

# Guidance for Industry

## Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)

### *DRAFT GUIDANCE*

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Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

Copies of this draft guidance document are available from the Drug Information Branch, Division of Communications Management, HFD-210, 5600 Fishers Lane, Rockville, MD 20857, (Tel) 301-827-4573, or from the Internet at <http://www.fda.gov/cder/guidance/index.htm>. For questions on the content of the draft document contact Cheryl Turner, (301)827-2222.

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Labeling #

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## GUIDANCE FOR INDUSTRY<sup>1</sup>

### **Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)**

#### **I. INTRODUCTION**

Until 1990, topical drug products for the treatment of vulvovaginal candidiasis (VVC) were available by prescription only. In 1990, the U.S. Food and Drug Administration (FDA) convened an advisory committee meeting to obtain expert opinion whether the Agency should allow topical VVC therapies to be made available for over-the-counter (OTC) use. The advisory committee recommended that women whose initial episode of VVC was diagnosed and treated by a physician could adequately self-treat their condition *without* the supervision of a healthcare provider. The first seven-day intravaginal drug product for the treatment of VVC was approved for OTC use in 1990; the first three-day product in 1995; and the first single-dose product in 1997.

On February 27, 1997, the Agency published a notice in the Federal Register (“Over-the-Counter Human Drugs; Proposed Labeling Requirements; Proposed Rule” (62 FR 9024) proposing a standardized format for the labeling of OTC drug products. This proposed format is frequently referred to as the *Drug Facts Format*.

Current labeling for OTC VVC drug products varies widely among manufacturers. In the OTC setting, the Agency believes that labeling takes on the critical role of providing information to the consumer. Therefore, consumers must have information that is easily understood to allow for appropriate self-selection and appropriate use of the product. Since there are a variety of vaginal

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<sup>1</sup>This guidance has been prepared by the Division of OTC Drug Products and the Division of Special Pathogens and Immunologic Drug Products in the Center of Drug Evaluation and Research (CDER) at the Food and Drug Administration. This guidance document represents the Agency’s current thinking on class labeling for OTC vaginal antifungal drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable, statute, regulations, or both. Additional copies of this draft guidance document are available from the Drug Information Branch, HFD-210, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4573.

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antifungal products currently available OTC and, in most cases, the content to be communicated in labeling is nearly identical for each product, labeling for these products should convey a clear and consistent message to the consumer. The intent of this guidance document is to issue class labeling for OTC vaginal antifungal drug products.

OTC VVC drug product labeling consists of three components: (1) carton; (2) educational brochure; and (3) overwrap. This guidance provides labeling guidance for both the carton and the educational brochure. In developing this guidance, the Agency has drafted proposed labeling in accordance with the Drug Facts Format. Where differences exist from product to product that are substantial enough to warrant unique labeling, these differences should also be clearly communicated to the consumer. Such *product-specific deviations* should be supported by adequate data and discussed with the Agency as it pertains to the specific product.

II. CARTON LABEL

<b>Fungistat-X</b>	
<b>Active ingredient (in each _____)</b> Fungizole X% (X00 mg)	<b>Purpose</b> Vaginal Antifungal
<b>Uses</b> See your doctor if this is the first time you have vaginal itching and discomfort to find out if you have a vaginal yeast infection. <ul style="list-style-type: none"><li>. To treat repeat vaginal yeast infections</li><li>. To relieve external itching and irritation due to a repeat vaginal yeast infection</li></ul>	
<b>Warnings</b> For vaginal use only <i>Fungistat-X</i> may damage condoms and diaphragms and cause them to fail.	
<b>Ask a doctor before use if you</b> <ul style="list-style-type: none"><li>. have 1 or more of the following: abdominal pain, fever, chills, nausea, vomiting, foul-smelling discharge</li><li>. get vaginal yeast infections often (such as once a month or three in 6 months)</li><li>. may have been exposed to the human immuno-deficiency virus (HIV) that causes AIDS</li><li>. are under 12 years of age</li></ul>	
<b>When using this product</b> <ul style="list-style-type: none"><li>. do not use tampons, douches, spermicides, or other vaginal products</li><li>. do not have vaginal intercourse</li></ul>	
<b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"><li>. symptoms do not improve in 3 days</li><li>. symptoms remain after 7 days</li><li>. you get abdominal pain, fever, chills, nausea, vomiting, foul-smelling discharge, or hives</li></ul>	
<b>If pregnant or breast-feeding</b> , ask a health professional before use. <b>Keep out of the reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> Before using <i>Fungistat-X</i> read the enclosed educational brochure for complete instructions and information. <ul style="list-style-type: none"><li>. Insert 1 _____ into the vagina at bedtime for X days in a row.</li></ul>	
<b>Other information</b> <ul style="list-style-type: none"><li>. Store at room temperature between 59-86 °F (15-30 °C). Avoid excessive heat and cold.</li></ul>	
<b>Inactive ingredients</b> xxx, xxxx, xxxxx	
If you have any questions about <i>Fungistat-X</i> , call toll-free, 1-800-XXX-XXXX during xx hours, EST	

