ATOPALM CLOTRIMAZOLE ANTIFUNGAL - clotrimazole cream NeoPharm Co., Ltd.

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.

ATOPALM CLOTRIMAZOLE ANTIFUNGAL CREAM

Drug Facts

Active Ingredients

Clotrimazole 1%

Purpose

Antifungal

Uses

- cures most athlete's foot, jock itch and ringworm
- relieves itching, burning, cracking, scaling and discomfort which accompany these conditions.

Warnings For external use only.

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

When using this product avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ring worm) or 2 weeks (for jock itch).

Keep out of reach of children to avoid accidental ingestion. If swallowed, get medical help or contact a Poison Control Center immediately.

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 the use of this product
- for athlete's foot, pay special attention to spaces between toes, wear well-fitting, ventilated shoes and change shoes and socks at least once a day.
- for athlete's foot and ringworm, use daily for 4 weeks, for jock itch use daily for 2 weeks
- if condition persists longer, ask a doctor
- this product not effective on the scalp or nails

Other Information

- store at 20 degrees to 25 degrees (68 degrees to 77 degrees F)
- see end of carton or tube crimp for lot number and expiration date

Inactive Ingredients

Water, Glycerin, Cetyl Alcohol, Mineral Oil, Glyceryl Stearate, PEG Glyceryl Stearate, Stearic Acid, Benzyl Alcohol, Carbomer 940, Cholesterol, Myristoyl/Palmitoyl Oxostearamide/Arachamide MEA, Triethanolamine

Questions? Call 1-855-ATOPALM

US Patent US 6221371B1

Distributed by: NeoPharm Co., Ltd, 80 Wood Rd, 212 Camarillo, CA 93010

Made in Korea

Clotrimazole 1% Antifungal Cream

Product Labeling

CLOTRIMAZOLE ANTIFUNGAL CREAM

ATOPALM[®]

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Drug Facts (continued)

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Questions or information call toll free: 1-855-ATCPALM

US Patent # US 6221371B1

Distributed by: NeoPharm USA, 1 Oyster Bay Drive, Rumson, NJ 07760 Made in Korea

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ATOPALM CLOTRIMAZOLE ANTIFUNGAL

clotrimazole cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51141-1000
Route of Administration	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
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
MYRISTO YL/PALMITO YL O XOSTEARAMIDE/ARACHAMIDE MEA (UNII: 1211AIM8G7)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51141-1000-1	1 in 1 CARTON		
1	28.3 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	03/16/2011	

Labeler - NeoPharm Co., Ltd. (965502912)

Establishment			
Name	Address	ID/FEI	Business Operations
Neo Pharm Co., Ltd.		631101883	manufacture(51141-1000)

Revised: 5/2015 NeoPharm Co., Ltd.