Enclosure: Attachment A: Approved labeling text for the **carton** and **educational brochure**.

Attachment B: Approved labeling text for the **tube**.

Attachment C: Approved labeling text for the **carton** and **educational brochure**, to be used after 6 months following approval of this application or at the next printing of the product labeling, whichever comes first.

Attachment D: Approved labeling text for the **tube,** to be used after 6 months following approval of this application or at the next printing of the product labeling.

Attachment A:

Gyne-Lotrimin 3 ® Vaginal Cream

Carton

Hanging flap

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal
3 Disposable Applicators

3-Day
Treatment

Front Panel

Cures Most Vaginal Yeast Infections

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

3-Day
Treatment

Educational Brochure Enclosed

One 21g (0.74 oz.) Tube of Vaginal Cream
(Clotrimazole (2%) (100 mg per applicator)
and 3 Disposable Applicators

Schering-Plough logo

Top Panel

Cures Most Vaginal Yeast Infections

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal
3 Disposable Applicators

3-Day
Treatment

Bottom Panel

Cures Most Vaginal Yeast Infections

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal
3 Disposable Applicators

3-Day Treatment

Side Panels

Cures Most Vaginal Yeast Infections

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal
3 Disposable Applicators

3-Day Treatment

Back Panel

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal
3 Disposable Applicators

3-Day Treatment

Cures Most Vaginal Yeast Infections

GYNE-LOTRIMIN 3 ® Vaginal Cream is a 3-day treatment that cures most vaginal yeast infections. **If this is the first time you have had vaginal itching and discomfort, consult your doctor.** If you have had a doctor diagnose a vaginal yeast infection before and have the same symptoms now, use this cream as directed for 3 days in a row.

Active Ingredient: Clotrimazole (2%) (100 mg per applicator).

Use:

- For the treatment of vaginal yeast infections (*candidiasis*).

Warnings:

- **For vaginal use only. Do not use in eyes or take by mouth.**
- Do not use GYNE-LOTRIMIN 3 Vaginal Cream if you have any of the following signs and symptoms:

- fever (higher than 100°F).
- pain in the lower abdomen, back, or either shoulder.
- a foul-smelling vaginal discharge.

- While using GYNE-LOTRIMIN 3 Vaginal Cream, if you get a fever, abdominal pain, or a foul-smelling vaginal discharge, **stop using the product** and contact your doctor right away. You may have a more serious illness.
- If your symptoms do not improve in 3 days, or you still have symptoms after 7 days, you should call your doctor.
- If your symptoms return within 2 months, you should consult your doctor. You could be pregnant or there could be a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system (which may be due to HIV – the virus that causes AIDS).
- Contact your doctor if you get hives or a skin rash while using this product.
- Do not use tampons, douches, or spermicides while using this product.
- Do not rely on condoms or diaphragms to prevent sexually transmitted diseases or pregnancy. This product may damage condoms and diaphragms and cause them to fail.
- If pregnant or breast-feeding, ask a health professional before use.
- Do not use in girls less than 12 years of age.
- **Keep this and all drugs out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions:
Applicator and instructions are enclosed.

- Before using, read the enclosed brochure for complete instructions.
- To open: use cap to puncture seal.
- Insert one applicatorful of cream into the vagina at bedtime for 3 days in a row.

Inactive Ingredients: Benzyl alcohol, cetearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, purified water, sorbitan monostearate

Store at room temperature 15° - 30°C (59° - 86°F). Avoid heat over 30°C or 86°F.
See end flap of carton and end of tube for lot number and expiration date.

Important: Do not purchase if carton is opened. The tube opening should be sealed. If seal has been punctured or the embossed design ***SP*** is not visible, do not use the product. Return the product to the store where you bought it.

Medical questions should be answered by your doctor. If you have any other questions, or need more information on this product, call our **TOLL-FREE Number, at 1-8XX-(XXX-XXXX),** between 8:00 a.m. and 5:00 p.m. Eastern Standard Time, Monday through Friday.

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Educational Brochure

Read This Before Using

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

Clotrimazole (2%) (100 mg per applicator).

3-day treatment of vaginal yeast infections (*Candidasis*)

Schering-Plough logo

Use:

- For the treatment of vaginal yeast infections (*candidiasis*).

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 GYNE-LOTRIMIN 3 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 *(Candidiasis)?*

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 HOTLINE. The CDC phone numbers are: 1-800-342-AIDS (English), 1-800-344-7432 (Spanish), or 1-800-243-7889 (hearing impaired, TDD).

