

**MICONAZOLE NITRATE- miconazole nitrate cream**  
**NuCare Pharmaceuticals, Inc.**

*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.*

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**Miconazole Nitrate Cream - Antifungal Cream**

**Drug Facts**

**Active ingredient**

Miconazole nitrate, USP 2%

**Purpose**

Antifungal

**Uses**

- proven clinically effective in the treatment of most athlete's foot, jock itch and ringworm
- for effective relief of itching, scaling, cracking, burning and discomfort

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

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

**Directions**

- wash 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 lasts longer, contact a doctor
- this product is not effective on the scalp or nails

**Other information**

- store at controlled room temperature 59°-86°F (15°-30°C).
- before using any medication, read all label directions. Keep carton, it contains important information.

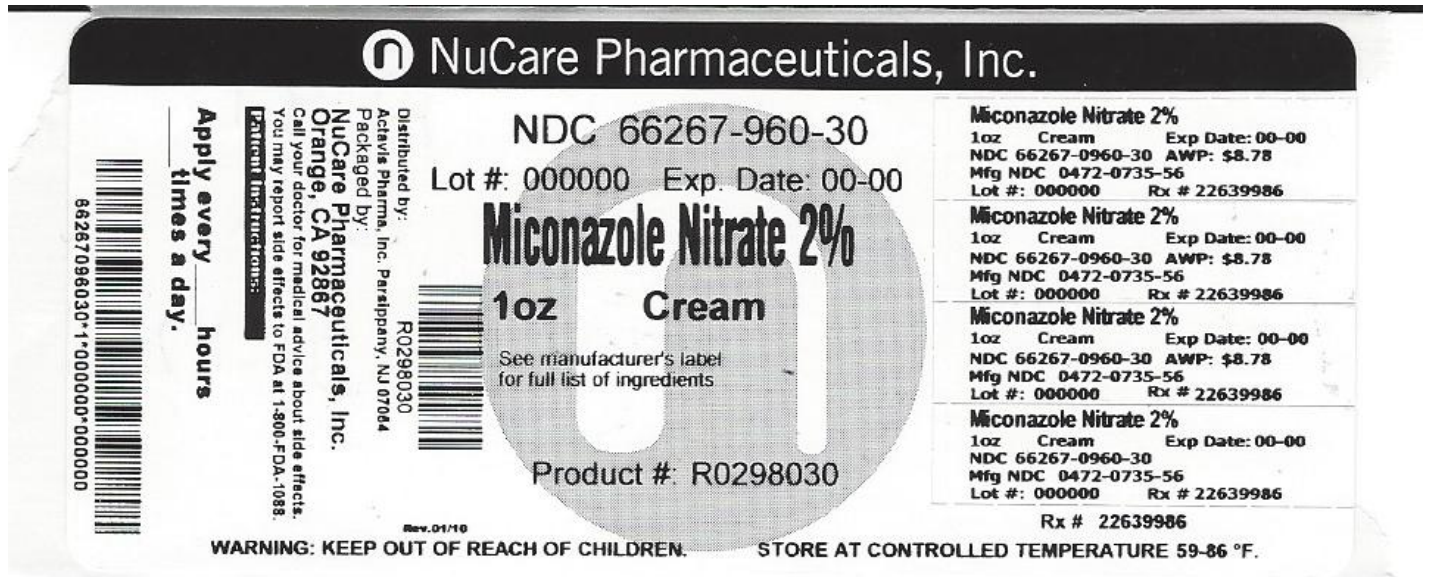
**Inactive ingredients**

benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxylglycerides, pegoxol 7 stearate, purified water

**Questions?**

1-800-432-8534 between 9 am and 4 pm EST, Monday- Friday.

**Principal Display Panel**



**MICONAZOLE NITRATE**

miconazole nitrate cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66267-960(NDC:0472-0735)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66267-960-30	30 g in 1 TUBE; Type 0: Not a Combination Product	07/24/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/01/2007	

**Labeler** - NuCare Pharmaceuticals, Inc. (010632300)

## Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(66267-960)

Revised: 1/2021

NuCare Pharmaceuticals, Inc.