole USP 1% W/W</p>	<p>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.</p>
<p>Directions • Wash the affected area and dry thoroughly. • Apply a thin layer over affected area twice daily (morning and night), or as directed by a doctor.</p>	<p>Warnings Do not use on children under 2 years of age unless directed by a doctor. When using this product avoid contact with eyes.</p>	<p>Other Information • If condition persists longer, consult a doctor. • If condition persists longer, consult a doctor. • For 2 weeks. • For athlete's foot and ringworm, use daily for 4 weeks. For jock itch, use 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.</p>
<p>DRUG FACTS (continued)</p>	<p>Questions? Adverse drug event call 1-888-296-9067</p>	<p>Keep this and all drugs out of the reach of children. • There is no improvement within 4 weeks (for athlete's foot or ringworm) or within 2 weeks (for jock itch). • In case of accidental ingestion, seek professional assistance or contact a Poison Control Center right away.</p>

INNER TUBE

NDC: 69396-087-01

Clotrimazole

CREAM USP, 1%

Net Wt. 1 oz. (28.4g) antifungal cream

Active Ingredient
 Clotrimazole USP 1% w/w

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**
 • irritation occurs • 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 condition persists longer, consult a doctor. • This product is not effective on the scalp or nails. **Other information** • Store at controlled room temperature 15°-30°C (59°-86°F). • Close cap tightly after use. **Inactive ingredients:** Cetomacrogol 1000, Cetostearyl alcohol, Mineral oil, Methylparaben, Propylene glycol, Propylparaben, Purified water, White petrolatum. **Questions?** Adverse drug event call 1-888-296-9067

Distributed by: **Trifecta Pharmaceuticals USA***
 101 NE Third Avenue, Suite 1500, Ft. Lauderdale, FL 33301 USA | Made in India | www.trifecta-pharma.com

GO/DRUGS/910/L (MFG License No.)

CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-087
Route of Administration	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		
LIGHT MINERAL OIL (UNII: N6K5787QVP)				
PETROLATUM (UNII: 4T6H12BN9U)				
WATER (UNII: 059QF0K00R)				
CETETH-20 (UNII: I835H2IHHX)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-087-01	1 in 1 BOX	06/04/2022	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69396-087-55	5 in 1 BOX	04/08/2022	
2		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 Drug	M005	04/08/2022		

Labeler - TRIFECTA PHARMACEUTICALS USA LLC (079424163)

Registrant - Trifecta Pharmaceuticals USA (079424163)