

CLOTRIMAZOLE- family wellness 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.

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. If swallowed get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Uses

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

Warnings

- **Do not use on children under 2 years of age except under the advice of a doctor.**
- **For external use only**
- **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).

If Pregnant or breastfeeding

If Pregnant or breastfeeding, ask a health professional before use.

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 20°-25°C (68°- 77°F)
- Close cap tightly after use.

Questions or Comments?

Call 1-888-296-9067 Mon-Fri 9AM - 5PM

DISTRIBUTED BY: MIDWOOD BRANDS, LLC.

500 Volvo Parkway, Chesapeake, VA. 23320

NOT SATISFIED?

Return Package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.

This product is not manufactured or distributed by Bayer, owner of the registered trademark Lotrimin®

Packaging

OUTSIDE BOX





INNER TUBE

COMPARE TO THE ACTIVE INGREDIENT IN LOTRIMIN® AF*

FAMILYwellness™

ANTIFUNGAL CREAM

For ATHLETE'S FOOT

Clotrimazole 1%

NET WT. 0.5 oz. (14.2g)

DRUG FACTS Active ingredient Clotrimazole 1% w/w Purpose Antifungal Uses • Cures most athlete's foot, jock itch, and ringworm • Relieves itching, burning, cracking, scaling and discomfort which can accompany these conditions. Warnings For external use only Do not use on children under 2 years of age except under the advice of 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). If pregnant or breastfeeding , ask a health professional before use. Keep this and all drugs out of the reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	DRUG FACTS (continued) Directions • Wash the affected area and dry thoroughly. • Apply a thin layer over affected area twice daily (morning and night) • 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 20°-25°C (68°-77°F). • Close cap tightly after use. Inactive ingredients Dimethyl sulfoxide, Ethylparaben, Glycerin, Glyceryl searate SE, Laureth-23, Light Mineral Oil, Stearyl alcohol, Water, White petrolatum. Questions or Comments? Call 1-888-296-9067 Mon-Fri 9 AM-5 PM
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DISTRIBUTED BY: MIDWOOD BRANDS, LLC 500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

NOT 100% SATISFIED? Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-038
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
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: 2KR89I4H1Y)	
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:69396-038-05	1 in 1 BOX	08/30/2019	
1		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	08/30/2019	

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)

