

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

74-926

APPROVED DRAFT LABELING

NOW AVAILABLE WITHOUT A PRESCRIPTION

ALPHARMA
NDC 0472-7310-03

Combination
Pack

M-ZOLE 3 COMBINATION PACK

Miconazole Nitrate Vaginal Suppositories USP, 200 mg and Miconazole Nitrate External Vulvar Cream, 2%

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

3 DAY TREATMENT • FULL PRESCRIPTION STRENGTH

Vaginal Suppositories plus Cream for External Relief

M-ZOLE 3 COMBINATION PACK

Miconazole Nitrate Vaginal Suppositories USP, 200 mg and Miconazole Nitrate External Vulvar Cream, 2%

16 1995

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3 MICONAZOLE NITRATE VAGINAL SUPPOSITORIES USP, 200 mg
plus MICONAZOLE NITRATE EXTERNAL VULVAR CREAM

NET WT 0.32 OZ (9 g) TUBE

ALPHARMA

M-ZOLE 3
COMBINATION PACK
Miconazole Nitrate Vaginal Suppositories USP, 200 mg and
Miconazole Nitrate External Vulvar Cream, 2%



BDXALL, INC.

usually transmitted diseases or pregnancy while using
Miconazole Nitrate Vaginal Suppositories
• DO NOT USE IN GIRLS LESS THAN 12 YEARS OF AGE.
• If you are pregnant or think you may be pregnant, do not use
this product 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 help or
contact a poison control center immediately.
IMPORTANT: DO NOT PURCHASE IF CARTON IS WRAPPED EACH
SUPPOSITORY IS INDIVIDUALLY WRAPPED. IF WRAPER IS
MISSING OR DAMAGED, DO NOT USE. THE TUBE OPENING
SHOULD BE SEALED. IF SEAL HAS BEEN PUNCTURED OR IS NOT
VISIBLE, DO NOT USE. RETURN THE PRODUCT TO THE STORE
WHERE YOU BOUGHT IT.
ACTIVE INGREDIENT:
Miconazole Nitrate Vaginal Suppositories USP—miconazole nitrate
(200 mg each).
Miconazole Nitrate External Vulvar Cream—miconazole nitrate 2%.
INACTIVE INGREDIENTS:
Miconazole Nitrate Vaginal Suppositories USP—hydrogenated
vegetable oil base.
Miconazole Nitrate External Vulvar Cream—benzoic acid, BHA,
mineral oil, petrolatum, polyethylene glycol, purified water.
Store at room temperature 59°-86°F (15°-30°C).
Avoid heat (over 86°F or 30°C).
See end flap for lot number and expiration date.
Manufactured by Alpharma USP, Inc., Baltimore, MD 21244
7310109681 VC12236

SUPPOSITORIES AND CREAM AS DIRECTED
INSTRUCTIONS: For the treatment of vaginal yeast infections
(candidiasis) and the relief of external vulvar itching and irritation
associated with a yeast infection.
Before using, read the enclosed brochure.
FOR VAGINAL USE ONLY. DO NOT USE IN EYES OR TAKE BY
MOUTH.
DIRECTIONS: Suppositories—Insert one Miconazole Nitrate Vaginal
Suppository high into the vagina at bedtime for three nights in a
row to treat vaginal yeast infection. Applicator and instructions are
enclosed.
Cream—squeeze a small amount of cream onto your finger and
gently spread the cream onto the affected area of the vulva twice
daily (morning and bedtime) 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.
WARNINGS: DO NOT USE M-ZOLE 3 COMBINATION PACK IF YOU
HAVE ANY OF THE SIGNS AND SYMPTOMS LISTED BELOW.
ALSO, IF THEY OCCUR WHILE USING M-ZOLE 3 COMBINATION
PACK, STOP USING THE PRODUCT AND CONTACT YOUR DOCTOR
RIGHT AWAY. YOU MAY HAVE A MORE SERIOUS ILLNESS.
• FEVER (HIGHER THAN 100°F ORALLY).
• PAIN IN THE LOWER ABDOMEN, BACK, OR EITHER SHOULDER.
• A VAGINAL DISCHARGE THAT SMELLS BAD.
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
YEAST INFECTION. CONSULT YOUR DOCTOR. If your symptoms
return within two months or if you have infections that do not
clear up easily with proper treatment, consult your doctor. You
could be pregnant or there could be a serious underlying medical

ALPHARMA.
NDC 0472-7310-03

Combination
Pack

M-ZOLE 3 COMBINATION PACK

Miconazole Nitrate Vaginal Suppositories USP, 200 mg and Miconazole Nitrate External Vulvar Cream, 2%

3 DAY TREATMENT • FULL PRESCRIPTION STRENGTH

M-Zole 3 Combination Pack is now available without a prescription. This full prescription strength 3 day treatment cures most vaginal yeast infections and provides external relief.