Symptoms of A Vaginal Yeast Infection

There are many signs and 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 consult your doctor before using GYNE-LOTRIMIN 3 Vaginal Cream.

Warnings

- For vaginal use only. Do not use in eyes or by mouth.
- This product is effective only in treating vaginal yeast infections.
- Do not use GYNE-LOTRIMIN 3 Vaginal Cream if you have any of the following signs and symptoms:
    - fever (higher than 100°F).
    - pain in the lower abdomen, back, or either shoulder.
    - a foul-smelling vaginal discharge.
- While using GYNE-LOTRIMIN 3 Vaginal Cream, if you get a fever, abdominal pain, or a foul-smelling vaginal discharge, **stop using the product** and contact your doctor right away. You may have a more serious disease.
- If your symptoms do not improve in 3 days, or you still have symptoms after 7 days, you should call your doctor.
- If your symptoms return within 2 months, you should consult your doctor. You could be pregnant or there could be a serious underlying medical cause for your infections, including diabetes or a weakened immune system (which may be due to HIV - the virus that causes AIDS).
- Contact your doctor if you get hives or a skin rash while using this product.
- Do not use tampons, douches, or spermicides while using this medicine.
- Do not rely on condoms or diaphragms to prevent sexually transmitted diseases or pregnancy. This product may damage condoms and diaphragms and cause them to fail.
- If pregnant or breast-feeding, ask a health professional before use.
- Do not use in girls less than 12 years of age.
- **Keep this and all drugs out of the reach of children**. If swallowed, get medical help or contact a Poison Control Center right away.

Adverse Reactions (Side Effects)

A mild increase in vaginal burning, itching, or irritation may occur when GYNE-LOTRIMIN 3 Vaginal Cream is inserted. Stop using GYNE-LOTRIMIN 3 Vaginal Cream

and consult your doctor if you have abdominal pain, hives, or skin rash, or if you have severe vaginal burning, itching, or irritation.

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 GYNE-LOTRIMIN 3 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.

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 more information on this product, call our **TOLL-FREE Number, at 1-8XX-(XXXXXXX),** between 8:00 a.m. and 5:00 p.m. Eastern Standard Time, Monday though Friday.

Active Ingredient

Clotrimazole (2%)

Inactive Ingredients

Benzyl alcohol, cetearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, purified water, sorbitan monostearate.

Storage

Store at room temperature 15° - 30°C (59° - 86°F). Avoid heat over 30°C or 86°F. See end flap of carton and end of tube for lot number and expiration date.

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How to use GYNE-LOTRIMIN 3 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 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 by placing "A" end of the applicator firmly onto tube of cream. (See picture.)

{picture showing the applicator being firmly attached to the tube, label the "A" end of the tube}

3. Gently squeeze the cream into the applicator, continue squeezing until line on plunger marked "FULL" reaches end of barrel. Separate the applicator from the tube. After each use, replace cap and roll up the tube from the bottom.

{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. The Gyne-Lotrimin 3 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.

{picture showing recumbant position. Show 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 after each use. Do not flush it down the toilet.

