

PRO-EX ANTI FUNGAL- 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.

PRO-EX Anti Fungal

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 - 42 g Tube Carton

Natureplex™

**NATUREPLEX
QUALITY
GUARANTEED**

*Pro-Ex
clotrimazole cream*

**NET WT. 1.5 Oz.
(42g)**

ANTIFUNGAL CREAM • CURES MOST JOCK ITCH

Natureplex

Pro-Ex

Antifungal Cream

Contains The Drug Clotrimazole

** Compare to the active ingredients of Lotrimin AF®*

NDC 67234-014-01

Cures Most Jock Itch
Relieves Itching, Burning and Chafing

30608 V-15

Antifungal Cream

Pro-Ex

Antifungal Cream

Natureplex

QUALITY GUARANTEED

Pro-Ex

clotrimazole cream

NET WT. 1.5 Oz. (42g)

Natureplex

Pro-Ex

Antifungal Cream

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



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Natureplex

MADE IN THE USA

NATUREPLEX, Olive Branch, MS 38654

Questions or comments? 866-22-3-0107 or www.natureplex.com

Inactive ingredients also includes red wax, carbomer, cetostearyl alcohol, DM DMAcridon, glyceryl stearate, isopropyl alcohol, methylparaben, polyethylene glycol, propylene glycol, sorbitol, water, and white mineral oil.

Other information ■ Tamper Evident: DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING. ■ Store at 20° to 25° C (68° to 77° F).

Directions
 Wash the area and dry thoroughly.
 Apply a thin layer over affected area twice daily (morning and night).
 Do not use over affected area if the product is dry.
 For athlete's foot, pay special attention to spaces between the toes, webbing, and between toes and socks at least once daily.
 For athlete's foot and ingrown toenail, use daily for 4 weeks; for jock itch, use daily for 2 weeks.
 For athlete's foot and ingrown toenail, use daily for 4 weeks; for jock itch, use daily for 2 weeks.
 For athlete's foot and ingrown toenail, use daily for 4 weeks; for jock itch, use daily for 2 weeks.
 For athlete's foot and ingrown toenail, use daily for 4 weeks; for jock itch, use daily for 2 weeks.

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 2 weeks for athlete's foot and ingrown toenail or 2 weeks for jock itch.
 ■ there is no improvement within 2 weeks for athlete's foot and ingrown toenail or 2 weeks for jock itch.

Uses
 ■ athlete's foot, jock itch, and ingrown toenail.
 ■ relief of itching, burning, cracking, scaling and discomfort.

Drug Facts
Active ingredient
 Clotrimazole 1%
Purpose
 Antifungal

Pro-Ex
Antifungal Cream

Natureplex

PRO-EX ANTI FUNGAL
 clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-014
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 HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67234-014-01	42 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(67234-014)