

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-329

APPROVED DRAFT LABELING



APR 20 1993



EDUCATIONAL BROCHURE
 FULL PRESCRIPTION STRENGTH
MICONAZOLE NITRATE VAGINAL SUPPOSITORIES
and EXTERNAL VULVAR CREAM
 CURES MOST VAGINAL YEAST INFECTIONS

RELIEVES EXTERNAL VULVAR ITCHING AND IRRITATION ASSOCIATED WITH A YEAST INFECTION

INDICATIONS

For the treatment of vaginal yeast infections and the relief of external vulvar itching and irritation associated with a yeast infection.

If you have any or all of the symptoms of a vaginal yeast infection (vaginal itching, burning, discharge) accompanied by external vulvar itching and irritation and if at some time in the past your doctor has told you that these symptoms are due to a vaginal yeast infection, then this product should work for you. If, however, you have never had these symptoms before, you should see your doctor before using this product. **THIS COMBINATION PACK IS FOR THE TREATMENT OF VAGINAL YEAST INFECTIONS AND FOR THE RELIEF OF EXTERNAL VULVAR ITCHING AND IRRITATION ASSOCIATED WITH A YEAST INFECTION. IT DOES NOT TREAT OTHER INFECTIONS OR EXTERNAL ITCHING AND IRRITATION DUE TO CAUSES OTHER THAN YEAST INFECTIONS. IT DOES NOT PREVENT PREGNANCY.**

WHAT ARE VAGINAL YEAST INFECTIONS (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. Even 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 also experience a yeast infection on the external skin (vulva) associated with the internal vaginal infection.

A yeast infection can occur at almost any time of life. It is most common during the childbearing years. The infection tends to develop most often in some women who are pregnant, diabetic, taking antibiotics, taking birth control pills, or have a damaged immune system.

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 1-800-342-AIDS (English), 1-800-344-7432 (Spanish), or 1-800-243-7889 (hearing impaired, TDD).

IF YOU EXPERIENCE FREQUENT YEAST INFECTIONS (THEY RECUR WITHIN A TWO MONTH PERIOD) OR IF YOU HAVE 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.

SYMPTOMS OF VAGINAL YEAST INFECTIONS

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

- Vaginal itching (ranging from mild to intense);
- A clumpy, vaginal discharge that may look like cottage cheese;
- Vaginal soreness, irritation, or burning, especially during vaginal intercourse;
- Rash or redness around the vagina (vulvar irritation).

NOTE: Vaginal discharge that is different from above, for example, a yellow/green discharge or a discharge that smells "fishy", may indicate that you have something other than a yeast infection. If this is the case, you should consult your doctor before using this product.

WARNINGS

- This product is only effective in treating vaginal infection caused by yeast and in relieving vulvar itching and irritation associated with a yeast infection. Do not use in the eyes or take by mouth.
- Do not use this product if you have any of the following signs and symptoms.

Also, if they occur while using this product, STOP using these products and contact your doctor right away. You may have a more serious illness.

Fever (Above 100°F orally)

Pain in the lower abdomen, back, or either shoulder

A vaginal discharge that smells bad

- If there is no improvement or if the infection worsens within 3 days, or complete relief is not felt within 7 days, or your symptoms return within two months, then you may have something other than a yeast infection. You should consult your doctor.

- If you may have been exposed to the human immunodeficiency virus (HIV-the virus that causes AIDS) and are now having recurrent vaginal infections, especially infections that don't clear up easily with proper treatment, see your doctor promptly to determine the cause of your symptoms and to receive proper medical care.

- Hydrogenated vegetable oil may weaken latex in condoms or in diaphragms. These suppositories contain hydrogenated vegetable oil. Do not rely on condoms or diaphragms to prevent sexually transmitted diseases or pregnancy while using this product.

- Do not use tampons while using this medication.

- Do not use in girls less than 12 years of age.

- If you are pregnant or think you may be, do not use these products except under the advice and supervision of a doctor.

- Keep this and all drugs out of the reach of children.

- In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

CONTENTS

VAGINAL SUPPOSITORIES: Three vaginal suppositories each containing 200 mg of miconazole nitrate.

EXTERNAL VULVAR CREAM: One tube of cream for external vulvar use containing miconazole nitrate 2%.

PLASTIC APPLICATOR: The **COMBINATION PACK** contains one plastic, reusable applicator. The **COMBINATION PACK with Disposable Applicators** contains three plastic, disposable applicators.

