

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

Clotrimazole Vaginal Cream, USP

Drug Facts

Active ingredient

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 external 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 or comments?

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

Principal display panel

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

g (OZ) Tube

Tube of Vaginal Cream (1%) and 1 Reusable Applicator

Distributed by: CDMA, Inc.

Novi, MI 48375

Package label

Drug Facts (continued)

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 contains important information.

Inactive ingredients benzyl alcohol, cetearyl alcohol, cetyl esters wax, 2-octyldodecanol, polyorbene 60, purified water, sodium phosphate monobasic, sorbitan monostearate

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

Drug Facts

Active ingredients Clotrimazole, USP 1% (50 mg in each applicator)
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.

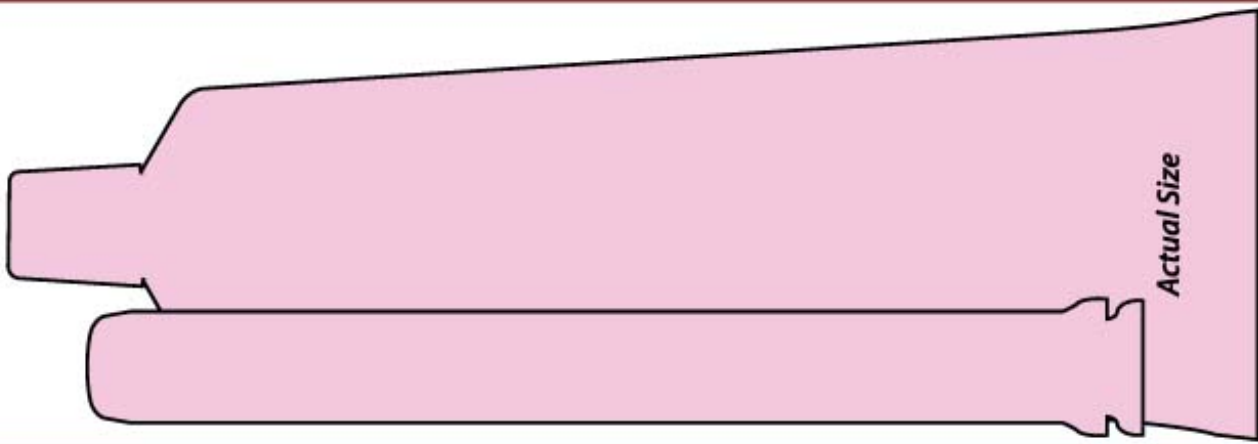
Ask a doctor before use if you have

- 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



NDC 83324-154-15



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
Questions: 800-935-2362



Code: G0/DRUGS/361 AAD3B/04

QUALITY CHOICE Vaginal Antifungal

CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83324-154
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:83324-154-15	1 in 1 CARTON	07/31/2024	
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

ANDA074165

07/31/2024

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

Revised: 5/2024

QUALITY CHOICE (Chain Drug Marketing Association)