IF THIS IS THE BEST TIME YOU HAVE HAD VAGINAL OR VULVAR ITCH AND DISCOMFORT, CONSULT YOUR DOCTOR. IF YOU HAVE HAD A DOCTOR DIAGNOSE A VAGINAL YEAST INFECTION BEFORE AND HAVE THE SAME SYMPTOMS NOW, USE THESE SUPPOSITORIES AND CREAM AS DIRECTED.

INDICATIONS: For the treatment of vaginal yeast infections (candidiasis) and the relief of external vulvar itching and irritation associated with a yeast infection.

Before using, read the enclosed brochure.

FOR VAGINAL USE ONLY. DO NOT USE IN EYES OR TAKE BY MOUTH.

DIRECTIONS: Suppositories—Insert one Miconazole Nitrate Vaginal Suppository high into the vagina at bedtime for three nights in a row to treat vaginal yeast infection. Applicator and instructions are enclosed.

Cream—Squeeze a small amount of cream onto your finger and gently spread the cream onto the affected area of the vulva twice daily (morning and bedtime) 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.**

WARNINGS: DO NOT USE M-ZOLE 3 COMBINATION PACK IF YOU HAVE ANY OF THE SIGNS AND SYMPTOMS LISTED BELOW. ALSO, IF THEY OCCUR WHILE USING M-ZOLE 3 COMBINATION PACK, STOP USING THE PRODUCT AND CONTACT YOUR DOCTOR RIGHT AWAY. YOU MAY HAVE A MORE SERIOUS ILLNESS.

- FEVER (HIGHER THAN 100°F ORALLY).
- PAIN IN THE LOWER ABDOMEN, BACK, OR EITHER SHOULDER.
- A VAGINAL DISCHARGE THAT SMELLS BAD.

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 YEAST INFECTION. CONSULT YOUR DOCTOR. If your symptoms return within two months or if you have infections that do not clear up easily with proper treatment, consult your doctor. You could be pregnant or there could be a serious underlying medical

cause for your infections, including diabetes or a damaged immune system (including damage from infection with HIV—the virus that causes AIDS). (PLEASE READ EDUCATIONAL BROCHURE FOUND INSIDE PACKAGE.)

Hydrogenated vegetable oil may weaken latex in condoms or diaphragms. These suppositories contain hydrogenated vegetable oil. Do not rely on condoms or diaphragms to prevent sexually transmitted diseases or pregnancy while using Miconazole Nitrate Vaginal Suppositories.

- 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 pregnant, do not use this product 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 help or contact a poison control center immediately.

IMPORTANT: DO NOT PURCHASE IF CARTON IS OPENED. EACH SUPPOSITORY IS INDIVIDUALLY WRAPPED. IF WRAPPER IS MISSING OR DAMAGED, DO NOT USE. THE TUBE OPENING SHOULD BE SEALED. IF SEAL HAS BEEN PUNCTURED OR IS NOT VISIBLE, DO NOT USE. RETURN THE PRODUCT TO THE STORE WHERE YOU BOUGHT IT.

ACTIVE INGREDIENT:

Miconazole Nitrate Vaginal Suppositories USP—miconazole nitrate (200 mg each).

Miconazole Nitrate External Vulvar Cream—miconazole nitrate 2%.

INACTIVE INGREDIENTS:

Miconazole Nitrate Vaginal Suppositories USP—hydrogenated vegetable oil base.

Miconazole Nitrate External Vulvar Cream—benzoic acid, BHA, mineral oil, pegicol 5 oleate, pegocol 7 stearate, purified water.

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

Avoid heat (over 86°F or 30°C).

See end flap for lot number and expiration date.

Manufactured by Alpharma USPO Inc., Baltimore, MD 21244
731010681 VC10238



BOXALL, INC.

NET WT 0.32 OZ (9 g) TUBE

3 MICONAZOLE NITRATE VAGINAL SUPPOSITORIES USP, 200 mg plus MICONAZOLE NITRATE EXTERNAL VULVAR CREAM

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

Miconazole Nitrate Vaginal Suppositories USP, 200 mg and Miconazole Nitrate External Vulvar Cream, 2%

M-ZOLE
COMBINATION
PACK

ALPHARMA.

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M-Zole 3 Combination Pack
ANDA#74-926
Alpharma USPD Inc.