DIRECTIONS FOR USE

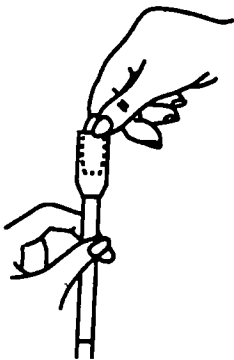
Vaginal Suppositories

Begin treatment at bedtime. Before going to bed:

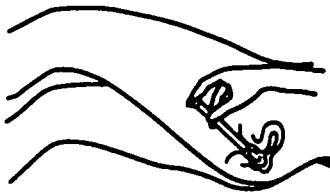
- 1 Tear off one suppository from the strip. Separate the plastic wrap with your thumb. With thumb and forefinger on each hand, hold the plastic tabs and pull apart (see illustration).



- 2 Place suppository in the top of the applicator as shown.



- 3 Hold the applicator containing the suppository by the opposite end from where the suppository is. Gently insert the applicator into the vagina as far as it will go comfortably. As shown in the picture, this can be done while lying on your back with your knees bent or you

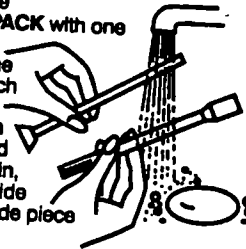


can stand with your feet spread a few inches apart and your knees bent.

Once you are ready, push the inside piece of the applicator in and place the suppository as far back in the vagina as possible. Then remove the applicator from the vagina. You should go to bed as soon as possible after inserting the suppository. This will keep leakage to a minimum.

You may want to use deodorant-free mini-pads or pantyshields during the time that you are using the Vaginal Suppositories. This is because the suppository can leak and/or you may see some discharge. **DO NOT USE TAMPONS.**

- 4 If you are using the **COMBINATION PACK with Disposable Applicators**, throw away the applicator after each use. **DO NOT FLUSH IN TOILET.** Use a new applicator for each dose. If you are using the **COMBINATION PACK with one plastic applicator**, be sure to clean the applicator after each use. Pull the two pieces apart. Wash them with soap and warm water. To rejoin, gently push the inside piece into the outside piece as far as it will go.

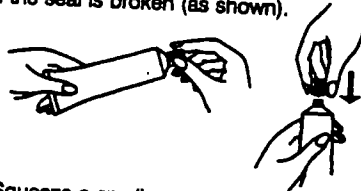


- 5 Repeat steps 1 through 4 before going to bed on each of the next two evenings.

External Vulvar Cream

Use the cream twice daily if needed as follows:

- 1 Open the tube. To do this, unscrew the cap, turn the cap upside down and place the cap in the end of the tube. Push down firmly until the seal is broken (as shown).



- 2 Squeeze a small amount of cream onto your finger.

- 3 Gently apply the cream onto the skin (vulva) that itches and is irritated.

- 4 Repeat steps 2 and 3 each morning and evening as needed.

ADVERSE REACTIONS (SIDE EFFECTS)

The following side effects have been reported with the use of the products in this **COMBINATION PACK**: a temporary increase in burning, itching, and/or irritation when the suppository is inserted. Abdominal cramping, headaches, hives, and skin rash have also been reported. If any of these occur, stop using this product and consult your doctor.

FOR BEST RESULTS

1. Be sure to use all of the suppositories even if your symptoms go away before you have used all the suppositories.
2. Use one suppository at bedtime for three nights in a row, even during your menstrual period.
3. Wear cotton underwear.
4. If your partner has any penile itching, redness, or discomfort, he should consult his doctor and mention 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-workout clothes as soon as possible. A dry area is less likely to encourage the growth of yeast.
6. Wipe from front to rear (away from the vagina) after a bowel movement or urination.
7. Do not douche unless your doctor tells you to do so. Douching may disturb the vaginal bacterial balance.
8. Do not scratch if you can help it. Scratching can cause more irritation and can spread the infection.
9. Discuss with your doctor any medication you are now taking. Certain types of medication can make your vagina more prone to infection.

IF YOU HAVE A QUESTION

Questions of a medical nature should be taken up with your doctor.

ACTIVE INGREDIENTS

VAGINAL SUPPOSITORIES - miconazole nitrate (200 mg each suppository).
EXTERNAL VULVAR CREAM - miconazole nitrate 2%.

STORAGE

Store at room temperature 15 to 30°C (59 to 86°F). Avoid heat (over 30°C or 86°F).

