

MICONAZOLE NITRATE 2%- miconazole nitrate cream
Pharmaceutica North America, Inc.

Active Ingredient

Miconazole Nitrate 2%

Purpose

Anti-Fungal

Uses

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

Warnings

For external use only.

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

Stop use and ask a doctor 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).

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

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 doctor
- Pay special attention to the spaces between the toes
- Wear well fitting, ventilated shoes
- Change socks at least once daily.

For ringworm: Use daily for 4 weeks. If condition persists, consult a doctor.

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.

Other information

- store at 15° - 30°C (59 - 86°F)

Inactive Ingredients

Carbomer, alcohol, cetostearyl alcohol, dimethyl sulfoxide, edetate disodium, ethylparaben, glycerol, mineral oil, mono and di glycerides, polyoxyethylene lauryl ether, purified water, stearic acid, triethanolamine, petrolatum.

Questions or comments? (888)788-6472

Product label

NDC: 45861-078-03



Miconazole Nitrate 2%

Anti-fungal

30gm

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Miconazole Nitrate 2%.....	Anti-fungal

Uses ■ Proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis) ■ Relieves itching, scaling, cracking, burning and discomfort associated with these conditions
Warnings For external use only. Do not use on children under 2 years of age unless directed by a doctor. When using this product avoid contact with the eyes. **Stop using and ask a doctor 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).
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center 1-800-222-1222 immediately.
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 doctor ■ Supervise children in the use of this product. **For athlete's foot** ■ Use daily for 4 weeks. If condition persists, consult a doctor. ■ Pay special attention to the spaces between toes ■ Wear well fitting, ventilated shoes ■ Change socks at least once daily. **For ringworm:** Use daily for 4 weeks. If condition persists, consult a doctor.
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Questions or comments? 1-888-788-6472 Manufactured For: Pharmaceutica North America, Inc. Glendale, CA 91205

Drug Facts		Drug Facts (continued)
Active Ingredient Miconazole Nitrate 2%	Purpose Anti-fungal	night) or as directed by a healthcare professional <ul style="list-style-type: none"> Supervise children in the use of this product.
Uses <ul style="list-style-type: none"> Proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis) Relieves itching, scaling, cracking, burning and discomfort associated with these conditions. 	For athlete's foot: <ul style="list-style-type: none"> Use daily for 4 weeks. If condition persists, consult a doctor Pay special attention to the spaces between the toes Wear well fitting, ventilated shoes Change socks at least once daily 	
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 doctor. When using this product avoid contact with eyes. Stop use and ask a doctor if <ul style="list-style-type: none"> 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) 	For ringworm: Use daily for 4 weeks. If condition persists, consult a doctor. For jock itch: Use daily for 2 weeks. If condition persists longer, consult a doctor. <ul style="list-style-type: none"> This product is not effective on the scalp or nails. 	
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Manufactured For:
Pharmaceutical North America, Inc.
Glendale, CA 91205

Anti-fungal

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30gm

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MICONAZOLE NITRATE 2%

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45861-078
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
LAURETH-30 (UNII: W9D845551A)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
PETROLATUM (UNII: 4T6H12BN9U)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERYL MONO AND DIPALMITOSTEARATE (UNII: KC98RO82HJ)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45861-078-03	1 in 1 BOX	02/01/2025	
1		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	M017	02/01/2025	

Labeler - Pharmaceutica North America, Inc. (962739699)