

CLOTRIMAZOLE- clotrimazole cream
Taro Pharmaceuticals U.S.A., Inc.

Clotrimazole

Drug Facts

Active ingredients	Purpose
Clotrimazole USP 2% (100 mg in each applicatorful)	Vaginal Antifungal
Clotrimazole USP 2% (external cream)	Vaginal Antifungal

Use

- 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 3 days in a row. Throw applicator away after 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

EDUCATIONAL BROCHURE

Read This Before Using

Clotrimazole Vaginal Cream USP (2%)

Vaginal Antifungal

Clotrimazole USP 2% (100 mg in each applicatorful).

3-day treatment of vaginal yeast infections.

Uses:

- For the treatment of vaginal yeast infections.
- Relieves external itching and irritation due to a vaginal yeast infection.

If you have symptoms such as vaginal itching, burning, or discharge, and if at some time in the past your doctor has told you that these symptoms were due to a vaginal yeast infection, then Clotrimazole Vaginal Cream should work for you. **If, however, you have never had these symptoms or a vaginal yeast infection before, you should see your doctor before using this product.**

What is a Vaginal Yeast Infection?

A yeast infection is a common type of vaginal infection. Your doctor may call it candidiasis. This condition is caused by an organism called Candida, which is a type of yeast. Healthy women usually have this yeast on the skin, in the mouth, in the digestive tract, and in the vagina. At times, the yeast can grow very quickly. In fact, the infection is sometimes called yeast (*Candida*) "overgrowth." Some

women may have a yeast infection on the skin outside the vagina (vulva) associated with the vaginal infection.

A yeast infection can occur at any age. It is most common during the childbearing years. Women who are pregnant or diabetic, taking antibiotics, birth control pills or steroids, or who have a weakened immune system are more likely to get repeated yeast infections.

Various medical conditions can damage the body's normal defenses against infection.

One of the most serious of these conditions is infection with the human immuno-deficiency virus (HIV-the virus that causes AIDS). The HIV virus causes the body to be more likely to get infections, including vaginal yeast infections. Therefore, women with HIV infection may have frequent vaginal yeast infections that do not clear up easily with proper treatment. If you may have been exposed to HIV and are experiencing repeated vaginal yeast infections, you should see your doctor right away. For additional information on HIV infection, please contact your doctor or the CDC National AIDS HOT-LINE. The CDC phone numbers are: 1-800-CDC-INFO (1-800-232-4636) for English or Spanish or 1-888-232-6348 (hearing impaired, TDD/TTY).

Symptoms of a Vaginal Yeast Infection

There are many symptoms of a vaginal yeast infection. They can include:

- Vaginal itching (ranging from mild to severe).
- A clumpy, vaginal discharge that may look like cottage cheese.
- Vaginal soreness, irritation, or burning.
- Rash or redness on the skin outside the vagina (vulvar irritation).

Note: Vaginal discharge that is different from above, for example, a yellow/green discharge or a foul-smelling discharge may mean that you have a different infection. If this is the case, you should talk to your doctor before using Clotrimazole Vaginal Cream.

For Best Results

1. Be sure to use this product for the full 3 days, even if your symptoms go away sooner.
2. Use one applicatorful of Clotrimazole Vaginal Cream at bedtime for three days in a row, even during your menstrual period.
3. Wear cotton underwear.
4. If your partner has itching, redness or discomfort of his penis, he should consult his doctor. He should tell the doctor that you are treating yourself for a vaginal yeast infection.
5. Dry the outside vaginal area thoroughly after a shower, bath or swim. Change out of a wet bathing suit or damp clothes as soon as possible. A dry area is less likely to lead to the growth of yeast.
6. Wipe from front to rear after a bowel movement or urination.
7. Do not douche unless your doctor tells you to do so. Douching may wash the product out of the vagina.
8. Try not to scratch the skin outside the vagina. Scratching can cause more irritation and can spread the infection.
9. Discuss with your doctor any drugs you are now taking. You are more likely to get a vaginal yeast infection with certain drugs.
10. Do not have vaginal intercourse while using this product.
11. When using this product, condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs).

