# CLOTRIMAZOLE- clotrimazole cream NuCare Pharmaceuticals, Inc.

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Clotrimazole Vaginal Cream, USP

#### **Drug Facts**

#### Active ingredients

Clotrimazole, USP 1% (50 mg in each applicatorful)

#### Active ingredients

Clotrimazole, USP 1% (external cream)

#### **Purpose**

Vaginal antifungal

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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

- store at room temperature between 2° and 30°C (36° to 86°F)
- see end flaps of carton and tube for lot number and expiration date
- **Tamper-evident: Safety sealed:** the tube opening should be sealed. If seal has been punctured or is not visible, do not use the product.

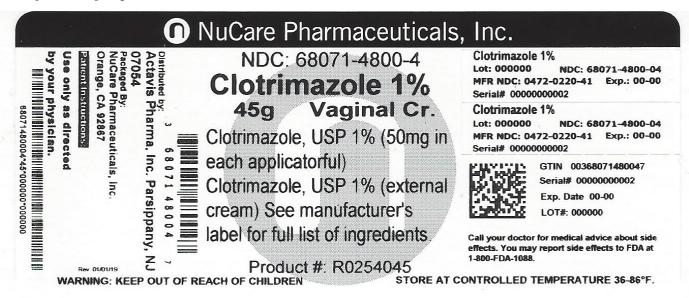
# Inactive ingredients

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

#### **Questions?**

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

#### **Principal Display Panel**



#### **CLOTRIMAZOLE**

clotrimazole cream

Product	Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68071-4800(NDC:0472-0220)

Route of Administration VAGINAL

# **Active Ingredient/Active Moiety**

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

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Ingredient Name	Strength			
BENZYL ALCOHOL (UNII: LKG8494WBH)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				

CETYL ESTERS WAX (UNII: D072FFP9GU)
OCTYLDODECANOL (UNII: 461N10614Y)
POLYSORBATE 60 (UNII: CAL22UVI4M)

WATER (UNII: 059QF0KO0R)

**Inactive Ingredients** 

SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)

SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:68071- 4800-4	45 g in 1 BOX; Type 0: Not a Combination Product	03/12/2019	

Marketing I	Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
ANDA	ANDA074165	07/01/2003					

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

Establishment							
Name	Address	ID/FEI	<b>Business Operations</b>				
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-4800)				

Revised: 2/2021 NuCare Pharmaceuticals,Inc.