

DERMAFUNGAL- antimicrobial drug products cream
DermaRite industries, LLC

DRUG LISTING: DERMAFUNGAL

Active Ingredient:

Miconazole Nitrate 2%

Purpose:

Antifungal

Uses:

- For the treatment and prevention of most: athlete's foot, jock itch, ringworm
- relieves itching, scaling, cracking, and discomfort associated with these conditions.

Warnings:

- **For external use only.**
- **Avoid contact with eyes.** In case of contact, flush thoroughly with water.
- **Stop use and ask doctor if** irritation occurs , condition worsens or does not improve in 2 weeks for jock itch, or within 4 weeks for athlete's foot and ringworm.

Warnings

- **Keep out of reach of children.** In case of accidental ingestion contact physician or Poison Control Center right away.

Directions

Cleanse affected area and dry thoroughly. Apply a thin layer to affected area twice daily or as directed by physician.

- **For jockitch** use daily for two weeks.
- **For athelete's foot** use daily for four weeks.

Other Information:

- This product is not effective on the scalp and nails.
- Store at room temperature (59°-86°F)

Inactive Ingredients:

Caprylic/Capric Triglyceride, Cetareth-20, Disodium EDTA, Glyceryl Stearate, Methylparaben, PEG-40 Castor Oil, PEG-100 Stearate, Petrolatum, Propylene Glycol, Propylparaben, Stearic Acid, Water, Xantham Gum

Durmafungal Principal Display Panel and Drug Facts

NDC 61924-234-04



ANTIFUNGAL CREAM
with 2% MICONAZOLE NITRATE

TREATS:
Athletes Foot
Jock Itch
Ringworm

DermaRite®

REORDER #00234 Net Wt. 106 g (3.75 oz.)

Drug Facts	
Active ingredient	Purpose
Miconazole Nitrate 2%.....	Antifungal
Uses ■ For the treatment and prevention of most: ■ athlete's foot ■ jock itch ■ ringworm ■ relieves itching, scaling, cracking, and discomfort associated with these conditions.	
Warnings Do not use on children under 2 years of age unless directed by a doctor. For external use only. Avoid contact with eyes. In case of contact, flush thoroughly with water. Stop use and ask a doctor if ■ irritation occurs. ■ condition worsens or does not improve within 2 weeks for jock itch, or within 4 weeks for athlete's foot and ringworm. Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center right away.	
Directions Cleanse affected area and dry thoroughly. Apply a thin layer to affected area twice daily or as directed by a physician. Supervise children in the use of this product. 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 the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily. This product is not effective on the scalp or nails.	
Other information ■ Store at room temperature (59°-86°F). ■ You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047.	
Inactive ingredients Caprylic/Capric Triglyceride, Ceteareth-20, Cetearyl Alcohol, Dimethicone, Disodium EDTA, Glyceryl Stearate, Imidiazolidinyl Urea, Methylparaben, PEG-40 Castor Oil, PEG-100 Stearate, Petrolatum, Propylene Glycol, Propylparaben, Stearic Acid, Sodium Cetearyl Sulfate, Water, Xantham Gum	
Questions? Call 1-800-337-6296 Mon - Fri 9AM - 5PM EST.	

Patient Name

Room #



DermaRite Industries LLC • 7777 West Side Ave.
North Bergen, NJ 07047 • www.dermarite.com

MADE IN THE USA
101032

DERMAFUNGAL

antimicrobial drug products cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61924-234
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	0.02 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
IMIDUREA (UNII: M629807ATL)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-234-05	5 g in 1 PACKET; Type 0: Not a Combination Product	12/12/2005	
2	NDC:61924-234-04	106 g in 1 TUBE; Type 0: Not a Combination Product	12/12/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	12/12/2005	

Labeler - DermaRite industries, LLC (883925562)

Registrant - Fabian McCarthy (883925562)

Establishment

Name	Address	ID/FEI	Business Operations
DermaRite industries, LLC		883925562	manufacture(61924-234)

Revised: 12/2024

DermaRite industries, LLC