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Miconazole Nitrate Vaginal Cream (4%)

VAGINAL ANTIFUNGAL

Cures Most Vaginal Yeast Infections
and Relieves Associated External Itching and Irritation

Why should I use MONISTAT® 3 Vaginal Cream?

MONISTAT® 3 Vaginal Cream contains 4% Miconazole Nitrate cream in prefilled applicators that cures most vaginal yeast infections. **Do not use MONISTAT® 3 Vaginal Cream if this is the first time you have vaginal discharge, itching, burning, or discomfort. See your doctor or health professional first to find out the cause of your symptoms.** If a doctor has told you in the past that you had a yeast infection and you have the same symptoms now (such as vaginal discharge, itching, or burning), then MONISTAT® 3 Vaginal Cream may work for you.

What is a vaginal yeast infection?

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 of the vagina (vulva) at the same time that 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 immunodeficiency 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 number is: 1-800-232-4636 (English and Spanish), or 1-888-232-6348 (hearing impaired, TDD).

How can I tell if 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
- vaginal discharge that may be thick, white, and lumpy like cottage cheese
- vaginal soreness, irritation, or burning
- 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, chills, lower abdominal, back or shoulder pain, foul-smelling vaginal discharge, or a missed period. These may be signs of a sexually transmitted disease (STD) or a tubal pregnancy. If you have these symptoms, call your doctor right away.

What are other causes of a vaginal discharge?

It is normal to have a small amount of vaginal discharge at certain times of the month. This normal discharge may be clear or slightly white and does not cause itching, pain or a foul odor.

The most common cause of an abnormal vaginal discharge is an infection. These infections include bacterial vaginosis (BV), trichomoniasis (Trich), gonorrhea (GC) and/or chlamydia. All of these may be transmitted sexually and are called sexually transmitted diseases (STDs). If you have more questions about sexually transmitted diseases (STDs) call the CDC STD Hotline at 1-800-227-8922.

Although many of the infections mentioned above can cause symptoms similar to a vaginal yeast infection (vaginal discharge, irritation and itching), their diagnosis must be made by a doctor so that proper treatment can be given.

If these infections are not properly treated or if proper treatment is delayed, serious problems, such as pelvic inflammatory disease (PID) may result, which may prevent you from having children in the future. If you are pregnant and do not get the proper treatment, the infection may be passed to your baby before or during delivery and may cause your baby to have permanent damage. If you have multiple

sex partners or a new sex partner, you should also ask a doctor before use to make sure you do not have an STD.

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 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 immunodeficiency virus (HIV - the virus that causes AIDS). Infection with HIV causes the person to be more prone to get infections, including vaginal yeast infections.

If you get vaginal yeast infections often (such as once a month or 3 in 6 months), you should talk to a doctor.

Are vaginal yeast infections sexually transmitted?

Vaginal yeast infections are usually not spread by having intercourse (sex). However, if your partner has a rash, itching or discomfort in his genital area, he should contact a doctor to find out the cause of his symptoms and tell the doctor that you are treating your vaginal yeast infection with MONISTAT® 3 Vaginal Cream. **See your doctor or health professional first to find out the cause of your symptoms.** If a doctor has told you in the past that you had a yeast infection and you have the same symptoms now (such as vaginal discharge, itching, or burning), then MONISTAT® 3 Vaginal Cream may work for you.

How can I prevent repeated vaginal yeast infections?
To lower your chances of getting another yeast infection:

- 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.

■ 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. Do not stop taking these drugs without first asking your doctor. A doctor may need to see you to make sure that you do not have other medical conditions such as diabetes or a weakened immune system.

Can I use MONISTAT® 3 Vaginal Cream during my menstrual period?

Yes, this product can be used during your menstrual period. In fact, many women get vaginal yeast infections just before their period because of hormonal changes. Using MONISTAT® 3 Vaginal Cream during your period will not affect how well this product works. If you have started treatment and your period occurs, you should complete the full course of treatment.

Do not use tampons while using this product, because tampons may remove some of the drug from the vagina. Use deodorant-free sanitary napkins or pads instead, and change them often.

Can I use other vaginal products with MONISTAT® 3 Vaginal Cream?

This drug should not be used with other vaginal products.

- Douches and tampons may remove some of the MONISTAT® 3 Vaginal Cream from the vagina.
- Spermicides may interfere with MONISTAT® 3 Vaginal Cream.
- Condoms and diaphragms may be damaged by this product and fail to prevent pregnancy or sexually transmitted diseases (STDs).

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

■ Use 1 prefilled applicator of vaginal cream at bedtime, even during your menstrual period for 3 nights in a row.

■ 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.

■ Wear cotton underwear and loose-fitting clothes.

■ Wipe front to back after a bowel movement or after urination.

■ Do not douche, because douching may wash the drug out of the vagina.

■ Do not use tampons, because they remove some of the drug from the vagina. Use deodorant-free sanitary napkins or pads as needed.

■ Do not use spermicides, as they may interfere with MONISTAT® 3 Vaginal Cream.

■ Do not have vaginal intercourse while using MONISTAT® 3 Combination Pack.

■ 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 are taking any of these drugs do not stop taking them without first asking a doctor.

If these infections are not properly treated or if proper treatment is delayed, serious problems, such as pelvic inflammatory disease (PID) may result, which may prevent you from having children in the future. If you are pregnant and do not get the proper treatment, the infection may be passed to your baby before or during delivery and may cause your baby to have permanent damage. If you have multiple

vaginal itching and discomfort for the first time. You may need a different treatment.

What side effects may occur with Monistat® 3 Vaginal Cream?

A mild increase in vaginal burning, itching, or irritation may occur when the applicator containing the cream is inserted. Abdominal cramping has also been reported.

If these infections are not treated adequately or if the treatment adequately used, the infection may pass to the fetus in the future. If you are pregnant and have vaginal burning, rash, or if you have severe vaginal burning, itching, or irritation, stop using MONISTAT® 3 Vaginal Cream and consult your doctor if you have abdominal pain, hives, skin rash, or if you have severe vaginal burning, itching, or irritation or swelling.

What should I do if I have questions about Monistat® 3 Vaginal Cream?

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. Call between 8AM and 5PM EST Monday through Friday. A healthcare specialist will gladly answer your questions. Call toll-free 1-877-MONISTAT (1-877-666-4782).

Other Information:

- TAMPER EVIDENT FEATURE - do not use if printed applicator wrapper is torn, open or incompletely sealed.
- store at 20°-25°C (68°-77°F).

Active ingredients: miconazole nitrate 4% (200 mg per applicator)

Inactive ingredients: benzoic acid, cetyl alcohol, isopropyl myristate,

polysorbate 60, potassium hydroxide, propylene glycol, purified water, stearyl alcohol.

How Should I Use MONISTAT® 3 Vaginal Cream in 3 prefilled applicators?

This product is for adults and children 12 years of age and over. For children under 12 years, ask a doctor.

Directions for using the applicator containing the vaginal cream:

Begin treatment before going to bed:

- 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.
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