

## **RUGBY ANTIFUNGAL CLOTRIMAZOLE- clotrimazole cream**

### **RUGBY**

*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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## **RUGBY® ANTIFUNGAL CREAM CLOTRIMAZOLE 1%**

### ***Drug Facts***

#### **Active ingredient**

Clotrimazole 1%

#### **Purpose**

Antifungal

#### **Uses**

- cures most athlete's foot, jock itch, and ringworm
- relieves itching, burning, cracking, scaling and discomfort

#### **Warnings**

**For external use only.**

**Avoid contact with eyes.**

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

#### **Stop use and ask a doctor if**

- irritation occurs
- there is no improvement within 4 weeks for athlete's foot and ringworm or 2 weeks for jock itch

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

#### **Directions**

- wash affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night) or as directed by a doctor
- supervise children in use of this product
- for athlete's foot, pay special attention to 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 scalp or nails

#### **Other information**

- store at 15 to 30°C (59 to 86°F)
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

**Inactive ingredients**

aloe barbadensis leaf juice, carbomer, cetyl alcohol, DMDM hydantoin, glyceryl stearate, isopropyl alcohol, methylparaben, mineral oil, polysorbate-20, propylparaben, purified water, stearic acid, triethanolamine, trisodium EDTA

**Questions or comments?****1-800-645-2158**

Distributed by:

**RUGBY® LABORATORIES**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

**PRINCIPAL DISPLAY PANEL - 28 g Tube Carton**

Rugby®

NDC 0536-1272-22

Compare to the  
active ingredient  
of Lotrimin® AF\*

Antifungal Cream  
Clotrimazole 1%

Cures most athlete's foot

NET WT 1 OZ (28 g)



NDC 0536-1272-22

Compare to the active ingredient of Lotrimin® AF\*

# Antifungal Cream

## Clotrimazole 1%

Cures most athlete's foot

Cures most athlete's foot  
In a soothing and cooling cream enriched with aloe

NO COLOR

PL-1002B  
V01  
NO COLOR

Rugby®  
Antifungal Cream  
Clotrimazole 1%



NDC 0536-1272-22

Compare to the active ingredient of Lotrimin® AF\*

# Antifungal Cream

## Clotrimazole 1%

Cures most athlete's foot

NET WT 1 OZ (28 g)

NO COLOR

NO COLOR

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**RUGBY® LABORATORIES**  
17177 N Laurel Park Drive, Suite 233  
Livonia, MI 48152  
www.rugbylaboratories.com

Rev. 12/19 R-139 Re-order No. 370915



\*This product is not manufactured or distributed by Schering-Plough, Inc., the distributor of Lotrimin® AF.

GLUE FLAP  
NO COLOR / TEXT  
NO COATING

GLUE FLAP  
NO COLOR / TEXT  
NO COATING

<b>Drug Facts</b>
<b>Active Ingredient</b> Clotrimazole 1% Antifungal
<b>Uses</b> ■ cures most athlete's foot, jock itch, and ringworm ■ relieves itching, burning, cracking, scaling and discomfort
<b>Warnings</b> For external use only. Avoid contact with eyes. Do not use on children under 2 years of age unless directed by a doctor. Stop use and ask a doctor if ■ irritation occurs ■ there is no improvement within 4 weeks for athlete's foot and ringworm or 2 weeks for jock itch
<b>Directions</b> ■ wash affected area and dry thoroughly ■ apply a thin layer over affected area twice daily (morning and night) or as directed by a doctor ■ supervise children in use of this product ■ for athlete's foot, pay special attention to 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 scalp or nails
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<b>Questions or comments?</b> 1-800-645-2158



# RUGBY ANTIFUNGAL CLOTRIMAZOLE

clotrimazole cream

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1272
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	0.01 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE TRISODIUM (UNII: 420IP921MB)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1272-22	1 in 1 CARTON	01/14/2020	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0536-1272-11	1 in 1 CARTON	01/14/2020	
2		14 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	01/14/2020	

Labeler - RUGBY (079246066)

## Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(0536-1272)

Revised: 2/2020

RUGBY