

Gyne-Lotrimin[®] 7-Day Treatment
Clotriazole Vaginal Cream (1%)
 Vaginal Antifungal

Cures most vaginal yeast infections

Vaginal Cream

Drug Facts

Active ingredients

Clotriazole 1% (50 mg in each applicatorful)
 - Clotriazole 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 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

Gyne-Lotrimin[®] 7 Antifungal Vaginal Cream can kill the yeast that may cause vaginal infection. It is greaseless and does not stain clothes.

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Drug Facts (continued)

Other information

- store between 20° to 25°C (68° to 77°F)
- see end panel of carton and tube crimp for lot number and expiration date
- tamper-evident: do not use if seal embossed with "S" over tube opening is missing, open or broken

Inactive ingredients

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

Questions or comments?

If you have questions or need more information on this product, call toll free 1-800-317-2165 between 8:00 AM and 5:00 PM Central Standard Time, Monday through Friday.



(b) (4) Cures print

Gyne-Lotrimin[®] 7-Day Treatment
 Clotriazole Vaginal Cream (1%)
 Vaginal Antifungal

Vaginal Cream

Cures most vaginal yeast infections

ONE 45g (1.5 oz) TUBE OF VAGINAL CREAM (1%) AND APPLICATOR (7-Day Therapy)

EDUCATIONAL PAMPHLET ENCLOSED

Gyne-Lotrimin[®] 7-Day Treatment
 Clotriazole Vaginal Cream (1%)
 Vaginal Antifungal

Vaginal Cream

Cures most vaginal yeast infections

Gyne-Lotrimin[®] 7-Day Treatment
 Clotriazole Vaginal Cream (1%)
 Vaginal Antifungal

Vaginal Cream

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**EDUCATIONAL
BROCHURE**
Read This
Before Using

Gyne-Lotrimin⁷

Clotrimazole
Vaginal Cream USP, 1%
Antifungal

FOR TREATMENT OF
VAGINAL YEAST (*CANDIDA*)
INFECTION and the RELIEF
OF ASSOCIATED
EXTERNAL VULVAR
ITCHING AND IRRITATION.

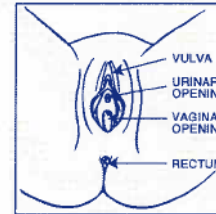


LPK 4011-2 0508-1 267
24483-03

**1 How To Recognize A
Recurrent Yeast
Infection of the Vaginal
and Vulvar Area**

Gyne-Lotrimin⁷ will cure most vaginal yeast (*Candida*) infections. But not every vaginal infection is caused by yeast. If this is the first time you are experiencing vaginal itch and discomfort or if you are experiencing external vulvar itch, it is important to visit your doctor to be sure that yeast is the problem. Do not use if you have abdominal pain, fever, or foul-smelling vaginal discharge. You may have a condition more serious than a yeast infection, and you should see your doctor immediately.

The main symptom of a vaginal yeast infection is itching which can be moderate to intense. The itching is usually in the folds of the vagina and on the external skin (vulva) around the vagina.



Yeast infection may also cause a white discharge from the vagina. The discharge may be thick like paste or lumpy like cottage cheese. The irritated skin of the vulva may be swollen, cracked and red, or may have small red sore spots. The vagina may also feel sore inside or have a burning sensation, particularly during vaginal intercourse.

If you have one or more of these symptoms, especially

in the days before your period, you could have a vaginal yeast infection.

2 Gyne-Lotrimin 7 can kill the yeast that causes the infection.

To cure vaginal yeast infection, it is necessary to eliminate the yeast cells. Gyne-Lotrimin 7 does more than just relieve itching. It can kill the yeast that cause vaginal yeast infections and can relieve the associated itching and burning.

3 How To Use
WARNING: Do not take by mouth or use in the eyes, for vaginal use only.
Directions: Fill the applicator with the cream and then insert one applicatorful of cream into the vagina every day, preferably at bedtime. Repeat this procedure daily for seven consecutive days.



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AP0 #: P0387-09
10.09.09

TBD Gyne-Lotrimin 7 day cream 45g insert (1.5 oz) 12" X

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COLORS...



OUTPUT
SPECIFICATIONS.
Illustrator CS3


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Item Code	Date	Artist	Nature of Revisions
24483-03	10.09.09	(b) (4)	PU 041675 for die and elements; Update Drug F

For relief of external vulvar itching, squeeze a small amount of cream onto your finger and gently spread the cream onto the irritated area of the vulva. Use once or twice a day for up to 7 days as needed to relieve external vulvar itching. **THE CREAM SHOULD NOT BE USED FOR VULVAR ITCHING DUE TO CAUSES OTHER THAN A YEAST INFECTION.**



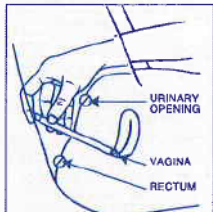
Important:
 In order to kill the yeast completely, you must use Gyne-Lotrimin 7 the full seven days as instructed above, even if your symptoms are relieved sooner.