Final Printed Labeling - Suppository Foil

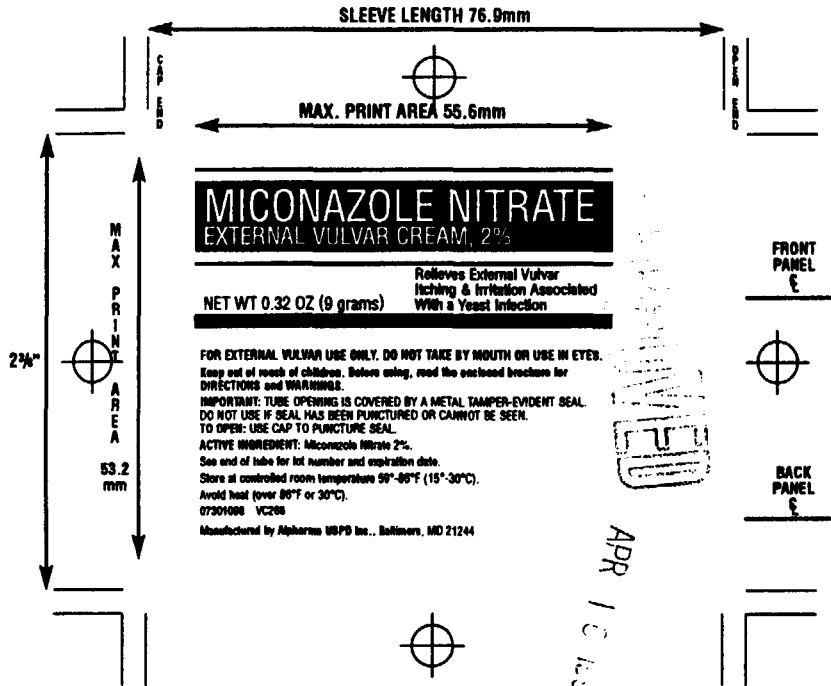
NOT FOR ORAL USE • FOR VAGINAL USE ONLY
MICONAZOLE NITRATE
VAG. SUPP. USP 200 mg
Mfg. by: Alpharma USPD Inc., Baltimore, MD 21244

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VAG. SUPP. USP 200 mg
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APPROVED

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APR 16 1999



**EDUCATIONAL BROCHURE
FULL PRESCRIPTION STRENGTH
M-ZOLE 3 COMBINATION PACK**
MICONAZOLE NITRATE VAGINAL SUPPOSITORIES USP, 200 mg and
MICONAZOLE NITRATE EXTERNAL VULVAR CREAM, 2%
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 M-ZOLE 3 COMBINATION PACK should work for you. If, however, you have never had these symptoms before, you should see your doctor before using M-ZOLE 3 COMBINATION PACK. M-ZOLE 3 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 M-ZOLE 3 COMBINATION PACK.

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 M-ZOLE 3 COMBINATION PACK if you have any of the following signs and symptoms. Also, if they occur while using M-ZOLE 3 COMBINATION PACK, **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 M-ZOLE 3 COMBINATION PACK.
- 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.

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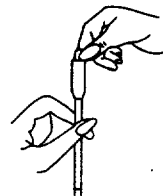
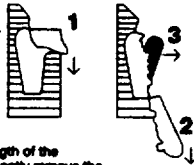
MICONAZOLE NITRATE VAGINAL SUPPOSITORIES USP: Three vaginal suppositories each containing 200 mg of miconazole nitrate. One plastic applicator.

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

DIRECTIONS FOR USE

Miconazole Nitrate Vaginal Suppositories
Begin treatment at bedtime. Before going to bed:

- 1** Break off suppository from the foil wrap. Tear the foil at the V-out and peel the foil in a downward motion (1). Continue tearing downward to almost the full length of the suppository (2). Gently remove the suppository from the foil pocket (3).



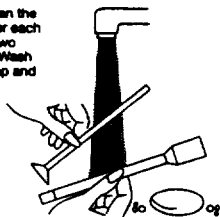
- 2** Place suppository in the top of the applicator as shown.

- 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 pictures, this can be done while standing with your feet spread a few inches apart and your knees bent. Or, you can lie on your back with 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.



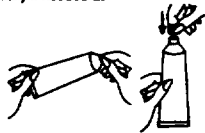
You may want to use deodorant-free mini-pads or pantyshield during the time that you are using miconazole nitrate vaginal suppositories. This is because the suppository can leak. **DO NOT USE TAMPONS.**

- 4** 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.



Miconazole Nitrate 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 M-ZOLE 3 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 M-ZOLE 3 COMBINATION PACK 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

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

STORAGE

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

Manufactured by
Alphaforma USPD Inc.
Baltimore, MD 21244

FORM NO. 7310

VC1381

Rev. 11/97