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**III. PATIENT EDUCATIONAL BROCHURE**

The following 15 questions are examples of the kinds of information that should be provided in the patient educational brochure.

1. Why should I use Fungistat-X?
2. What is a vaginal yeast infection (Candidiasis)?
3. Who can get a vaginal yeast infection?
4. How can I tell that I have a vaginal yeast infection?
5. Why do women get repeated vaginal yeast infections?
6. Are vaginal yeast infections sexually transmitted?
7. How can I prevent vaginal yeast infections?
8. Can I use Fungistat-X during my menstrual period?
9. Can I use other vaginal products with Fungistat-X?
10. How can I get the best results when treating my infection?
11. What warnings should I know about when using Fungistat-X?
12. What side effects may occur with Fungistat-X?
13. How should I use Fungistat-X?
14. What should I do if I have questions about Fungistat-X?
15. Other Information

Recommended wording to answer these questions is provided in the following pages.

## **Why should I use Fungistat-X?**

Fungistat-X is for the treatment of vaginal yeast infections. 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 symptoms like these were due to a vaginal yeast infection, then Fungistat-X may work for you. ***If this is the first time you have vaginal itching and discomfort, you should see your doctor or health professional to find out what is the cause of your symptoms.***

## **What is a vaginal yeast infection (Candidiasis)?**

A vaginal yeast infection is a common condition caused by an overgrowth of yeast (*Candida*) that may normally live in the vagina. Your doctor may call this infection “monilia” or “candidiasis.” Some women may have a yeast infection on the skin outside the vagina (vulva) at the same time they have a vaginal infection.

## **Who can get a vaginal yeast infection?**

You can get a vaginal yeast infection 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 that may not clear up easily with proper treatment.

Some medical conditions can weaken the body’s normal ability to fight 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 that may not clear up easily with proper treatment. If you may have been exposed to HIV and get repeated vaginal yeast infections, you should see your doctor right away. For more information on HIV infection, please contact your doctor or the CDC National AIDS HOTLINE. The CDC phone numbers are: 1-800-342-AIDS (English), 1-800-344-7432 (Spanish), or 1-800-243-7889 (hearing impaired, TDD).

## **How can I tell that I have a vaginal yeast infection?**

When you have a vaginal yeast infection, you may have one or more of the following symptoms:

- vaginal itching
- discharge that may be thick, white, and lumpy like cottage cheese
- vaginal soreness, irritation, or burning

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- rash or redness on the skin outside the vagina (vulva)
- burning on urination
- painful vaginal intercourse (sex)

**Note:** Vaginal yeast infections do *not* cause fever, abdominal pain, or a foul-smelling vaginal discharge. If you have these symptoms, you should call your doctor right away.

### **Why do women get repeated vaginal yeast infections?**

Women may get repeated vaginal yeast infections that may not clear up easily with proper treatment. Listed below are some of the causes of repeated yeast infections:

- **hormonal changes** occurring a few days before the monthly period
- **use of antibiotics**
- **use of some birth control pills**
- **pregnancy**
- **diabetes (“sugar” or “high blood sugar”)**
- **clothing** - wearing many tight layers or moist clothing in the genital area
- **weakened immune system** - some drugs (such as chemotherapy or steroids) and medical conditions can weaken the body’s normal ability to fight infection. One of the most serious of these conditions is infection with the human immuno- deficiency virus (HIV- the virus that causes AIDS). Infection with HIV causes the person to be more likely to get infections, including vaginal yeast infections.

### **Are vaginal yeast infections sexually transmitted?**

Yeast infections are usually not spread by having vaginal intercourse (sex). However, if your partner has a rash, itching, or discomfort in his genital area, he should see a doctor. He should tell the doctor that you are treating your vaginal yeast infection with Fungistat-X.



