

CLOTRIMAZOLE- clotrimazole cream

Kinray Inc.

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.

Antifungal

Purpose

- For treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), Ringworm (tinea corporis).
- For the treatment of superficial skin infections caused by Yeast (Candida Albicans).
- Relieves itching, scaling, cracking, burning, redness, soreness, irritation discomfort and chafing associated with jock itch.

Active Ingredient

Active Ingredient	Purpose
Clotrimazole 1.0%	Antifungal

Warnings

Do not use:

- Do not use on children under 2 years of age unless directed by a doctor.
- Avoid contact with eyes.
- For athlete's foot and ringworm - if irritation occurs, or if there is no improvement within 4 weeks, discontinue use and consult a doctor.
- For jock itch - if irritation occurs, or if there is no improvement within two weeks, discontinue use and consult a doctor.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Indications & Usage

- Supervise children in the use of this product.
- If conditions persist longer, consult a doctor.
- This product is not effective on scalp or nails.

Other information.

Protect from freezing. Avoid excessive heat.

Dosage & Administration

- Clean the affected area and dry thoroughly. Apply a layer of cream over affected area twice daily (morning and night) or as directed by a doctor.
- For athlete's foot and ringworm, use daily for 4 weeks.
- For jock itch, use daily for 2 weeks.
- For athlete's foot, pay special attention to spaces between toes: wear well fitting, ventilated shoes,

and change shoes and socks at least once daily.

Inactive Ingredients

Inactive Ingredients: Cetomacrogol 1000, cetostearyl alcohol, liquid paraffin, methylparaben, propylene glycol, propylparaben, purified water, white soft paraffin.

Keep Out of Reach of Children

- KEEP OUT OF REACH OF CHILDREN
- If swallowed get medical help or contact a Poison Control Center.

Principal Display Panel

Kinray Antifungal

KR_Antifungal.jpg

NDC # 63777-231-01

Compare to the Active Ingredient in Lotrimin®AF†



CLOTRIMAZOLE

CREAM USP 1% ANTIFUNGAL

Drug Facts	
Active Ingredient	Purpose
Clotrimazole 1.0%	Antifungal
Uses: For external treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), Ringworm (tinea corporis). • For the treatment of superficial skin infections caused by Yeast (Candida Albicans) • Relieves itching, scaling, cracking, burning, redness, soreness, irritation, discomfort and chafing associated with jock itch.	
Warnings • For external use only.	
Do not use • on children under 2 years of age unless directed by a doctor • avoid contact with eyes • for athletes foot and ringworm — if irritation occurs, or if there is no improvement within 4 weeks, discontinue use and consult a doctor • for jock itch — if irritation occurs, or if there is no improvement within 2 weeks, discontinue use and consult a doctor.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions: • Clean the affected area and dry thoroughly. Apply a layer of cream 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 daily • For athlete's foot and ringworm, use daily for 4 weeks • For jock itch, use daily for 2 weeks • if conditions persists longer, consult a doctor • This product is not effective on scalp or nails ▼	

Drug Facts (continued)	All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased. Manufactured by: Dynarex Corp. Distributed by: Kinray Inc. Whitestone, NY 11357
Other information: • Store at 15°-30°C (59°-86°F)	
Inactive ingredients Cetomacrogol 1000, Cetostearyl Alcohol, Liquid Paraffin, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, White Soft Paraffin	

†This product is not manufactured or distributed by Schering-Plough Healthcare Products, Inc., owner of registered trademark Lotrimin®AF



MH/DRUGS/ND-214

CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63777-231
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
CETETH-20 (UNII: I835H2IHXX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63777-231-01	28.4 g in 1 TUBE; Type 0: Not a Combination Product	01/11/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/11/2012	

Labeler - Kinray Inc. (012574513)

Registrant - Dynarex Corporation (008124539)

Establishment

Name	Address	ID/FEI	Business Operations
Blossom Pharmaceuticals		677381470	manufacture(63777-231)