

**CLOTRIMAZOLE- clotrimazole cream  
QUALITY CHOICE (Chain Drug Marketing Association)**

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**Clotrimazole Vaginal Cream, USP**

***Drug Facts***

***Active ingredients***

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

Clotrimazole USP, 1% (external cream)

***Purpose***

Vaginal antifungal

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)
- before using any medication, read all label directions. Keep carton, it contain important information.

### ***Inactive ingredients***

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

### ***Questions?***

Call 1-800-935-2362 Monday-Friday 9AM-5PM EST

**Principal display panel**

Educational Pamphlet Enclosed

7-Day Treatment

Clotrimazole

Vaginal Cream USP, 1%

**Vaginal Antifungal**

**Clotrimazole Vaginal Cream Can Kill The Yeast That May Cause Vaginal Infection**

**Cures Most Vaginal Yeast Infections**

One 45g (1.59 OZ) Tube of Vaginal Cream (1%) and 1 Reusable Applicator (7-Day Therapy)

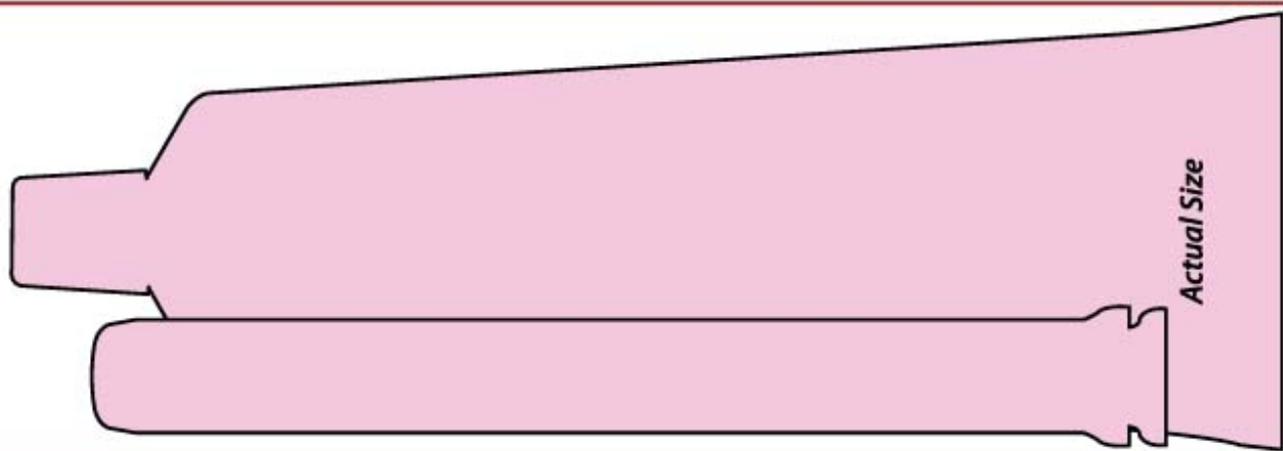
Distributed by CDMA, Inc.

Novi, MI 48375

[www.qualitychoice.com](http://www.qualitychoice.com)

**Package label**

<p><b>Drug Facts</b></p> <p><b>Active ingredients</b> Clotrimazole, USP 1% (external cream)..... Vaginal antifungal Vaginal antifungal</p>	<p><b>Drug Facts</b></p> <p><b>Uses</b> ■ treats vaginal yeast infections ■ relieves external itching and irritation due to a vaginal yeast infection</p>
<p><b>Warnings</b></p> <p>Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.</p> <p>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</p>	<p><b>When using this product</b> ■ do not use tampons, douches, spermicides, or other vaginal products. Conditions 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. ■ if you do not get better in 3 days ■ symptoms do not get better in 7 days ■ you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or a foul-smelling vaginal discharge</p>
<p><b>Directions</b> ■ 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.</p>	<p><b>Other information</b> ■ 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) ■ before using any medication, read all label directions. Keep carton, it contains important information.</p>
<p><b>Inactive ingredients</b> benzyl alcohol, cetylalcohol, cetostearyl alcohol, cetyl esters wax, 2-octyldodecano, polyacrylate 60, purified water, sodium phosphate monobasic, sorbitan monostearate</p>	<p><b>Questions?</b> Call 1-800-935-2362 Monday-Friday 9AM-5PM EST</p>
<p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p>	<p><b>Questions?</b> Call 1-800-935-2362 Monday-Friday 9AM-5PM EST</p>
<p><b>Drug Facts (continued)</b></p>	



NDC 63868-259-15



Educational Pamphlet Enclosed

7-Day Treatment

# Clotrimazole

Vaginal Cream USP, 1%

## Vaginal Antifungal

Clotrimazole Vaginal Cream Can Kill The Yeast That May Cause Vaginal Infection  
Cures Most Vaginal Yeast Infections

One **45g** (1.59 OZ) Tube of Vaginal Cream (1%) and 1 Reusable Applicator (**7-Day Therapy**)



Distributed by CDMA, Inc.  
Novi, MI 48375  
www.qualitychoice.com



PLD-C713B F0308245



Code: GO/DRUGS/361 AAD3B/03

**QUALITY CHOICE Vaginal Antifungal Cream**

**CLOTRIMAZOLE**

clotrimazole cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-259
<b>Route of Administration</b>	VAGINAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-259-15	1 in 1 CARTON	10/15/2014	
1		45 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
ANDA	ANDA074165	10/15/2014	

**Labeler** - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 9/2022

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