

DYNAREX ANTIFUNGAL- antifungal cream

Dynarex Corporation

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.

1231, 1233

Active Ingredient

Active Ingredient	Purpose
Clotrimazole 1.0%	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.

Warnings

Do not use:

- 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 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 and Usage

- 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.

Dosage and Administration

- For athlete's foot and ringworm, use daily for 4 weeks.

- For jock itch, use daily for 2 weeks. If conditions persist longer, consult a doctor.
- This product is not effective on scalp or nails.

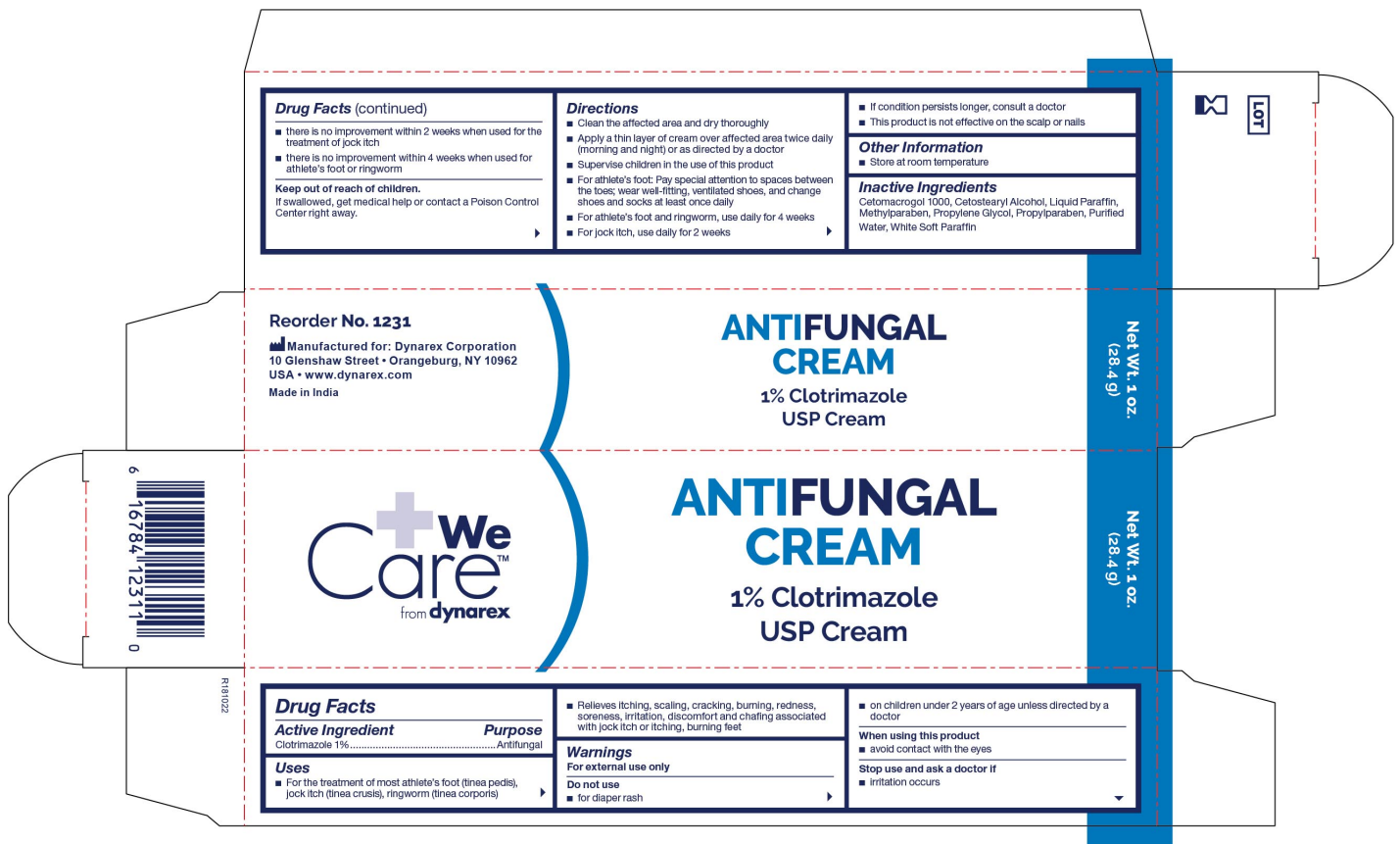
Keep Out Of Reach Of Children

KEEP OUT OF REACH OF CHILDREN

INACTIVE INGREDIENTS

Inactive Ingredients: Cetomicrogol 1000, Cetostearyl alcohol, Liquid paraffin, Methylparaben, Propylene glycol, Propylparaben, Purified water, White soft paraben

Label



Label



DYNAREX ANTIFUNGAL

antifungal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-231
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
PETROLATUM (UNII: 4T6H12BN9U)	
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-231-13	72 in 1 CASE	05/18/2010	
1	NDC:67777-231-12	1 in 1 BOX		
1	NDC:67777-231-02	28.25 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:67777-231-11	24 in 1 CASE	05/18/2010	
2	NDC:67777-231-10	6 in 1 BOX		
2	NDC:67777-231-01	113 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	05/18/2010	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)