## **How can I help prevent repeated vaginal yeast infections?**

To lower your chances of getting another yeast infection:

- **Talk with your doctor about any drugs you are now taking.** You are more likely to get a vaginal yeast infection if you are taking certain drugs, such as antibiotics, steroids, or birth control pills.
- **Try to keep the genital area cool and dry.** Yeast grow well in warm, moist areas. The following suggestions may be helpful:
  - (1) Wear cotton underwear and loose-fitting clothes.
  - (2) Change out of damp clothes or a wet bathing suit as soon as possible.
  - (3) If you use minipads when you are not having a menstrual period, change the minipads often.

## **Can I use Fungistat-X during my menstrual period?**

Yes, Fungistat-X can be used during your menstrual period. In fact, many women get vaginal yeast infections just before their period because of hormonal changes. Using Fungistat-X during your period will not affect how well this product works. Do not use tampons while using this product, because tampons may remove some of the Fungistat-X from the vagina. Use deodorant-free sanitary napkins or pads instead and change them often.

## **Can I use other vaginal products with Fungistat-X?**

This drug should **not** be used with other vaginal products.

- Douches and tampons may remove some of Fungistat-X from the vagina.
- Spermicides may interfere with Fungistat-X.
- Fungistat-X may damage condoms and diaphragms and cause them to fail. Do not rely on condoms and diaphragms to prevent pregnancy or sexually transmitted diseases while using this product.

## **How can I get the best results when treating my infection?**

- Be sure to use this product for the full   x   days, even if your symptoms go away sooner. The cream should only be used externally while symptoms are present.

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- Use the medicine at bedtime for   x   days in a row, even during your menstrual period.
- Wear cotton underwear and loose-fitting clothes.
- Dry the genital 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 overgrowth of yeast.
- Wipe from front to back after a bowel movement or after urination.
- Do not douche because douching may wash Fungistat-X out of the vagina.
- Do not use tampons, because they may remove some Fungistat-X from the vagina. Use deodorant-free sanitary napkins or pads as needed.
- Do not use spermicides, as they may interfere with Fungistat-X.
- Do not have vaginal intercourse (sex) while using Fungistat-X.
- Do not scratch the skin outside the vagina. Scratching can cause more irritation and can spread the infection.
- Tell your doctor about any drugs you are now taking. Certain drugs, such as antibiotics, steroids, and birth control pills, may make it more likely for you to get a vaginal yeast infection.
- If you have any other medical questions or concerns about vaginal yeast infections, call your doctor.

**What warnings should I know about when using Fungistat-X?**

**For vaginal use only.**

**Fungistat-X may damage condoms and diaphragms and cause them to fail.**

**Ask a doctor before use if you:**

- have 1 or more of the following: abdominal pain, fever, chills, nausea, vomiting, foul-smelling discharge.

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- get vaginal yeast infections often (such as once a month or three in 6 months).
- may have been exposed to the human immunodeficiency virus (HIV) that causes AIDS.
- are under 12 years of age.

**Stop use and ask a doctor if:**

- symptoms do not improve in 3 days.
- symptoms remain after 7 days.
- you get abdominal pain, fever, chills, nausea, vomiting, foul-smelling discharge, or hives.

These may be signs that this product is not working, or you may have a more serious condition or an allergic reaction.

**When using this product:**

- do not use tampons, douches, or spermicides. They may decrease the amount of Fungistat-X in the vagina.
- do not have vaginal intercourse (sex).

**If pregnant or breast-feeding**, ask a health professional before use.

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

**What side effects may occur with Fungistat-X?**

A mild increase in vaginal burning, itching, or irritation may occur when Fungistat-X is inserted. Stop using Fungistat-X and talk to your doctor if you have abdominal pain, hives, skin rash, or if you have severe vaginal burning, itching, irritation, or swelling.

**How should I use Fungistat-X?**

<b>NOTE TO THE MANUFACTURER:</b>
See appendix for directions for the following 5 formulation types:  (A) cream - reusable applicator (Not prefilled) (B) cream - disposable applicator (Not prefilled) (C) cream/ointment - prefilled disposable applicator (D) insert/suppository (E) insert/suppository and external cream

**What should I do if I have questions about Fungistat-X?**

If you have any medical questions, call your doctor. If you have any other questions, or need more information on this product, call our **Toll-Free Number, 1-888-xxx-yyyy**.

