

ATHLETE S FOOT AFAC- clotrimazole cream

Natureplex, 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.

Athlete's Foot

Afac

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)
- 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

PRINCIPAL DISPLAY PANEL - 35 g Tube Carton

ANTIFUNGAL CREAM
CURES MOST ATHLETE'S FOOT

Natureplex™

Athlete's Foot
Antifungal Cream

Contains The Drug
Clotrimazole

* Compare to the active
ingredient of Lotrimin AF®

NDC 67234-009-01

clotrimazole cream

NET WT. 1.25 Oz. (35g)

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-009
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 TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIETHANOLAMINE DODECYLBENZENESULFONATE (UNII: 8HM7ZD48HN)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67234-009-01	35.5 g in 1 TUBE; Type 0: Not a Combination Product	01/22/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/22/2008	

Labeler - Natureplex, LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex, LLC		062808196	manufacture(67234-009)

