

RUGBY CLOTRIMAZOLE ANTIFUNGAL CREAM- clotrimazole cream

Rugby Laboratories

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. 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.**

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

Clotrimazole Antifungal Cream is not manufactured or distributed by Bayer, owners of the registered trademark Lotrimin®AF.

Questions

Keep carton for complete Drug Facts

Call 1-800-645-2158

Distributed by:

RUGBY® LABORATORIES

17177 N. Laurel Park Drive, Suite 233

Livonia, MI 48152

www.rugbylaboratories.com

Made in China

Packaging and Label

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1265
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: 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:0536-1265-26	1 in 1 BOX	03/19/2020	
1		45 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	03/19/2020	

Labeler - Rugby Laboratories (079246066)

Registrant - Trifecta Pharmaceuticals USA LLC (079424163)

