

**MICONAZOLE NITRATE 2% CREAM ANTIFUNGAL- miconazole nitrate cream**  
**Trifecta Pharmaceuticals Usa Llc**

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**MICONAZOLE Nitrate 2% Cream ANTIFUNGAL**

***Drug Facts***

***Active ingredient***

Miconazole Nitrate 2%

***Purpose***

Anti-Fungal

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

***Uses***

- proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea crurus), and ringworm (tinea capitis)
- relieves itching, scaling, cracking, burning and discomfort associated with these conditions.

***Warnings***

**For external use only. Do not use if the safety-sealed tube is punctured or damaged.**

**Do not use** on children under 2 years of age unless directed by a healthcare professional. When using this product avoid contact with the eyes.

**Stop use and ask a healthcare professional if** • irritation occurs or if there is no improvement within 4 weeks (for athlete's foot and ringworm) • Irritation occurs, or if there is no improvement within 2 weeks (for jock itch).

***Directions***

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 healthcare professional • Supervise children in the use of this product.

**For athlete's foot:** • Use daily for 4 weeks. If condition persists, consult a healthcare professional. • Pay special attention to the spaces between the toes • Wear well fitting, ventilated shoes • Change socks atleast once daily.

**For ringworm:** Use daily for 4 weeks. If condition persists, consult a healthcare professional.

**For jock itch:** Use daily for 2 weeks. If condition persists longer, consult a healthcare professional.

This product is not effective on the scalp or nails.

**Inactive ingredients** Carbomer, cetostearyl alcohol, dimethyl sulfoxide, edetate disodium, ethylparaben, glycerol, glyceryl distearate, mineral oil, peregalo, purified water, stearic acid, triethanolamine, petrolatum.

### **Other Information**

• Store at 15° - 30° c (59° - 86° f) • Lot number and expiration date see crimp of tube or see box. • To open: Unscrew cap, tear safety seal off.

You may report serious side effects to: [QC@trifecta-pharma.com](mailto:QC@trifecta-pharma.com)

### **FAST RELIEF 100% GUARANTEED**

**Relieves Itching and Burning**

**Also Cures Athlete's Foot and Ringworm**

**Distributed by:**

**Trifecta Pharmaceuticals USA™**

101 NE Third Avenue Suite 1500

Ft. Lauderdale, FL 33301 USA

**[www.trifecta-pharma.com](http://www.trifecta-pharma.com)**

### **Packaging**

<b>Drug Facts</b>	<b>Drug Facts</b> (continued)
<b>Active ingredient</b> Miconazole Nitrate 2% .....	<b>Purpose</b> Anti-Fungal
<b>Uses</b> ■ proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea capitis) ■ relieves itching, scaling, cracking, burning and discomfort associated with these conditions. ▶	<b>Warnings</b> <b>For external use only. Do not use if the safety-sealed tube is punctured or damaged.</b> <b>Do not use</b> on children under 2 years of age unless directed by a healthcare professional. When using this product avoid contact with the eyes. <b>Stop use and ask a healthcare professional if</b> ■ irritation occurs or if there is no improvement within 4 weeks (for athlete's foot and ringworm) ■ Irritation occurs, or if there is no improvement within 2 weeks (for jock itch). ▼

<b>Drug Facts</b> (continued)	<b>Drug Facts</b> (continued)
<b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.</b>	<b>For jock itch:</b> Use daily for 2 weeks. If condition persists longer, consult a healthcare professional. This product is not effective on the scalp or nails.
<b>Directions</b> 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 healthcare professional ■ Supervise children in the use of this product. <b>For athlete's foot:</b> ■ Use daily for 4 weeks. If condition persists, consult a healthcare professional. ■ Pay special attention to the spaces between the toes ■ Wear well fitting, ventilated shoes ■ Change socks at least once daily. <b>For ringworm:</b> Use daily for 4 weeks. If condition persists, consult a healthcare professional. ▶	<b>Other Information</b> ■ Store at 15° - 30° c (59° - 86° f) ■ Lot number and expiration date see crimp of tube or see box. ■ To open: Unscrew cap, tear safety seal off. You may report serious side effects to: QC@trifecta-pharma.com <b>Inactive ingredients</b> Carbomer, cetostearyl alcohol, dimethyl sulfoxide, edetate disodium, ethylparaben, glycerol, glyceryl distearate, mineral oil, peregol-o, purified water, stearic acid, triethanolamine, petrolatum.

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100%  
GUARANTEED**

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FL, Lauderdale, FL 33301 USA  
Product of PRC  
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**Relieves Itching and Burning  
Also Cures Athlete's Foot  
and Ringworm**



NDC: 69396-014-20



**Miconazole**  
**Nitrate 2% Cream ANTIFUNGAL**

**CURES JOCK ITCH** Net Wt. 1 oz. (30g)

**Package Label**

# OUTSIDE BOX



## MICONAZOLE NITRATE 2% CREAM ANTIFUNGAL

miconazole nitrate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69396-014
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>MICONAZOLE NITRATE</b> (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>CARBOXPOLYMETHYLENE</b> (UNII: 0A5MM307FC)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>DIMETHYL SULFOXIDE</b> (UNII: YOW8V9698H)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL DISTEARATE</b> (UNII: 73071MW2KM)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-014-20	1 in 1 BOX	03/22/2016	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69396-014-05	15 g in 1 TUBE; Type 0: Not a Combination Product	03/22/2016	
3	NDC:69396-014-04	118.3 g in 1 TUBE; Type 0: Not a Combination Product	09/23/2022	
4	NDC:69396-014-44	4 in 1 BOX	02/29/2024	
4		30 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:69396-014-33	3 in 1 BOX	03/22/2024	
5		30 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	03/22/2016	

Revised: 6/2024

Trifecta Pharmaceuticals Usa Llc