**Other Information:**

**Active ingredients:**

**Fungizole** 200mg (X%) per \_\_\_\_\_

**Inactive ingredients:**

**Storage:**

Keep at room temperature 59° to 86°F (15 to 30°C). Avoid excessive heat and cold.

**(A) Cream - Reusable Applicator (Not prefilled)**

**How do I use Fungistat-X Vaginal Cream?**

Use the cream at bedtime, for x days in a row.

Read the full directions below before using.

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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 pictures: - 2 hands unscrewing the cap from a tube of cream  
- 2 hands used to break the seal at the end of the tube}
  
2. Attach the applicator to the tube of cream. (See picture.)  
  
{picture showing the applicator being firmly attached to the tube. Identify the applicator in the diagram.}
  
3. Squeeze the cream into the applicator until the applicator is full. Separate the applicator from the tube.  
  
{picture showing the applicator being filled by squeezing the tube from the bottom. Identify the plunger and the barrel of the applicator in this same picture.}
  
4. Hold the barrel as shown in the picture.  
  
{picture with a hand holding the barrel.}
  
5. 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. (See picture.)  
  
{Frontal view of the human anatomy: vagina and urinary opening. Side view would show vagina, urinary opening, and rectum and where the applicator would be inserted. Place an X over the urinary opening and rectum to indicate where the applicator should not be inserted.}
  
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. Clean the applicator after each use. Pull the two pieces apart. Wash them with soap and warm water. Rinse well and dry. Put the two pieces back together and store in a clean, dry place.
  
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   x   days.

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To protect your clothing, you may use deodorant-free pads or panty shields while you are using Fungistat-X.

**How do I use Fungistat-X if I have external vaginal symptoms?**

Use the same tube of cream if you have itching and irritation on the skin outside the vagina. Apply the cream every morning and evening.

1. Squeeze a small amount of cream onto your fingertip.
2. Gently apply the cream onto the itchy, irritated skin outside the vagina.
3. Screw the cap back on the tube.
4. Repeat steps 1-3 each morning and evening as needed.

**(B) Cream - Disposable Applicator (Not prefilled)**

**How do I use Fungistat-X Vaginal Cream?**

Use the cream at bedtime for   x   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 pictures: - 2 hands unscrewing the cap from a tube of cream  
- 2 hands used to break the seal at the end of the tube }

2. Attach the applicator to the tube of cream. (See picture.)

{picture showing the applicator being firmly attached to the tube }

3. Squeeze the cream into the applicator until the applicator is full. Separate the applicator from the tube.

{picture showing the applicator being filled by squeezing the tube from the bottom.  
Identify the plunger and the barrel of the applicator in this same picture. }

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4. Hold the barrel as shown in the picture.

{picture with a hand holding the barrel.}

5. 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. (See picture.)

{Frontal view of the human anatomy: vagina and urinary opening. Side view would show vagina, urinary opening, and rectum and where the applicator would be inserted. Place an X over the urinary opening and rectum to indicate where the applicator should not be inserted.}

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. Do not flush it down the toilet.
8. Lie down as soon as possible to keep the cream from leaking out.
9. Repeat steps 2 through 8 with a new applicator before bedtime for the next x days.

To protect your clothing, you may want to use deodorant-free pads or panty shields while you are using Fungistat-X.

### **How do I use Fungistat-X if I have external vaginal symptoms?**

Use the same tube of cream if you have itching and irritation on the skin outside the vagina. Apply the cream every morning and evening.

1. Squeeze a small amount of cream onto your fingertip.
2. Gently apply the cream onto the itchy, irritated skin outside the vaginal opening.
3. Screw the cap back on the tube.
4. Repeat steps 1-3 each morning and evening as needed.

## **(C) Cream/Ointment - Disposable Applicator (prefilled)**

### **How do I use Fungistat-X Vaginal Cream/Ointment?**

Use the cream/ointment at bedtime for x days in a row.  
Read the full directions below before using.

1. Tear the wrapper and take out the prefilled applicator.
2. Get the applicator ready for use. (See picture.)  
  
{picture showing plunger and barrel parts of the applicator}
3. Hold the barrel as shown in the picture.  
  
{picture with a hand holding the barrel.}
4. 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. (See picture.)  
  
{Frontal view of the human anatomy: vagina and urinary opening. Side view would show vagina, urinary opening, and rectum and where the applicator would be inserted. Place an X over the urinary opening and rectum to indicate where the applicator should not be inserted.}
5. 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.
6. Throw the applicator away. Do not flush it down the toilet.
7. Lie down as soon as possible to keep the cream from leaking out.
8. Repeat steps 1 through 7 before bedtime for the next x days.

