

**CLOTRIMAZOLE- clotrimazole cream**  
**NuCare Pharmaceuticals, Inc.**

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**Clotrimazole**

***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
Clotrimazole USP, 1% (50 mg in each applicatorful)	Vaginal antifungal
Clotrimazole USP, 1% (external cream)	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

**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 a 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 educational brochure for complete directions and information
- adults and children 12 years of age and over:
  - **vaginal cream:** insert one applicatorful of cream into the vagina at bedtime for 7 days in a row. Wash applicator after each use.
  - **external cream:** 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. 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**

benzyl alcohol, cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sodium phosphate monobasic, sorbitan monostearate

### **Questions?**

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

Distributed by: **H2-Pharma, LLC**

Montgomery, AL 36117

[www.h2-pharma.com](http://www.h2-pharma.com)

### **PRINCIPAL DISPLAY PANEL**

NDC: 68071-2614-4

**Clotrimazole 1%  
1.59oz Vaginal Cr.**

Clotrimazole USP 1% (50mg in each applicatorful)

Clotrimazole USP 1% (external cream) See manufacturer's label for full list of ingredients

Product #: R0254045

Clotrimazole 1%

Lot: 00000 NDC: 68071-2614-04  
MFR NDC: 61269-220-63 Exp.: 00-00  
Serial# 0000000002

Clotrimazole 1%

Lot: 00000 NDC: 68071-2614-04  
MFR NDC: 61269-220-63 Exp.: 00-00  
Serial# 0000000002



GTIN 00368071261448  
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.

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H2-Pharma, LLC Montgomery, AL 36117  
Packaged By:  
NuCare Pharmaceuticals, Inc.  
Orange, CA 92867

Use only as directed by your physician.  
Patient Instructions

88071261404\*1.59-00000-00000

Rev 01/01/19

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 68-77°F.

**CLOTRIMAZOLE**

clotrimazole cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68071-2614(NDC:61269-220)
<b>Route of Administration</b>	VAGINAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

**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:68071-2614-4	1 in 1 CARTON	01/07/2022	
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	ANDA074165	06/29/2021	

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

## Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-2614)

Revised: 1/2022

NuCare Pharmaceuticals, Inc.