To load the applicator:



Remove cap from tube of cream. Screw open end of applicator onto tube of cream. Gently squeeze opposite end of tube, forcing cream into barrel of applicator. The plunger will stop moving outward when the barrel contains the proper amount of cream. When the barrel is full, unscrew applicator from tube. After each use, replace cap and roll up the tube from the bottom.

To insert the vaginal cream:



Lie on your back with knees bent. Insert the open end of the filled applicator into the vagina as deeply as it will go comfortably. Holding the applicator in place with thumb and middle finger, press the plunger until it stops. Withdraw the applicator. **IMPORTANT: Insert one applicatorful of Gyne-Lotrimin 7 cream each day for the full 7 days.**

Care of the applicator:
 After use, pull the plunger all

the way out of the barrel. Wash both parts of the applicator in warm (not boiling), soapy water. Rinse thoroughly and dry. To reassemble, gently push the plunger back into the barrel as far as it will go.

Gyne-Lotrimin 7 usually starts to relieve itching and other symptoms within 3 days. If you do not improve in 3 days or if you do not get well in 7 days, you may have a condition other than a vaginal yeast infection. Discontinue use of the product and consult your doctor. Also, if symptoms recur within a 2-month period, contact your doctor.

During your period, continue to use Gyne-Lotrimin 7. Its action is not affected by menstruation. However, do not use tampons while the medicine is in use. Sanitary napkins may be used instead.

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PIF: OTC081116002 Item Code: 24483-03 (b) (4) Item Number: LPK-4011-2 Pharma Code: 267 ID Code: NA Comments: Same template as Item 24483-02 Printer: (b) (4)	<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"><input type="checkbox"/> Verify UPC (if applicable)</div> <div style="text-align: center;"><input type="checkbox"/> Verify SP PDF</div> <div style="text-align: center;"><input type="checkbox"/> Verify Illustrator Version</div> </div> Proofread: _____ Date: _____
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Gyne-Lotrimin 7 may reduce the effectiveness of some methods of birth control. Condoms, diaphragms, or vaginal spermicide may be so affected.

4 Are There Reasons You Get Vaginal Yeast Infections and Vulvar Irritation?

The vagina normally has a mixture of two kinds of germs called bacteria and yeast. Under certain conditions, the yeast in the vagina can grow too much—causing vaginal itching, vulvar irritation, and often, a discharge. In some women, the conditions that allow the yeast to multiply can include the use of certain birth control pills, routine hormonal changes, or taking antibiotics. Pregnancy and diabetes are two other important

conditions that can lead to vaginal yeast infections. In women with frequently recurrent vaginal yeast infections, especially infections that don't clear up easily with proper treatment, the vaginal yeast infections may also be the result of serious medical conditions, including infection with HIV (the virus that causes AIDS), that can damage the body's normal defenses against infection.

Hormonal changes are sometimes the cause. Hormonal changes can cause some women to be prone to yeast infections. Some women get vaginal yeast infections during pregnancy, while taking certain birth control pills, or every month just before their period.

Antibiotics are sometimes the cause.

Killing the normal bacteria of the vagina may allow yeast to multiply. That is why women taking antibiotics are more likely to get vaginal yeast infections.

Damage to the body's normal defenses against infection is sometimes the cause.

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 immunodeficiency virus (HIV - the virus that causes AIDS). Infection with HIV causes the body to be more susceptible to infections, including vaginal yeast infections. Women with HIV infection may have frequent vaginal yeast infections or, especially, vaginal yeast infections that do not clear up easily with proper treatment. If you may have been

exposed to HIV and are experiencing either frequently recurring vaginal yeast infections or, especially, vaginal yeast infections that do not clear up easily with proper treatment, you should see your doctor promptly. If you wish further information on risk factors for HIV infection or on the relationship between recurrent or persistent vaginal yeast infections and HIV infection, please contact your doctor, or the CDC National AIDS HOTLINE at 1-800-CDC-INFO (1-800-232-4636) for English or Spanish or 1-888-232-6348 (hearing impaired, TDD/TTY). **IF YOU EXPERIENCE FREQUENT YEAST INFECTIONS (THEY RECUR WITHIN A TWO MONTH PERIOD) OR IF YOU HAVE VAGINAL YEAST INFECTIONS THAT DO NOT CLEAR UP EASILY WITH PROPER**

TREATMENT, YOU SHOULD SEE YOUR DOCTOR PROMPTLY TO DETERMINE THE CAUSE AND TO RECEIVE PROPER MEDICAL CARE.

Can yeast be transmitted sexually?

Men usually do not get or spread yeast infections through sexual intercourse. However, if a woman's yeast infections keep recurring, she should ask her partner to seek evaluation by a doctor.

