

**MICONAZOLE NITRATE 2% CREAM ANTIFUNGAL- miconazole nitrate cream
GERI-GENTLE CORPORATION**

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.

MICONAZOLE Nitrate 2% Cream ANTIFUNGAL

Drug Facts

Active ingredient

Miconazole Nitrate 2% w/w

Purpose

Anti-Fungal

Uses

- For the treatment and prevention 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

on children under 2 years of age unless directed by Doctor

When using this product

Avoid contact with eyes

Stop use and ask a doctor if

irritation occurs

there is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock itch)

Keep out of reach of children

In case of accidental ingestion contact a physician or Poison Control Center right away and discomfort which accompany these conditions

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.

Other Information

- Store at 15° - 30° c (59° - 86° f)

Caprylic/capric triglyceride, Cetereath-20, Cetearyl Alcohol, Chlorocresol, Dimethicone, Disodium EDTA, Glyceryl Stearate, Imidazolidinyl Urea, PEG-100 Stearate, PEG-40 Castor Oil, Petrolatum, Propylene Glycol, Sodium Cetearyl Sulfate, Stearic Acid, Water, Xanthum Gum

Drug Facts	
Active Ingredient	Purpose
Miconazole Nitrate 2% w/w	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	
Do not use on children under 2 years of age unless directed by doctor	
When using this product ■ Avoid contact with eyes	
Stop use and ask a doctor if ■ Irritation occurs ■ There is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock itch)	
Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center right away and discomfort which accompany these conditions	
Directions ■ 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 space 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	
Other Information ■ Store at room temperature 15°-30°C (59°-86°F)	
Inactive Ingredients Caprylic/Capric Triglyceride, Ceteareth-20, Cetearyl Alcohol, Chlorocresol, Dimethicone, Disodium EDTA, Glyceryl Stearate, Imidazolidinyl Urea, PEG-100 Stearate, PEG-40 Castor Oil, Petrolatum, Propylene Glycol, Sodium Cetearyl Sulfate, Stearic Acid, Water, Xanthan Gum	

Patient Name:
Room #:

Manufactured for the:
Ger Gentle Corporation
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 South Plainfield, NJ 07080
 718-802-1085
 www.ggentle.com
 Made In India
 HR/DRUGS 1105-05PI(H)



Reorder No.
04125



Ger Gentle®

*Tender
Anti Fungal
Cream*

**With 2% Miconazole
Nitrate**



SOOTHES AND PROMOTES HEALING
CURES JOCK ITCH & RING WORM

4 Oz. (113g)

MICONAZOLE NITRATE 2% CREAM ANTIFUNGAL

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69771-041
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)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CHLOROCRESOL (UNII: 36W53O7109)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
IMIDUREA (UNII: M629807ATL)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
PETROLATUM (UNII: 4T6H12BN9U)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69771-041-25	113 g in 1 TUBE; Type 0: Not a Combination Product	08/16/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/22/2016	

Labeler - GERI-GENTLE CORPORATION (080367686)