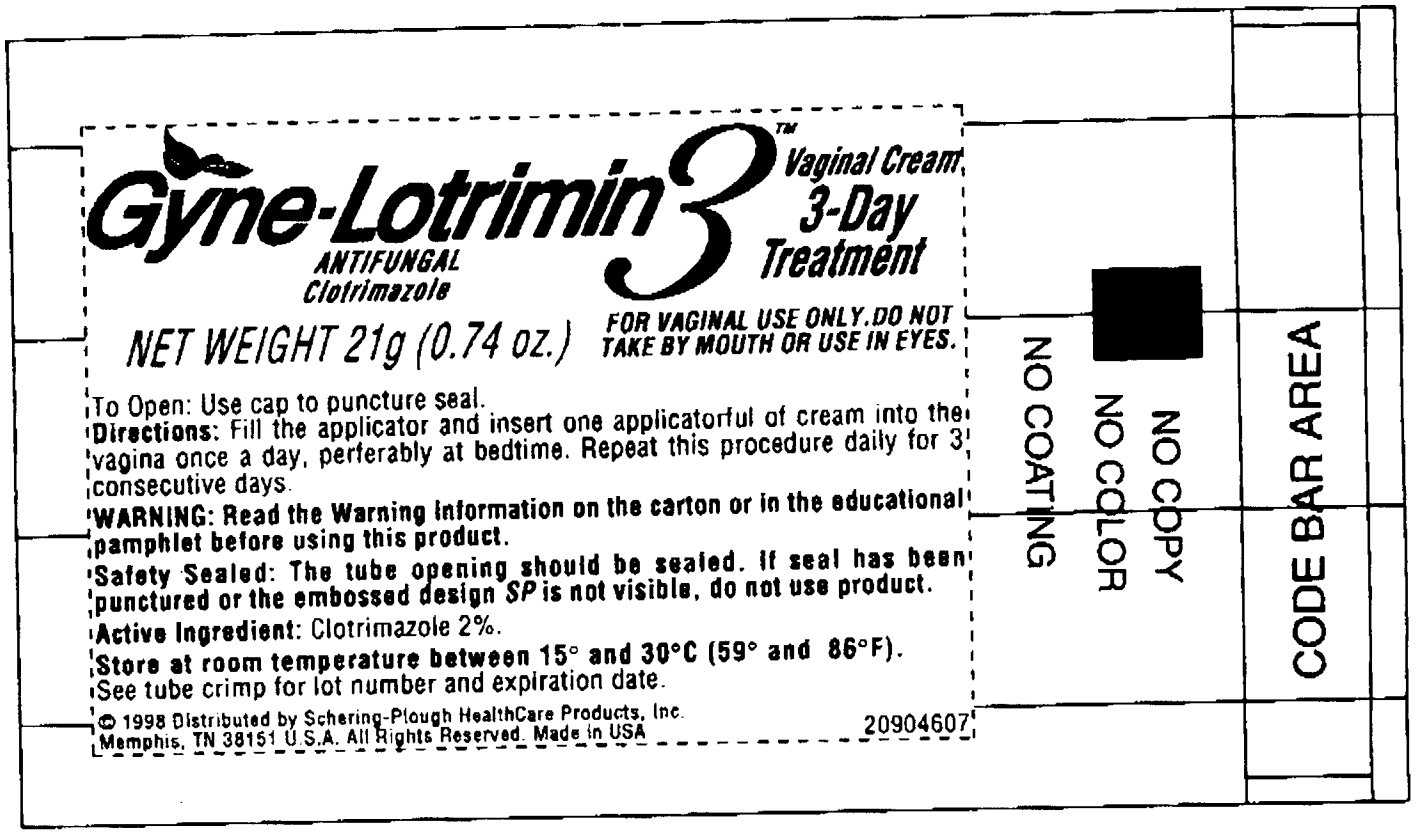
8. Lie down as soon as possible to keep the cream from leaking out.

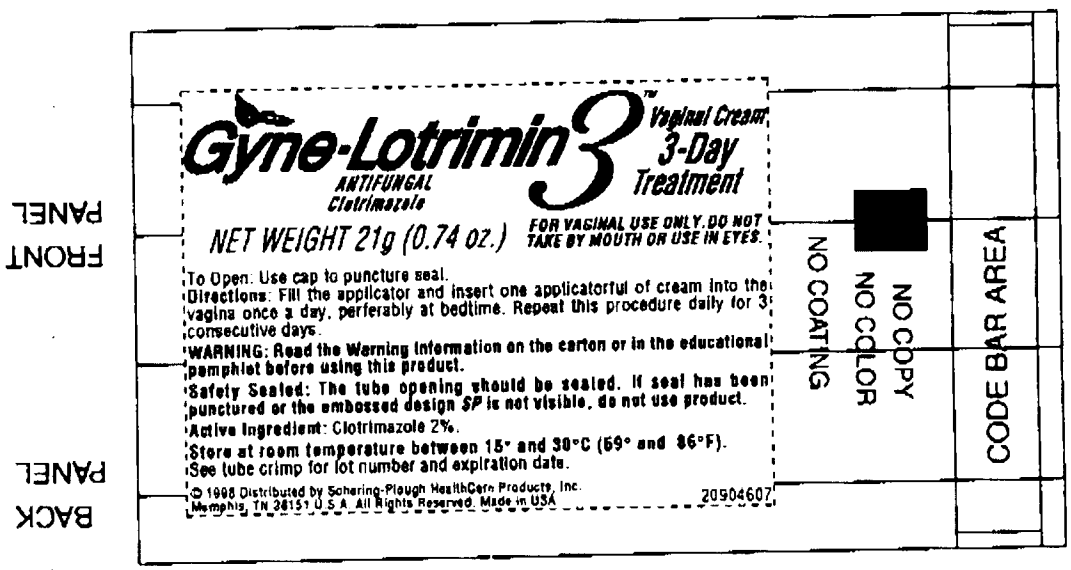
9. Repeat steps 2 through 8 with a new applicator before bedtime for the next 2 days.

