ROYCEDERM TINEA ANTIFUNGAL CREAM- miconazole nitrate 2% cream
RoyceDerm LLC

Initial Drug Listing - RoyceDerm Tinea Antifungal Cream

Miconazole Nitrate 2%

Antifungal

- For effective treatment of tinea pedis (athlete's foot), tinea cruris (jock itch), tinea corporis (ringworm).

- For effective relief of itching, scaling, cracking, burning, redness, soreness, irritation, discomfort, and chafing associated with the conditions.

For external use only

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

Avoid contact with the eyes.

If irritation occurs or if there is no improvement within 4 weeks, discountine use and consult a doctor.

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

Clean the 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. If condition persists longer, consult a doctor.

This product is not effective on the scalp or nails.

Store at room temperature and out of direct sunlight.

WATER, ARTEMISIA EXTRACT IFHFI], SOPHORA FLAVESCENS ROOT. CNIDIUM MONNIERI FRUITKOCHIA SCOPARIA POLLEN
DICTAMNUS DASYCARPUSROOT, SMILAX GLABRA WHOLE

Visit www.roycederm.com or email service@roycederm.com

ROYCEDERM TINEA ANTIFUNGAL CREAM

miconazole nitrate 2% cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:85424-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CNIDIUM MONNIERI FRUIT (UNII: V1IA3S3CUS)	
WORMWOOD (UNII: F84709P2XV)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
SMILAX GLABRA WHOLE (UNII: H51N91QNEB)	
BASSIA SCOPARIA POLLEN (UNII: 07A108ZKW5)	

DICTAMNUS DASYCARPUS ROOT (UNII: 6153LEN214)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85424-011-01	57 g in 1 TUBE; Type 0: Not a Combination Product	10/07/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	10/07/2025	

Labeler - RoyceDerm LLC (130329531)

Revised: 9/2025 RoyceDerm LLC