

**CLOTRIMAZOLE- clotrimazole cream**  
**Central Texas Community Health Centers**

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**Clotrimazole Vaginal Cream**

***Drug Facts***

***Active ingredients***

Clotrimazole 1% (50 mg in each applicatorful)

Clotrimazole 1% (external cream)

***Purpose***

Vaginal antifungal

Vaginal antifungal

***Uses***

- treats vaginal yeast infections
- relieves external itching and irritation associated 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 - 28 g Tube Label**

**Austin's Health & Human Services Dept.**

**Clotrimazole**

**1%**

**TOPICAL**

**Cream**

**Date:**

**Name:**

**Dr.**

**USE AS DIRECTED.**

**123456**

**1/1/01**

**Clotrimazole 1% TOPICAL Cream 30g NDC 76413-327-30**

**Batch: 123456**

**Lot: 123456**

Exp: 1/1/01  
PERRIGO

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

**Austin's Health & Human Services Dept.**

**Clotrimazole  
1%  
TOPICAL  
Cream**

**Date:**

**Name:**

**Dr.**

**USE AS DIRECTED.**

**USAR COMO INDICADO.**

**123456**

**1/1/01**

**Clotrimazole 1% TOPICAL Cream 30g NDC 76413-327-30**

**Batch: 123458**

**Lot: 123458**

**Exp: 1/1/01**

**PERRIGO**

*Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.*

**CLOTRIMAZOLE**

clotrimazole cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76413-327(NDC:45802-434)
<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	1 g in 100 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: 059QF0K00R)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	

SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-327-30	1 in 1 CARTON	08/12/2003	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074165	08/12/2003	

**Labeler** - Central Texas Community Health Centers (079674019)

### Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-327) , RELABEL(76413-327)

Revised: 11/2016

Central Texas Community Health Centers