

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

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**Miconazole Nitrate**

***Drug Facts***

**Active ingredient**

Miconazole nitrate USP 2% (100 mg in each applicatorful)

**Purpose**

Vaginal antifungal

**Uses**

- treats vaginal yeast infections
- relieves external itching and irritation due to a vaginal yeast infection

**Warnings**

**For vaginal use only**

**Do not use if you have never had a vaginal yeast infection diagnosed by a doctor**

**Ask a doctor before use if you have**

- **vaginal itching and discomfort for the first time**
- **lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You may have a more serious condition.**
- vaginal yeast infections often (such as once a month or 3 in 6 months). You could be pregnant or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system.
- been exposed to the human immunodeficiency virus (HIV) that causes AIDS

**Ask a doctor or pharmacist before use if you are** taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur

**When using this product**

- do not use tampons, douches, spermicides, or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse
- mild increase in vaginal burning, itching or irritation may occur
- if you do not get complete relief ask a doctor before using another product

**Stop use and ask a doctor if**

- **symptoms do not get better in 3 days**
- **symptoms last more than 7 days**
- **you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge.**

**If pregnant or breast-feeding,** ask a health professional before use.

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

### **Directions**

- before using this product read the enclosed consumer information leaflet for complete directions and information
- adults and children 12 years of age and over:
  - **applicator:** insert 1 applicatorful into the vagina at bedtime for 7 nights in a row. Wash applicator after use.
  - use the same tube of cream if you have itching and irritation on the skin outside the vagina. Squeeze a small amount of cream onto your fingertip. Apply to itchy, irritated skin outside the vagina (vulva). Use 2 times daily for up to 7 days as needed.
- **children under 12 years of age: ask a doctor**

### **Other information**

- do not purchase if carton is opened
- do not use if seal over tube opening has been punctured or is not visible
- store at 20° to 25°C (68° to 77°F)
- see carton or tube crimp for lot number and expiration date

### **Inactive ingredients**

benzoic acid (0.20%) as a preservative, butylated hydroxytoluene, mineral oil, oleoyl polyoxyglyceride, PEG-6-32 stearate/glycol stearate, and purified water.

### **Questions?**

call **1-866-923-4914**

Distributed by:

**Taro Pharmaceuticals U.S.A., Inc.**

Hawthorne, NY 10532

### **PRINCIPAL DISPLAY PANEL**

# NuCare Pharmaceuticals, Inc.

NDC: 68071-2943-7

## Miconazole Nitrate 2% 45g Vaginal Cream

See manufacturer's label  
for full list of ingredients.

### Miconazole Nitrate 2%

Lot: 00000 NDC: 68071-2943-07  
MFR NDC: 51672-2035-6 Exp.: 00-00  
Serial# 0000000002

### Miconazole Nitrate 2%

Lot: 00000 NDC: 68071-2943-07  
MFR NDC: 51672-2035-6 Exp.: 00-00  
Serial# 0000000002



GTIN 00368071294378  
Serial# 0000000002  
Exp. Date 00-00  
LOT#: 00000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Use only as directed  
by your physician.  
Patient Instructions:  
Packaged By:  
NuCare Pharmaceuticals, Inc.  
Orange, CA 92867  
Hawthorne, NY 10532  
Taro Pharmaceuticals U.S.A., Inc.  
Distributed by:  
3 68071 29437 8

68071294307-45\*00000-00000

Rev 01/01/19

WARNING: KEEP OUT OF REACH OF CHILDREN

Product #: R0299045

STORE AT CONTROLLED TEMPERATURE 68-77°F.

## MICONAZOLE NITRATE

miconazole nitrate cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-2943(NDC:51672-2035)
Route of Administration	VAGINAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII: 7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-2943-7	1 in 1 CARTON	02/23/2023	
1		45 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA074444	01/13/1997	

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-2943)

Revised: 2/2023

NuCare Pharmaceuticals, Inc.