MANUFACTURED BY
PERRIGO ALLEGAN, MI 49010 U.S.A.

REVISED 11/97

496064

Final Printed Labeling
strip for suppository

PERRIGO, ALLEGAN, MI 49010	Miconazole Nitrate Vaginal Suppository USP, 200 mg 9 650 00 00 XB
	Miconazole Nitrate Vaginal Suppository USP, 200 mg NOT FOR ORAL USE. FOR VAGINAL USE ONLY.
PERRIGO, ALLEGAN, MI 49010	Miconazole Nitrate Vaginal Suppository USP, 200 mg 9 650 00 00 XB
	Miconazole Nitrate Vaginal Suppository USP, 200 mg NOT FOR ORAL USE. FOR VAGINAL USE ONLY.

APR 20 1990

Final Printed Labeling
9 gram tube

**MICONAZOLE NITRATE 2%
EXTERNAL VULVAR CREAM**

RELIEVES EXTERNAL VULVAR ITCHING & IRRITATION
ASSOCIATED WITH A YEAST INFECTION

Net Wt. 0.32 oz. (9 grams)

FOR EXTERNAL VULVAR USE ONLY. DO NOT TAKE BY MOUTH OR USE IN EYES.
KEEP OUT OF REACH OF CHILDREN. Before using, read the enclosed brochure for
DIRECTIONS and WARNINGS.

TUBE OPENING IS COVERED BY A METAL TAMPER-EVIDENT SEAL. DO NOT USE IF
SEAL HAS BEEN PUNCTURED OR CANNOT BE SEEN
TO OPEN, USE CAP TO PUNCTURE SEAL.

ACTIVE INGREDIENT: miconazole nitrate 2%

See end of tube for lot number and expiration date.

Store at room temperature 15° to 30°C (59° to 86°F).

Avoid heat (over 30°C or 86°F).

MANUFACTURED BY **PERRIGO** ALLEGAN, MI 48801 U.S.A.

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CENTER
FRONT

CENTER
BACK

Final Printed Labeling

Carton
(for disposable applicator)

3 DISPOSABLE APPLICATORS

COMPARE TO ACTIVE INGREDIENT OF MONISTAT® 3

3 DAY TREATMENT FULL PRESCRIPTION STRENGTH MICONAZOLE NITRATE VAGINAL SUPPOSITORIES and EXTERNAL VULVAR CREAM

Vaginal Suppositories plus Cream for External Relief

MICONAZOLE NITRATE VAGINAL SUPPOSITORIES and EXTERNAL VULVAR CREAM

COMBINATION PACK WITH 3 DISPOSABLE APPLICATORS

3 DISPOSABLE APPLICATORS

MICONAZOLE NITRATE VAGINAL SUPPOSITORIES and EXTERNAL VULVAR CREAM

COMBINATION PACK

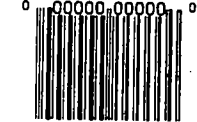
CURES MOST VAGINAL YEAST INFECTIONS
AND RELIEVES EXTERNAL VULVAR ITCHING & IRRITATION
ASSOCIATED WITH A YEAST INFECTION

COMBINATION PACK
3 VAGINAL SUPPOSITORIES
plus EXTERNAL VULVAR CREAM

Net Wt 0.32 oz. (9g) Tube

MICONAZOLE NITRATE VAGINAL SUPPOSITORIES and EXTERNAL VULVAR CREAM

COMBINATION PACK WITH 3 DISPOSABLE APPLICATORS



PERIGO
MILWAUKEE, WI 53210 USA
MANUFACTURED BY

See end flap for lot number and expiration date.
Store at room temperature (20° to 25°C (68° to 77°F)).
Avoid heat (over 30°C or 85°F).
External Vulvar Cream - benzoyl acid, BHA, glyceryl monostearate, mineral oil, polyol, stearyl alcohol, purified water.
External Vulvar Cream - hydroxyethyl vegetable oil base.
Vaginal Suppositories - miconazole nitrate 2%.

ACTIVE INGREDIENTS:
External Vulvar Cream - miconazole nitrate (200 mg each).
Vaginal Suppositories - miconazole nitrate 2%.

INACTIVE INGREDIENTS:
External Vulvar Cream - benzoyl acid, BHA, glyceryl monostearate, mineral oil, polyol, stearyl alcohol, purified water.
External Vulvar Cream - hydroxyethyl vegetable oil base.
Vaginal Suppositories - miconazole nitrate 2%.