To protect your clothing from leakage or discharge, you may want to use deodorant-free pads or panty shields while you are using Gyne-Lotrimin 3 Vaginal Cream. **Do not use tampons, douches, or spermicides** until after you have completed the treatment and your symptoms are gone.

Attachment B:

150%





TYPE SIZES ARE 6 POINTS AND LARGER

Attachment C:

Gyne-Lotrimin 3 ® Vaginal Cream

Carton

Hanging flap

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

3-Day
Treatment
3 Disposable Applicators

Vaginal Cream (in graphic bar)

Front Panel

Cures Most Vaginal Yeast Infections

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

3-Day
Treatment

Vaginal Cream (in graphic bar)

Educational Brochure Enclosed

One 21g (0.74 oz.) Tube of Clotrimazole Vaginal Cream (2%) and 3 Disposable Applicators

Schering-Plough logo **graphic of Gyne-Lotrimin 3 tube with 3 applicators**

Top Panel

Cures Most Vaginal Yeast Infections

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

3-Day
Treatment
3 Disposable Applicators

Vaginal Cream (in graphic bar)

Bottom Panel

Cures Most Vaginal Yeast Infections

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

3-Day
Treatment
3 Disposable Applicators

Vaginal Cream (in graphic bar)

Side Panels

Cures Most Vaginal Yeast Infections

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

3-Day
Treatment
3 Disposable Applicators

Vaginal Cream (in graphic bar)

Back Panel

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

3-Day
Treatment
3 Disposable Applicators

Vaginal Cream (in graphic bar)

GYNE-LOTRIMIN 3 ® Vaginal Cream is a 3-day treatment that cures most vaginal yeast infections. **If this is the first time you have had vaginal itching and discomfort, talk to your doctor.** If you have had a doctor diagnose a vaginal yeast infection before and have the same symptoms now, use this cream as directed for 3 days in a row.

Active Ingredient: Clotrimazole 2% (100 mg per applicator).

Use:
- For the treatment of vaginal yeast infections (*candidiasis*).

Warnings:
- **For vaginal use only. Do not use in eyes or take by mouth.**

- Do not use GYNE-LOTRIMIN 3 Vaginal Cream if you have any of the following symptoms:
  - fever (higher than 100°F).
  - pain in the lower abdomen, back, or either shoulder.
  - a foul-smelling vaginal discharge.
- While using GYNE-LOTRIMIN 3 Vaginal Cream, if you get a fever, abdominal pain, or a foul-smelling vaginal discharge, **stop using the product** and contact your doctor right away. You may have a more serious illness.
- If your symptoms do not improve in 3 days, or you still have symptoms after 7 days, you should talk to your doctor.
- If your symptoms return within 2 months, you should talk to your doctor. You could be pregnant or there could be a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system (which may be due to HIV – the virus that causes AIDS).
- Contact your doctor if you get hives or a skin rash while using this product.
- Do not use tampons, douches, or spermicides while using this product.
- Do not rely on condoms or diaphragms to prevent sexually transmitted diseases or pregnancy. This product may damage condoms and diaphragms and cause them to fail.
- If pregnant or breast-feeding, ask a health professional before use.
- Do not use in girls less than 12 years of age.
- **Keep this and all drugs out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions:
Applicator and instructions are enclosed.
- Before using, read the enclosed brochure for complete instructions.
- To open: use cap to puncture seal.
- Insert one applicatorful of cream into the vagina at bedtime for 3 days in a row.

Inactive Ingredients: Benzyl alcohol, cetearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, purified water, sorbitan monostearate

Store at room temperature 15° - 30°C (59° - 86°F). Avoid heat over 30°C or 86°F.
See end flap of carton and end of tube for lot number and expiration date.

Important: The tube opening should be sealed. If seal has been broken or the embossed design ***SP*** is not visible, do not use the product. Return the product to the store where you bought it.

Medical questions should be answered by your doctor. If you have any other questions, or need more information on this product, call our **TOLL-FREE**

Number, at 1-8XX-(XXX-XXXX between 8:00 a.m. and 5:00 p.m. Eastern Standard Time, Monday through Friday.

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Educational Brochure

Read This Before Using

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

Clotrimazole 2% (100 mg per applicator).

3-day treatment of vaginal yeast infections (*Candidasis*)

Schering-Plough logo

Use:

- For the treatment of vaginal yeast infections (*candidiasis*).

