

CLOTRIMAZOLE- clotrimazole cream
Chain Drug Consortium, LLC

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

- to open tube: unscrew cap, lift tab, and pull o 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 between 20°to25°C(68°to77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°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-**877-753-3935** Monday-Friday 9AM-5PM EST

Principal display panel

Clotrimazole

Vaginal Cream, USP 1%

Vaginal Antifungal (with 1 Reusable Applicator

7-Day Treatment

Cures most vaginal yeast infections

One 1.59 oz (45 g) Tube of Vaginal Cream (1%)
and 1 reusable plastic applicator (7-Day Therapy)

Distributed by:

Pharmacy Value Alliance, LLC

407 East Lancaster Avenue,

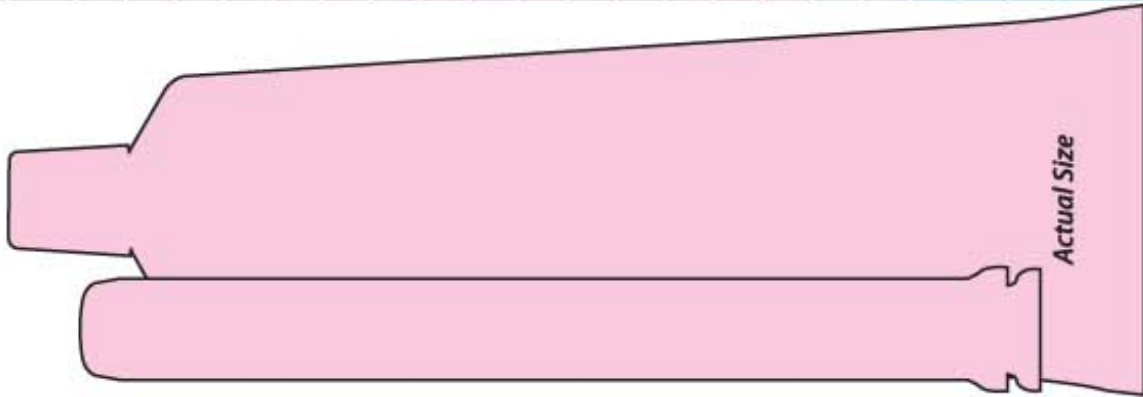
Wayne, Pa 19087

Package label



Clotrimazole

Vaginal Cream, USP 1%
Vaginal Antifungal (with 1 Reusable Applicator)



Educational Pamphlet Enclosed



Clotrimazole

Vaginal Cream, USP 1%
Vaginal Antifungal (with 1 Reusable Applicator)

7-Day Treatment
Cures most vaginal yeast infections



One 1.59 oz (45 g) Tube of Vaginal Cream (1%)
and 1 reusable plastic applicator (7-Day Therapy)



If for any reason you are not satisfied with
this product, please return it to the store
where purchased for a full refund.

Distributed by:
Pharmacy Value Alliance, LLC
407 East Lancaster Avenue,
Wayne, PA 19087

Code: GD/DRUGS/361 AAC3A/02 PLD-B713A FC007315



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Drug Facts		Drug Facts	
Active ingredients Clotrimazole, USP 1% (50 mg in each applicator).....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 abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or four-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.		Other information ● 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) (see USP Controlled Room Temperature) excursions permitted to 15°-30°C (59°-86°F) ● before using any medication, read all label directions. Keep carton, it contains important information.	
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 applicator 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.		Questions? Call 1-877-753-3835 Monday-Friday 9AM-5PM EST	
Drug Facts (continued) 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.		Inactive ingredients benzyl alcohol, cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sodium phosphate monobasic, sorbitan monostearate	

PREMIER VALUE Vaginal Cream with Reusable Applicator

CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-414
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: NVZ410H58X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-414-00	1 in 1 CARTON	10/09/2013	
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	10/09/2013	

Labeler - Chain Drug Consortium, LLC (101668460)**Registrant** - P & L Development, LLC (079765031)

Revised: 10/2023

Chain Drug Consortium, LLC