

**CLOTRIMAZOLE- clotrimazole cream**  
**Actavis Pharma, 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

***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

**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**

Actavis

NDC 0472-0220-63

Compare to the active ingredient  
in Gyne-Lotrimin® Vaginal Cream\*

Clotrimazole  
Vaginal Cream, USP 1%

Vaginal Antifungal

Cures Most Vaginal Yeast Infections  
 1 Reusable Applicator (7-Day Therapy)  
 7-Day Treatment

One 45 g (1.5 OZ) Tube of Vaginal Cream (1%) and  
 1 Reusable Applicator (7-Day Therapy)

Educational Pamphlet Enclosed

**Drug Facts**

**Active Ingredients**  
 Clotrimazole, USP 1% (external cream) ..... Vaginal antifungal

**Purpose**  
 Stop use and ask a doctor if symptoms do not get better in 3 days.

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

**Directions**  
 Before using this product, read the enclosed educational brochure for complete directions and information.

**Other Information**  
 Tamper-evident: Safety sealed: The tube opening should be sealed. If seal has been punctured or is not visible, do not use the product.

**Drug Facts (continued)**

**Uses** • Treats vaginal yeast infections 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 that-smelling vaginal discharge. You may have a more serious condition.
- vaginal yeast infections often (such as once a month) for 3 to 6 months. You could be pregnant or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system.

**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 disease (STD).
- do not have vaginal intercourse.
- if you do not get complete relief, ask a doctor before using another product.



Actual Size



NDC 0472-0220-63

Compare to the active ingredient  
 in Gyne-Lotrimin® Vaginal Cream\*

# Clotrimazole

Vaginal Cream, USP 1%

## Vaginal Antifungal

Cures Most Vaginal Yeast Infections

1 Reusable Applicator (7-Day Therapy) 7-Day Treatment

Made in India Code: GO/DRUGS/361

Distributed by: Actavis Pharma, Inc.  
 Parsippany, NJ 07054 USA

02200115 R0115  
 A4E3A/00

One 45 g (1.5 OZ) Tube of Vaginal Cream (1%) and  
 1 Reusable Applicator (7-Day Therapy)

Educational Pamphlet Enclosed

**Drug Facts (continued)**

**Inactive Ingredients**  
 benzyl alcohol, octodecyl alcohol, octyl esters wax, 2-ethylhexanoic acid, purified water, sodium phosphate monobasic, sorbitan monostearate

**Questions?** 1-800-432-8334 between 9 am and 4 pm EST, Monday-Friday.

This product is not affiliated with, manufactured by, or produced by the makers or owners of Gyne-Lotrimin®.



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clotrimazole cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0472-0220
<b>Route of Administration</b>	VAGINAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
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:0472-0220-63	1 in 1 CARTON	07/01/2003	
1		45 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0472-0220-41	1 in 1 CARTON	07/01/2003	
2		45 g in 1 TUBE; 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	ANDA074165	07/01/2003	

**Labeler** - Actavis Pharma, Inc. (119723554)

Revised: 11/2019

Actavis Pharma, Inc.