

LEADER ATHLETES FOOT CLOTRIMAZOLE- clotrimazole cream

LEADER

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.

LEADER™ ATHLETE'S FOOT 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 right away: 800-222-1222.

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?

866-323-0107 or www.natureplex.com

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

LEADER™

NDC 70000-0542-2

Athlete's Foot Cream
Clotrimazole, 1% | Antifungal

Cures Most Athlete's Foot

Soothing and Cooling Cream
Enriched with Aloe

Contains the Drug Clotrimazole

COMPARE TO
LOTRIMIN® AF
active ingredient*

100% Money Back Guarantee

NET WT 1 OZ (28 g)

LEADER²™

NDC70000-0542-2

Athlete's Foot Cream

Clotrimazole, 1% | Antifungal

PL31311B
V01

Athlete's
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DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
Essential to Care™ since 1979

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

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All LEADER[™] Brand Products Have A
100% Money Back Guarantee

Return to place of purchase if not satisfied.

CIN 5580246 REV. 1/20



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Drug Facts	
Active Ingredient	Clotrimazole 1%.....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 right away; 800-222-1222.
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 ■ supervised 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, babadensis leaf juice, carbomer, cetyl alcohol, DMDM hydantoin, glyceryl stearate, isopropyl alcohol, methylparaben, mineral oil, polysorbate-20, popyparaben, purified water, stearic acid, tetrahydroamine, titanium dioxide, EDTA
Questions or comments?	866-923-0107 or www.natureplex.com

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LEADER ATHLETES FOOT CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0542
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)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLPARABEN (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:70000-0542-2	1 in 1 CARTON	01/17/2020	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70000-0542-1	1 in 1 CARTON	01/22/2020	
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			

OTC MONOGRAPH FINAL	part333C	01/17/2020	
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Labeler - LEADER (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(70000-0542)

Revised: 6/2021

LEADER