CAUTION: DO NOT USE IF SEAL HAS A HOLE OR IF SEAL CANNOT BE SEEN. RETURN THE PRODUCT TO THE STORE WHERE YOU BOUGHT IT.

IMPORTANT: DO NOT USE IF CAPTION IS OPENED. THE TUBE OPENING SHOULD BE SEALED. DO NOT USE IF SEAL HAS A HOLE OR IF SEAL CANNOT BE SEEN. RETURN THE PRODUCT TO THE STORE WHERE YOU BOUGHT IT.

Directions: See end flap for lot number and expiration date.
• Keep this and all drugs out of the reach of children.
• In case of accidental ingestion, seek professional help or contact a poison control center immediately.

Warnings:
• Do not use if you are pregnant or think you may be pregnant. Do not use if you are pregnant or think you may be pregnant for less than 12 years of age.
• Do not use in girls less than 12 years of age.
• Do not use tampons while using this medication.
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Hydroxyethyl vegetable oil base: These suppositories contain hydroxyethyl vegetable oil base. These suppositories contain hydroxyethyl vegetable oil base. These suppositories contain hydroxyethyl vegetable oil base.

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3 DAY TREATMENT • FULL PRESCRIPTION STRENGTH

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Final Printed Labeling
Package Insert
(Educational Brochure)
Front

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790967

EDUCATIONAL BROCHURE
FULL PRESCRIPTION STRENGTH
**MICONAZOLE NITRATE VAGINAL SUPPOSITORIES
and EXTERNAL VULVAR CREAM**
CURES MOST VAGINAL YEAST INFECTIONS

RELIEVES EXTERNAL VULVAR ITCHING AND IRRITATION ASSOCIATED WITH A YEAST INFECTION

INDICATIONS

For the treatment of vaginal yeast infections and the relief of external vulvar itching and irritation associated with a yeast infection.

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WHAT ARE VAGINAL YEAST INFECTIONS (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. Even 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 also experience a yeast infection on the external skin (vulva) associated with the internal vaginal infection.

A yeast infection can occur at almost any time of life. It is most common during the childbearing years. The infection tends to develop most often in some women who are pregnant, diabetic, taking antibiotics, taking birth control pills, or have a damaged immune system.

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 1-800-342-AIDS (English), 1-800-344-7432 (Spanish), or 1-800-243-7889 (hearing impaired, TDD).

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SYMPTOMS OF VAGINAL YEAST INFECTIONS

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

- Vaginal itching (ranging from mild to intense);
- A clumpy, vaginal discharge that may look like cottage cheese;
- Vaginal soreness, irritation, or burning, especially during vaginal intercourse;
- Rash or redness around the vagina (vulvar irritation).

NOTE: Vaginal discharge that is different from above, for example, a yellow/green discharge or a discharge that smells "fishy", may indicate that you have something other than a yeast infection. If this is the case, you should consult your doctor before using this product.

WARNINGS

- This product is only effective in treating vaginal infection caused by yeast and in relieving vulvar itching and irritation associated with a yeast infection. Do not use in the eyes or take by mouth.
- **Do not use this product if you have any of the following signs and symptoms.**

Also, if they occur while using this product, STOP using these products and contact your doctor right away. You may have a more serious illness.

- Fever (Above 100°F orally)
- Pain in the lower abdomen, back, or either shoulder

A vaginal discharge that smells bad

- If there is no improvement or if the infection worsens within 3 days, or complete relief is not felt within 7 days, or your symptoms return within two months, then you may have something other than a yeast infection. You should consult your doctor.

- If you may have been exposed to the human immunodeficiency virus (HIV-the virus that causes AIDS) and are now having recurrent vaginal infections, especially infections that don't clear up easily with proper treatment, see your doctor promptly to determine the cause of your symptoms and to receive proper medical care.

- Hydrogenated vegetable oil may weaken latex in condoms or in diaphragms. These suppositories contain hydrogenated vegetable oil. Do not rely on condoms or diaphragms to prevent sexually transmitted diseases or pregnancy while using this product.