If you have a Question

Questions of a medical nature should be taken up with your doctor. **If you have any other questions or need information on this product call toll free 1-866-923-4914.**

Active Ingredient:

Clotrimazole USP, 2% (100 mg in each applicatorful)

Clotrimazole USP, 2% (external cream)

Inactive Ingredients:

Benzyl alcohol, cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sorbitan monostearate.

Storage

Store between 20° to 25°C (68° to 77°F).

See end panel of carton and end of tube for lot number and expiration date.

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**
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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Safety sealed: the tube opening should be sealed. If the seal has been punctured or is not visible, do not use the product.

How to use Clotrimazole Vaginal Cream with 3 Disposable Applicators

Directions for Use

Use the cream at bedtime for 3 days in a row.

Read the full directions below before using.

1. To open the tube, unscrew the cap.



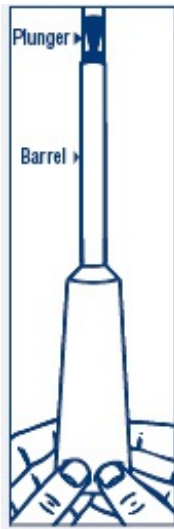
Press the sharp point of the cap into the sealed end of the tube. Push down firmly until the seal is broken. (see picture)



2. Attach the applicator to the tube of cream by placing end of the applicator firmly onto tube of cream. (see picture)



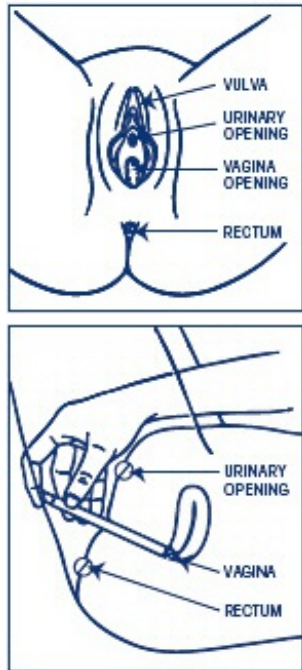
3. Gently squeeze opposite end of tube, forcing cream into barrel of applicator. The plunger will stop moving outward when the barrel is full. Separate the applicator from the tube. After each use, replace cap and roll up the tube from the bottom.



4. Hold the barrel as shown in the picture.



5. The Clotrimazole Vaginal Cream applicator is inserted into the vagina in much the same way as a tampon. Gently insert the applicator into the vagina as far back as it will go comfortably. This can be done while lying on your back with your knees bent (as shown in the picture), or while standing with your feet apart and your knees bent.



6. With one hand holding the barrel, use the other hand to push the plunger into the barrel as far as it will go. Remove the applicator from the vagina.

7. Throw the applicator away after each use. Do not flush down the toilet.

8. Lie down as soon as possible to keep the cream from leaking out.

9. Repeat steps 2 through 8 before bedtime for the next 2 days.

To protect your clothing from leakage or discharge, you may want to use deodorant-free pads or panty shields while you are using Clotrimazole Vaginal Cream. **Do not use tampons, douches, or spermicides or other vaginal products** until after you have completed the treatment and your symptoms are gone.

Mfd. by: **Taro Pharmaceuticals Inc.**
Brampton, Ontario, Canada L6T 1C1

LPK-3251-4
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161

PRINCIPAL DISPLAY PANEL - 21 g Tube Carton

Cures Most Vaginal Yeast Infections

3 Day Treatment

3 Day Vaginal Cream

Clotrimazole Vaginal Cream USP (2%)

Vaginal Antifungal

**One 21 g (0.74 oz) Tube Of Clotrimazole Vaginal Cream USP (2%)
& 3 Disposable Applicators**

Educational Brochure Enclosed

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2062
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Clotrimazole (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65)	Clotrimazole	2 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:51672-2062-0	1 in 1 CARTON	04/12/2000	
1		21 g in 1 TUBE, WITH APPLICATOR; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021143	04/12/2000	

Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2062)