Cotton underpants may help. Yeast flourish in a warm, moist environment. Since tight synthetic underpants and pantyhose can increase heat and moisture in the area of the vulva, it is probably better to wear cotton underpants if you are prone to vaginal yeast infections and vulvar irritation.

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).

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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.

Tamper-evidant: do not use if seal embossed with "S" over tube opening is missing, open or broken.

If you have questions about Gyne-Lotrimin 7 or vaginal yeast infections, contact your physician. If you have any other questions or need information on this product call toll free 1-800-317-2165.

Active Ingredient:
Clotrimazole 1%

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

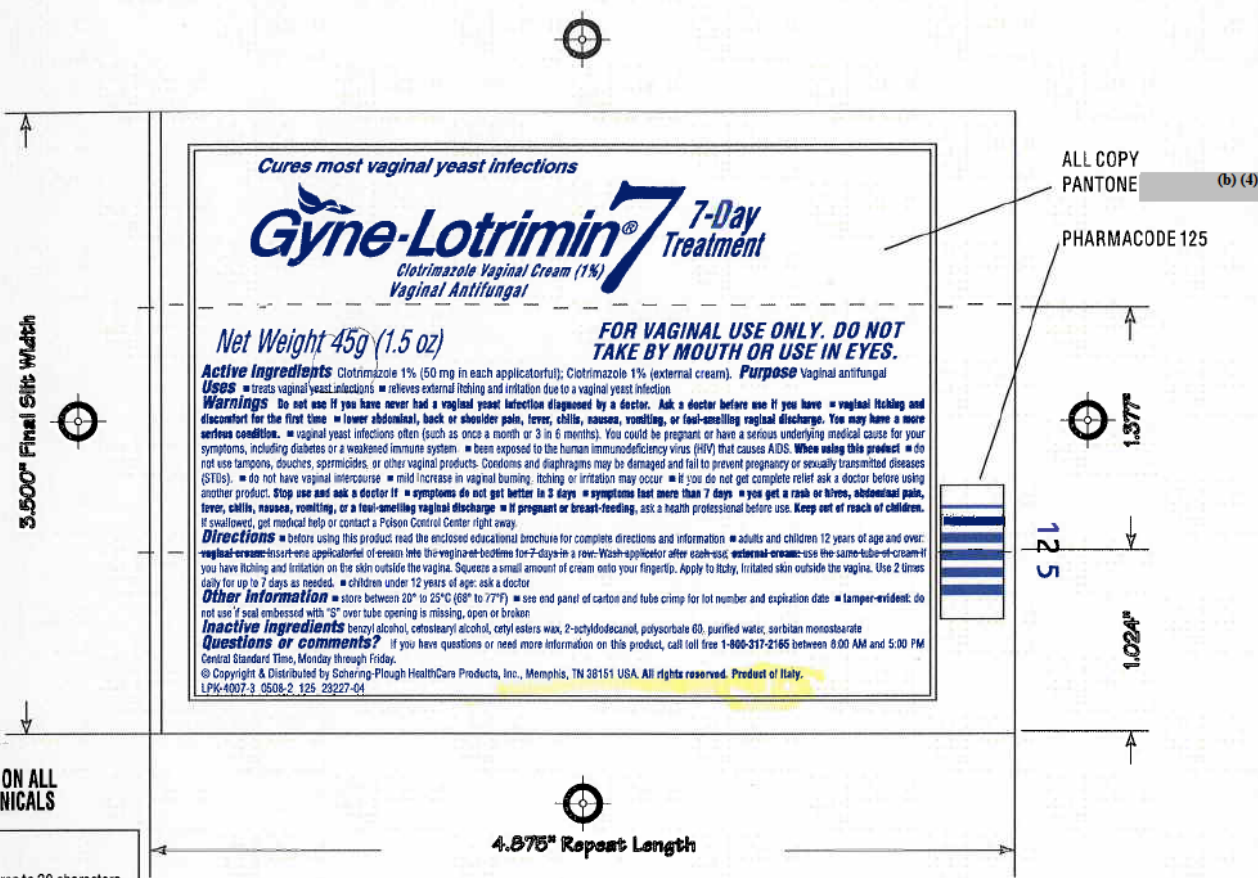
See end panel of carton and tube crimp for lot number and expiration date.

Store at 20° to 25°C (68° to 77°F).

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 PANTONE (b) (4)
 PHARMACODE 125

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Sub Heads - 5 pt Helvetica Cnd. Black
Text - 5 pt Helvetica Cnd, minimum leading 6
Square Bullets - 3.3 Zapf Dingbats no compression

AP0 #: P0386-09
 10.12.09

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- NDA-18052	----- SUPPL-32	----- SCHERING PLOUGH HEALTHCARE PRODUCTS INC	----- GYNE-LOTRIMIN

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/s/

JOEL SCHIFFENBAUER
04/12/2010