

CLOTRIMAZOLE- clotrimazole cream
Central Texas Community Health Centers

Clotrimazole

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Clotrimazole USP 1% (50 mg in each applicatorful)	Vaginal Antifungal
Clotrimazole USP 1% (external cream)	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 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: unscrew cap, use pointed end on cap to puncture seal
- do not use if carton is opened
- **safety sealed: the tube opening should be sealed. If the seal has been punctured or is not visible, do not use the product.**
- store between 20° to 25°C (68° to 77°F)
- see flap of carton or crimp of tube for lot number and expiration date

Inactive ingredients

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

Questions or comments?

call toll-free, **1-888-827-6222**, for our 24 hour automated response system.

Distributed by:

Taro Pharmaceuticals

U.S.A., Inc.

Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 45 gm Tube Label

CommUnityCare Federally Qualified Health Centers

Clotrim

VAGINAL

1%45gm

W/APL.

Date:

Name:

Dr.

USE AS DIRECTED.

123456

1/1/01

Clotrimazole VAG.Crm1% 45 gm W/ Apl.NDC 76413-305-45

Batch: 123456

Lot: 123456

Exp: 1/1/01

Taro

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

CommUnityCare Federally Qualified Health Centers

Clotrim
VAGINAL
1%45gm
W/APL.

Date:

Name:

Dr.

USE AS DIRECTED.

USAR COMO INDICADO.

123456

1/1/01

Clotrimazole VAG.Crm1% 45 gm W/ Apl.NDC 76413-305-45

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CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76413-305(NDC:51672-2003)
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Clotrimazole (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65)	Clotrimazole	1 g in 100 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: 059QF0K00R)	
sorbitan monostearate (UNII: NVZ4I0H58X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-305-45	1 in 1 CARTON		
1		45 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	ANDA072641	12/04/1995		

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-305) , RELABEL(76413-305)

Revised: 3/2016

Central Texas Community Health Centers