

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

-----  
**Clotrimazole cream USP, 1%**

***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.

**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.

**Do Not Use**

Do not use on children under 2 years of age unless directed by a doctor

**When using this product**

When using this product avoid contact with eyes

**Stop use and ask 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 Poison Control Centre 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.

### **Other Information**

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

### **Inactive Ingredients**

Dimethyl Sulfoxide, Ethylparaben, Glycerin, Laureth-23, Mineral Oil, Petrolatum, Water, alcohol, Glyceryl mono and dipalmitostearate, Cetostearyl alcohol, edetate disodium, Butylated Hydroxytoluene.

### **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

## **OUTSIDE BOX**





## INNER TUBE



NDC: 69396-001-20

Clotrimazole

CREAM USP, 1%

Net Wt. 1 oz. (28.4g)

ANTI-FUNGAL CREAM

Active ingredient

Clotrimazole USP 1% w/w.

Uses

Cures athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis), and 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.

Directions

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. 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.

Purpose

Antifungal

See carton for complete adverse effects reporting information.

Distributed by: Trifecta Pharmaceuticals USA

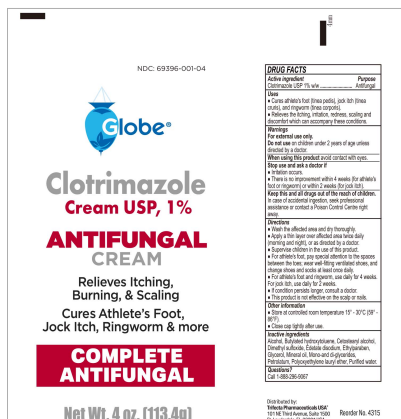
101 NE Third Avenue, Suite 1500, Ft. Lauderdale, FL 33301 USA | www.trifecta-pharma.com

OUTSIDE BOX

# OUTSIDE BOX




# INNER TUBE



OUTSIDE BOX





Clotrimazole

ANTIFUNGAL

Drug Facts

Active ingredient

Clotrimazole USP 1% w/w

Purpose

Antifungal

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

• Irritation occurs

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

INNER TUBE



Clotrimazole

CREAM USP, 1%

Net Wt. 1 oz. (28.4g)

ANTI-FUNGAL 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.

See carton for complete adverse effects reporting information.

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

Purpose

Antifungal

CLOTRIMAZOLE

clotrimazole cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-001
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
MINERAL OIL (UNII: T5L8T28FGP)			

<b>DIMETHYL SULFOXIDE</b> (UNII: YOW8V9698H)	
<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LAURETH-23</b> (UNII: N72LMW566G)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERYL MONO AND DIPALMITOSTEARATE</b> (UNII: KC98RO82HJ)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	

### 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:69396-001-55	5 in 1 BOX	11/06/2023	
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		
3	NDC:69396-001-09	144 in 1 BOX	03/09/2022	
3		0.9 g in 1 PACKAGE; Type 0: Not a Combination Product		
4	NDC:69396-001-04	1 in 1 BOX	05/03/2022	
4		113.4 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:69396-001-20	1 in 1 BOX	03/10/2015	
5		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	03/10/2015	

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

Revised: 11/2023

TRIFECTA PHARMACEUTICALS USA LLC