

CLOTRIMAZOLE- clotrimazole cream
NuCare Pharmaceuticals, Inc.

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

 **NuCare Pharmaceuticals, Inc.**

NDC: 68071-4800-4
**Clotrimazole 1%
45g 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: 000000 NDC: 68071-4800-04
MFR NDC: 0472-0220-41 Exp.: 00-00
Serial# 00000000002
Clotrimazole 1%
Lot: 000000 NDC: 68071-4800-04
MFR NDC: 0472-0220-41 Exp.: 00-00
Serial# 00000000002
GTIN 00368071480047
Serial# 000000000002
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.

**Use only as directed
by your physician.**
Rev 01/01/19
Distributed by:
Actavis Pharma, Inc. Parsippany, NJ
07054
Packaged By:
NuCare Pharmaceuticals, Inc.
Orange, CA 92867
Patient Instructions:
680714800045-000000-000000

WARNING: KEEP OUT OF REACH OF CHILDREN
STORE AT CONTROLLED TEMPERATURE 36-86°F.

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	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)	

Packaging

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

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	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-4800)

Revised: 2/2021

NuCare Pharmaceuticals,Inc.