<b>NOTE TO THE MANUFACTURER:</b>
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For a single-dose treatment, step 8 does not apply.
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To protect your clothing, you may want to use deodorant-free pads or panty shields while you are using Fungistat-X.

**How do I use Fungistat-X if I have external vaginal symptoms?**

<b>NOTE TO THE MANUFACTURER:</b>
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This only applies to prefilled applicators with a separate tube of external cream.
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Use the small tube of cream if you have itching and irritation on the skin outside the vagina. Apply the cream every morning and evening.

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 pictures:   -2 hands unscrewing the cap from a tube of cream  
                  -2 hands using the cap to break the seal at the end of the tube }
2. Squeeze a small amount of cream onto your fingertip.
3. Gently apply the cream onto the itchy, irritated skin outside the vaginal opening.
4. Screw the cap back on the tube.
5. Repeat steps 2-4 each morning and evening as needed.

**(D) Insert/Suppository**

**How do I use Fungistat-X insert/suppository?**

Use the insert/suppository at bedtime for x days in a row. Read the full directions below before using.

1. Remove the insert/suppository from its packaging. (See picture.)  
  
{picture showing the removal of the insert/suppository from its packaging}

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2. Place insert/suppository in the wider end of the applicator. (See picture.)

{picture of a hand holding an applicator and the other hand holding an insert/suppository which is placed into the wider end of the applicator; label parts of the applicator: plunger, barrel.}

3. Hold the barrel as shown in the picture.

{picture with a hand holding the barrel loaded with insert/suppository.}

4. 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.

{Frontal view of the human anatomy: vagina and urinary opening. Side view would show vagina, urinary opening, and rectum and where the applicator would be inserted. Place an X over the urinary opening and rectum to indicate where the applicator should not be inserted.}

5. While holding the barrel, push the plunger in as far as it will go. Remove the applicator from the vagina.
6. Clean the applicator after each use. Pull the two pieces apart. Wash them with soap and warm water. Rinse well and dry. Put the two pieces back together and store in a clean, dry place.
7. Once inside the vagina, the insert/suppository melts. Lie down as soon as possible. This will keep leakage to a minimum.
8. Repeat steps 1 through 7 before bedtime for the next x days.

To protect your clothing, you may want to use deodorant-free pads or panty shields while you are using Fungistat-X.

## **(E) Insert/Suppository and External Cream**

### **How do I use Fungistat-X Dual/Combo Pack?**

Use the insert/suppository at bedtime for x days in a row. Read the full directions below before using.

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1. Remove the insert/suppository from its packaging. (See picture.)  
  
{picture showing the removal of the insert/suppository from its packaging}
2. Place insert/suppository in the wider end of the applicator. (See picture.)  
  
{picture of a hand holding an applicator and the other hand holding an insert/suppository which is placed into the wider end of the applicator; label parts of the applicator: plunger, barrel.}
3. Hold the barrel as shown in the picture.  
  
{picture with a hand holding the barrel loaded with insert/suppository.}
4. 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.  
  
{Frontal view of the human anatomy: vagina and urinary opening. Side view would show vagina, urinary opening, and rectum and where the applicator would be inserted. Place an X over the urinary opening and rectum to indicate where the applicator should not be inserted.}
5. While holding the barrel, push the plunger in as far as it will go. Remove the applicator from the vagina.
6. Clean the applicator after each use. Pull the two pieces apart. Wash them with soap and warm water. Rinse well and dry. Put the two pieces back together and store in a clean, dry place.
7. Once inside the vagina, the insert/suppository melts. Lie down as soon as possible. This will keep leakage to a minimum.
8. Repeat steps 1 through 7 before bedtime for the next x days.

To protect your clothing, you may want to use deodorant-free pads or panty shields while you are using Fungistat-X.

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**How do I use Fungistat-X Cream if I have external vaginal symptoms?**

Use the small tube of cream if you have itching and irritation on the skin outside the vagina. Apply the cream every morning and evening.

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 pictures: -2 hands unscrewing the cap from a tube of cream  
-2 hands using the cap to break the seal at the end of the tube}
2. Squeeze a small amount of cream onto your fingertip.
3. Gently apply the cream onto the itchy, irritated skin outside the vaginal opening.
4. Screw the cap back on the tube.
5. Repeat steps 2-4 each morning and evening as needed.