

**DERMAFUNGAL- antimicrobial drug products cream**  
**DermaRite industries, LLC**

*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 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, Xanthan 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.)

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Miconazole Nitrate 2%.....	Antifungal
<b>Uses</b> ■ For the treatment and prevention of most: ■ athlete's foot ■ jock itch ■ ringworm ■ relieves itching, scaling, cracking, and discomfort associated with these conditions.	
<b>Warnings</b> 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.	
<b>Directions</b> 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.	
<b>Other information</b> ■ Store at room temperature (59°-86°F). ■ You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047.	
<b>Inactive ingredients</b> Caprylic/Capric Triglyceride, Ceteareth-20, Cetearyl Alcohol, Dimethicone, Disodium EDTA, Glyceryl Stearate, Imidazolidinyl Urea, Methylparaben, PEG-40 Castor Oil, PEG-100 Stearate, Petrolatum, Propylene Glycol, Propylparaben, Stearic Acid, Sodium Cetearyl Sulfate, Water, Xantham Gum	
<b>Questions?</b> 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**

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

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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 final	part333C	12/12/2005	

**Labeler** - DermaRite industries, LLC (883925562)

**Registrant** - Mark Friedman (883925562)

### Establishment

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

Revised: 1/2022

DermaRite industries, LLC