- Do not use tampons while using this medication.
- Do not use in girls less than 12 years of age.
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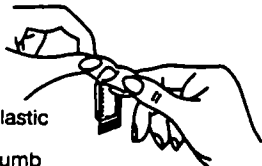
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(Educational Brochure)
Back**

DIRECTIONS FOR USE

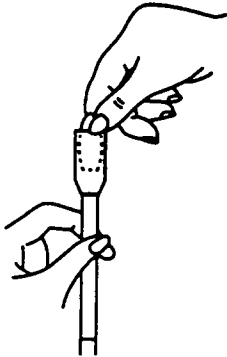
Vaginal Suppositories

Begin treatment at bedtime. Before going to bed:

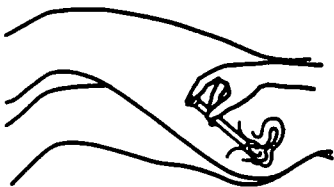
1 Tear off one suppository from the strip. Separate the plastic wrap with your thumb. With thumb and forefinger on each hand, hold the plastic tabs and pull apart (see illustration).



2 Place suppository in the top of the applicator as shown.



3 Hold the applicator containing the suppository by the opposite end from where the suppository is. Gently insert the applicator into the vagina as far as it will go comfortably. As shown in the picture, this can be done while lying on your back with your knees bent or you

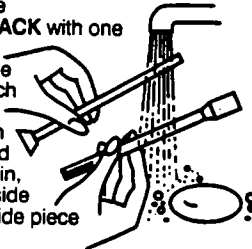


can stand with your feet spread a few inches apart and your knees bent.

Once you are ready, push the inside piece of the applicator in and place the suppository as far back in the vagina as possible. Then remove the applicator from the vagina. You should go to bed as soon as possible after inserting the suppository. This will keep leakage to a minimum.

You may want to use deodorant-free minipads or pantyshields during the time that you are using the Vaginal Suppositories. This is because the suppository can leak and/or you may see some discharge. **DO NOT USE TAMPONS.**

4 If you are using the **COMBINATION PACK with Disposable Applicators**, throw away the applicator after each use. **DO NOT FLUSH IN TOILET.** Use a new applicator for each dose. If you are using the **COMBINATION PACK** with one plastic applicator, be sure to clean the applicator after each use. Pull the two pieces apart. Wash them with soap and warm water. To rejoin, gently push the inside piece into the outside piece as far as it will go.

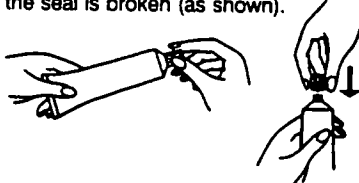


5 Repeat steps 1 through 4 before going to bed on each of the next two evenings.

External Vulvar Cream

Use the cream twice daily if needed as follows:

1 Open the tube. To do this, unscrew the cap, turn the cap upside down and place the cap in the end of the tube. Push down firmly until the seal is broken (as shown).



2 Squeeze a small amount of cream onto your finger.

3 Gently apply the cream onto the skin (vulva) that itches and is irritated.

4 Repeat steps 2 and 3 each morning and evening as needed.

ADVERSE REACTIONS (SIDE EFFECTS)

The following side effects have been reported with the use of the products in this **COMBINATION PACK**: a temporary increase in burning, itching, and/or irritation when the suppository is inserted. Abdominal cramping, headaches, hives, and skin rash have also been reported. If any of these occur, stop using this product and consult your doctor.

FOR BEST RESULTS

1. Be sure to use all of the suppositories even if your symptoms go away before you have used all the suppositories.
2. Use one suppository at bedtime for three nights in a row, even during your menstrual period.
3. Wear cotton underwear.
4. If your partner has any penile itching, redness, or discomfort, he should consult his doctor and mention 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 workout clothes as soon as possible. A dry area is less likely to encourage the growth of yeast.
6. Wipe from front to rear (away from the vagina) after a bowel movement or urination.
7. Do not douche unless your doctor tells you to do so. Douching may disturb the vaginal bacterial balance.
8. Do not scratch if you can help it. Scratching can cause more irritation and can spread the infection.
9. Discuss with your doctor any medication you are now taking. Certain types of medication can make your vagina more prone to infection.

IF YOU HAVE A QUESTION

Questions of a medical nature should be taken up with your doctor.

ACTIVE INGREDIENTS

VAGINAL SUPPOSITORIES - miconazole nitrate (200 mg each suppository).
EXTERNAL VULVAR CREAM - miconazole nitrate 2%.

STORAGE

Store at room temperature 15 to 30°C (59 to 86°F). Avoid heat (over 30°C or 86°F).

MANUFACTURED BY
PERRIGO ALLEGAN, MI 49010 U.S.A.

REVISED 11/97

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