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.

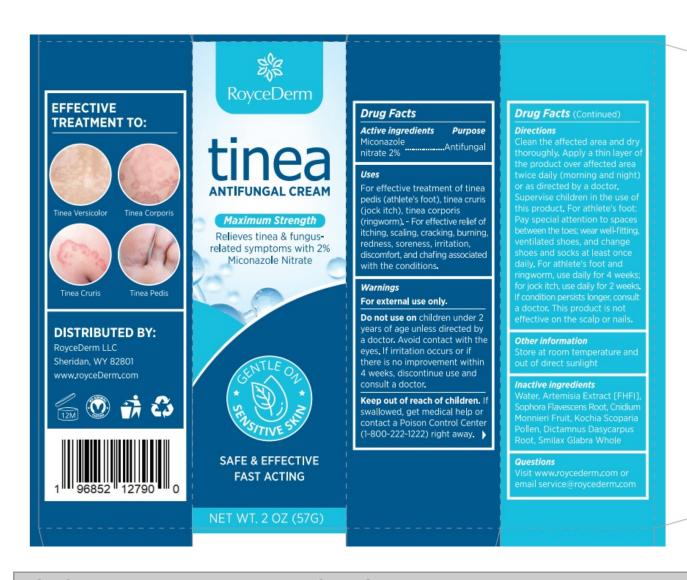
For athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks. If condition persists longer, consult a doctor.

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

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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 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)	

l	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 In	larketing 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