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 GYNE-LOTRIMIN 3 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 *(Candidiasis)?*

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 HOTLINE. The CDC phone numbers are: 1-800-342-AIDS (English), 1-800-344-7432 (Spanish), or 1-800-243-7889 (hearing impaired, TDD).

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 GYNE-LOTRIMIN 3 Vaginal Cream.

Warnings (this section can be shaded but not boxed)

- For vaginal use only. Do not use in eyes or by mouth.
- This product is effective only in treating vaginal yeast infections.
- Do not use GYNE-LOTRIMIN 3 Vaginal Cream if you have any of the following symptoms:
    - fever (higher than 100°F).
    - pain in the lower abdomen, back, or either shoulder.
    - a foul-smelling vaginal discharge.
- While using GYNE-LOTRIMIN 3 Vaginal Cream, if you get a fever, abdominal pain, or a foul-smelling vaginal discharge, **stop using the product** and contact your doctor right away. You may have a more serious disease.
- If your symptoms do not improve in 3 days, or you still have symptoms after 7 days, you should talk to your doctor.
- If your symptoms return within 2 months, you should talk to your doctor. You could be pregnant or there could be a serious underlying medical cause for your infections, including diabetes or a weakened immune system (which may be due to HIV - the virus that causes AIDS).
- Contact your doctor if you get hives or a skin rash while using this product.
- Do not use tampons, douches, or spermicides while using this medicine.
- Do not rely on condoms or diaphragms to prevent sexually transmitted diseases or pregnancy. This product may damage condoms and diaphragms and cause them to fail.
- If pregnant or breast-feeding, ask a health professional before use.
- Do not use in girls less than 12 years of age.
- **Keep this and all drugs out of the reach of children**. If swallowed, get medical help or contact a Poison Control Center right away.

Side Effects

A mild increase in vaginal burning, itching, or irritation may occur when GYNE-LOTRIMIN 3 Vaginal Cream is inserted. Stop using GYNE-LOTRIMIN 3 Vaginal Cream and talk to your doctor if you have abdominal pain, hives, or skin rash, or if you have

severe vaginal burning, itching, or irritation.

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 GYNE-LOTRIMIN 3 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.

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 more information on this product, call our **TOLL-FREE Number, at 1-8XX-(XXXXXXX),** between 8:00 a.m. and 5:00 p.m. Eastern Standard Time, Monday though Friday.

Active Ingredient

Clotrimazole 2% (100 mg per applicator)

Inactive Ingredients

Benzyl alcohol, cetearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, purified water, sorbitan monostearate.

Storage

Store at room temperature 15° - 30°C (59° - 86°F). Avoid heat over 30°C or 86°F. See end flap of carton and end of tube for lot number and expiration date.

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How to use GYNE-LOTRIMIN 3 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 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 by placing end of the applicator firmly onto tube of cream. (See picture.)

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

3. Gently squeeze the cream into the applicator, continue squeezing until line on plunger marked "FULL" reaches end of barrel. Separate the applicator from the tube. After each use, replace cap and roll up the tube from the bottom.

{picture showing the applicator being filled by squeezing the tube from the bottom. Label the plunger as "plunger" and the barrel as "barrel."}

4. Hold the barrel as shown in the picture.

{picture with a hand holding the barrel}

5. The Gyne-Lotrimin 3 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.

{picture showing recumbent position. Show 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. Use the symbol "⌀" (the international sign for do not enter) to indicate that the applicator should not be inserted in the urinary opening and rectum.}

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 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 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 Gyne-Lotrimin 3 Vaginal Cream. **Do not use tampons, douches, or spermicides** until after you have completed the treatment and your symptoms are gone.

Attachment D:

Tube

Vaginal Cream
3-Day Treatment

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

Net Weight 21g (0.74 oz.)

For vaginal use only. Do not use in eyes or take by mouth

If this is the first time you have had vaginal itching and discomfort, consult your doctor. If you have had a doctor diagnose a vaginal yeast infection before and have the same symptoms now, use this cream as directed for 3 days in a row.

Warnings: Read the Warnings and Directions on the carton and in the educational brochure before using this product.

Directions: To Open: Use cap to puncture seal. Insert one applicator of cream into the vagina at bedtime for 3 days in a row.

Active Ingredient: Clotrimazole 2% (100 mg per applicator).

Store at room temperature 15° - 30°C (59° - 86°F). Avoid heat over 30°C or 86°F. See end of tube for lot number and expiration date.

Safety Sealed: The tube opening should be sealed. If the seal has been punctured or the embossed design *SP* is not visible, do not use the product.

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