

**MICONAZOLE 7- miconazole nitrate cream**  
**NuCare Pharmaceuticals, Inc.**

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**Miconazole 7**

***Drug Facts***

**Active ingredient**

Miconazole nitrate USP, 2% (100 mg in each applicator)

**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. Throw applicator away 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**

- to open tube: unscrew cap, lift tab, and pull to remove foil seal prior to use
- do not use if foil seal on tube opening is broken or missing
- do not purchase if carton is open
- store at room temperature 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F)
- before using any medication, read all label directions. Keep carton, it contains important information.

### **Inactive ingredients**

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

### **Questions?**

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Distributed by: **H2-Pharma, LLC**  
Montgomery, AL 36117

**PRINCIPAL DISPLAY PANEL - 45 g Tube Carton**

**NuCare Pharmaceuticals, Inc.**

Distributed by:  
 H2-Pharma, LLC Montgomery, AL  
 36117  
 68071 24197  
 3  
 6  
 Packaged By:  
 NuCare Pharmaceuticals, Inc.  
 Orange, CA 92867  
 Patient Instructions:  
 Use only as directed  
 by your physician.  
 Rev 01/01/19  
 6807124197\*46-000000-000000

NDC: 68071-2419-7  
**Miconazole 7**  
**45g Vaginal Cream**  
 Miconazole Nitrate, USP 2%  
 (100mg in each applicator)  
 See manufacturer's label  
 for full list of ingredients.

**Miconazole 7**  
 Lot: 000000 NDC: 68071-2419-07  
 MFR NDC: 61269-730-41 Exp.: 00-00  
 Serial# 00000000005

**Miconazole 7**  
 Lot: 000000 NDC: 68071-2419-07  
 MFR NDC: 61269-730-41 Exp.: 00-00  
 Serial# 00000000005



GTIN 00368071241976  
 Serial# 00000000005  
 Exp. Date 00-00  
 LOT#: 000000

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

Product #: R0299045

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 68-77°F.

**MICONAZOLE 7**

miconazole nitrate cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68071-2419(NDC:61269-730)
<b>Route of Administration</b>	VAGINAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>APRICOT KERNEL OIL PEG-6 ESTERS</b> (UNII: DRG3KJZ1TJ)	
<b>PEGOXOL 7 STEARATE</b> (UNII: 3EW5AXE5X5)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-2419-7	1 in 1 CARTON	05/26/2021	
1		45 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074164	04/12/2021	

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

## Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-2419)

Revised: 10/2023

NuCare Pharmaceuticals,Inc.