

CAREALL MICONAZOLE NITRATE- miconazole nitrate cream
New World Imports, 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.

Drug Facts

Active Ingredient

Miconazole Nitrate 2%

Purpose

Antifungal

Keep out of Reach of Children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Uses

- Proven clinically effective in the treatment of most athlete's foot, jock itch and ringworm.
- For effective relief of itching, scaling, burning and discomfort that can accompany these conditions.

Warnings

For external use only.

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

When using this product avoid contact with eyes

Stop use and ask doctor if

- irritation occurs
- condition persists
- there is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock itch)

Directions

- wash affected area and dry thoroughly
- apply a thin layer of the product 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 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
- not effective on the scalp or nails

Inactive Ingredients

Cetostearyl Alcohol, Chlorocresol, Mineral Oil, Polyoxyl 20 Cetostearyl Ether, Propylene Glycol, Purified Water, White Petrolatum

CAREALL
Antifungal Cream
 For treatment of athlete's foot, jock itch, and ringworm

Miconazole Cream
 MICONAZOLE NITRATE 2%
 For treatment of athlete's foot, jock itch, and ringworm

CAREALL
Miconazole Cream
 MICONAZOLE NITRATE 2%
 COMPARE TO ACTIVE INGREDIENTS OF MICATIN®

RELIEVES ITCHING AND BURNING

NET WT. 1 OZ (28g)

Miconazole Cream
 Miconazole Nitrate 2%



This product is not manufactured or distributed by Wyething Pharmaceuticals Corporation, Owner of the Registered Trademark Miconazole. Distributed by Careall Products, 100 Lewis Way, Marlton, NJ 07228. MICH # 1454-0745-01 002PUS0522721X

Drug Facts	Active Ingredient Miconazole Nitrate 2% Antifungal
Drug Facts (continued)	Purpose Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).
Directions <ul style="list-style-type: none"> ■ 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 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. ■ Not effective on the scalp or nails. 	
Warnings <ul style="list-style-type: none"> ■ Do not use on children under 2 years of age unless directed by a doctor. ■ When using this product avoid contact with eyes. 	Stop use and ask a doctor if <ul style="list-style-type: none"> ■ Irritation occurs. ■ Condition persists. ■ There is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock itch).
Uses <ul style="list-style-type: none"> ■ Proven clinically effective in the treatment of most athlete's foot, jock itch, and ringworm. ■ For effective relief of itching, scaling, burning and discomfort that can accompany these conditions. 	Other Information <ul style="list-style-type: none"> ■ Store between 15° to 30°C (59° to 86°F). ■ Lot No., Ex. Date: See box or stamp of label.
Inactive Ingredients Ethox, Propylene Glycol, Purified Water, White Petrolatum, Cetostearyl Alcohol, Chlorocresol, Mineral Oil, Polyoxyl 20 Cetostearyl Ether.	

CAREALL MICONAZOLE NITRATE

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-078
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLOROCRESOL (UNII: 36W5307109)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-078-01	28 g in 1 TUBE; Type 0: Not a Combination Product	12/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	12/01/2020	

Labeler - New World Imports, Inc (075372276)