

## **CLOTRIMAZOLE- clotrimazole cream**

**Geritrex Corp**

*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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### **Clotrimazole Cream 1%**

#### **Drug Facts**

Active Ingredient:	Purpose
Clotrimazole 1%	Antifungal

#### **Uses**

Treats most athlete's foot, jock itch and ringworm, relieves itching, scaling, burning, irritation, and discomfort

#### **Directions**

Clean the affected area and dry thoroughly. Apply a thin layer of the product over affected area twice daily (morning and night), or as directed by a doctor. Supervise children in the use of this product. This product does not work on the scalp or nail. For athlete's foot and ringworm pay special attention to spaces between the toes: wear well fitting, ventilated shoes, and change shoes and socks at least once every day. Use every day for 4 weeks. For jock itch, use every day for 2 weeks. If condition lasts longer, contact a doctor.

#### **Warnings**

FOR EXTERNAL USE ONLY

When using this product do not get in to the 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). Do not use on children under 2 years, unless directed by a doctor.

#### **Inactive Ingredients**

Benzyl alcohol, Cetearth 20, Cetyl alcohol, Citric acid, Paraffin wax, Petrolatum, Polysorbate 80, Sodium citrate, Sorbitan sesquioleate, Stearyl alcohol, Water

KEEP OUT OF REACH OF CHILDREN

In the event of accidental ingestion, contact a Poison Control Center right away.

Store between 20'-30'C (36'-86'F)

Use every day for 4 weeks. For jock itch, use every day for 2 weeks. if condition lasts longer, contact a doctor

NDC# 54162-018-05



# Clotrimazole Cream 1%

## GRx<sup>®</sup>

Antifungal Cream  
NET WT. 14g

<b>DRUG FACTS:</b>
<b>Active Ingredient:</b> Clotrimazole 1% <b>Purpose:</b> Antifungal
<b>Uses:</b> Treats most athlete's foot, jock itch and ringworm, relieves itching, scaling, burning, irritation, and discomfort.
<b>Warnings:</b> <b>FOR EXTERNAL USE ONLY</b> When using this product: do not get into the 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). Do not use on children under 2 years, unless directed by a doctor.
<b>KEEP OUT OF REACH OF CHILDREN.</b> In the event of accidental ingestion, contact a Poison Control Center right away.
<b>Directions:</b> Clean the affected area and dry thoroughly. Apply a thin layer of the product over affected area twice daily (morning and night), or as directed by a doctor. Supervise children in the use of this product. This product does not work on the scalp or nails. For athlete's foot and ringworm pay special attention to spaces between the toes; wear well fitting, ventilated shoes, and change shoes and socks at least once every day. Use every day for 4 weeks. For jock itch, use every day for 2 weeks. If condition lasts longer, contact a doctor.
<b>Other information:</b> Store between 20° - 30°C (68° - 86°F)
<b>Inactive ingredients:</b> Benzyl alcohol, ceteareth 20, cetyl alcohol, citric acid, paraffin wax, petrolatum, polysorbate 80, sodium citrate, sorbitan sesquioleate, stearyl alcohol, water.

Geritrex Corporation

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## CLOTRIMAZOLE

clotrimazole cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54162-018
<b>Route of Administration</b>	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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETEARETH-2 PHOSPHATE (UNII: 8NSU66JGZR)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SORBITAN SESQUIOLEATE</b> (UNII: 0W8RRI5W5A)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4HIY)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-018-05	14 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	07/29/2014	

**Labeler** - Geritrex Corp (112796248)

**Registrant** - Geritrex Corp (112796248)

### Establishment

Name	Address	ID/FEI	Business Operations
Geritrex Corp		112796248	manufacture(54162-018)

Revised: 7/2014

Geritrex Corp