MICONAZOLE 7 - miconazole nitrate cream
Actavis Mid Atlantic LLC

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Miconazole Nitrate Vaginal Cream

ACTIVE INGREDIENT
Miconazole nitrate 2% (100 mg in each applicator/external cream)

PURPOSE
Vaginal antifungal

USES
- treats vaginal yeast infections
- relieves external itching and irritation due to a vaginal yeast infection

WARNINGS
For vaginal use only

DO NOT USE
If you have never had a vaginal yeast infection diagnosed by a doctor

ASK A DOCTOR BEFORE USE IF YOU HAVE
- vaginal itching and discomfort for the first time
- vaginal yeast infections often (such as once a month or 3 in 6 months). You could be pregnant or have a medical condition, such as diabetes or a weakened immune system.
- lower abdominal, back, or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You may have a more serious condition.
- been exposed to the human immunodeficiency virus (HIV) that causes AIDS

ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE
Taking a prescription blood thinning medicine, such as warfarin, because bleeding or bruising may occur

WHEN USING THIS PRODUCT
- do not use tampons, douches, spermicides or other vaginal products
- do not use condoms or diaphragms. They may be damaged by this product and not prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse (sex)
- mild increase in vaginal burning or irritation may occur

STOP USE AND ASK A DOCTOR IF
- symptoms do not get better after 3 days
- symptoms last more than 7 days
you get a rash, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge

IF PREGNANT OR BREAST-FEEDING
Ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN.
If swallowed, get medical help or contact the Poison Control Center right away.

DIRECTIONS
• before using this product read the enclosed brochure for complete instructions
• adults and children 12 years of age and over:
  • applicator: insert one applicatorful into the vagina at bedtime for 7 days in a row. Wash applicator after each use.
  • external cream: squeeze a small amount of cream onto your fingertip. Gently apply the cream onto the itchy, irritated skin outside the vagina. Use 2 times daily for up to 7 days as needed.
• children under 12 years: ask a doctor

Other Information
• to open tube use cap to puncture seal
• do not purchase if carton is opened
• do not use if seal over tube opening has been punctured or is not visible
• store at room temperature 15( - 30(C (59( - 86(F), avoid heat (over 30(C or 86(F).

INACTIVE INGREDIENTS
benzoic acid, BHA, mineral oil, peglicol-5 oleate, pegoxol 7 stearate, purified water

QUESTIONS?
1-800-432-8534 (select option #2) between 9 am and 4 pm EST, Monday – Friday.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL
NDC 0472-0730-63
Compare to the active ingredient in Monistat® 7 Vaginal Cream*
Miconazole 7
Miconazole Nitrate Vaginal Cream USP 2%
CURES MOST VAGINAL YEAST INFECTIONS
And Relieves Associated External Itching and Irritation
1 Reusable Applicator
7-DAY VAGINAL CREAM
NET WT 1.59 OZ (45 g)
Miconazole 7
Miconazole Nitrate Vaginal Cream USP 2%
VAGINAL ANTIFUNGAL (Miconazole Nitrate 100 mg per applicator)
CURES MOST VAGINAL YEAST INFECTIONS
And Relieves Associated External Itching and Irritation

Miconazole 7
Miconazole Nitrate Vaginal Cream USP 2%
CURES MOST VAGINAL YEAST INFECTIONS
And Relieves Associated External Itching and Irritation
1 reusable applicator
7 DAY VAGINAL CREAM
NET WT 1.59 OZ (45 g)
EDUCATIONAL BROCHURE

Miconazole Nitrate Vaginal Cream USP 2%

Vaginal Antifungal

1 Plastic Applicator (Miconazole Nitrate 100 mg per applicator)

Cures Most Vaginal Yeast Infections

Relieves External Vaginal Itching and Irritation Associated with a Yeast Infection

Use

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

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 Miconazole Nitrate 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. Do not use for external vaginal (vulvar) itching due to causes other than a yeast infection.**

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 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. 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 Miconazole Nitrate Vaginal Cream.

Warnings

- For vaginal use only. Do not use in eyes or take by mouth.
- This product is effective only in treating vaginal yeast infections.
- Do not use Miconazole Nitrate 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.
- Ask a doctor or pharmacist before use if you are taking a prescription blood thinning medicine, such as warfarin, because bleeding or bruising may occur.
- While using Miconazole Nitrate 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 out of 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 Miconazole Nitrate Vaginal
Cream is inserted. Abdominal cramping has also been reported. Stop using Miconazole Nitrate 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.

**How to use Miconazole Nitrate Vaginal Cream with 1 plastic applicator.**

**Directions for Use**

**Vaginal Application**

Use the cream at bedtime for 7 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 pictures.)

2. Attach the applicator to the tube of cream by placing “A” end of the applicator onto tube of cream then turning applicator clockwise. (See picture.)
3. Gently squeeze the cream into the applicator, continue squeezing until applicator is full. Separate the applicator from the tube. DO NOT release pressure on the tube until you have separated it from the filled applicator. After each use, replace the cap and roll up the tube from the bottom.

4. Hold the barrel as shown in the picture.
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 knees bent.

6. With one hand holding the barrel use the other hand to push the plunger as far into the barrel as it will go. Remove applicator from the vagina.

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

8. Clean the applicator after each use. Gently pull apart the applicator pieces and wash them with soap and warm water. To put back together gently push the inside piece into the larger end of the outside piece as far as it will go.

9. Repeat steps 2 through 8 before bedtime for the next 6 days.

You may want to use deodorant-free minipads or pantyshields to protect your clothing during the time that you are using Miconazole Nitrate Vaginal Cream. This is because the cream can leak or you may get some discharge. Do not use tampons, douches, or spermicides until after you have completed treatment and your symptoms are gone.

External Vaginal (Vulvar) Application

If you experience external irritation, use the cream twice daily as follows:

1. Squeeze a small amount of cream onto your finger.
2. Gently apply the cream onto the skin outside the vagina (vulva) that itches and is irritated.
3. Repeat each morning and evening as needed for up to 7 days.

For Best Results

1. Be sure to use this product for the full 7 days, even if your symptoms go away sooner.
2. Use one applicatorful of cream at bedtime for seven 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

1-800-432-8534 (select option #2).

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

Active Ingredient

Miconazole Nitrate (2%) (100 mg per applicator).

Inactive Ingredients: Benzoic acid, BHA, mineral oil, pegilcol 5 oleate, pegoxol 7 stearate, purified water.

Storage

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

Manufactured by:
Actavis Mid Atlantic LLC
1877 Kawai Road, Lincolnton, NC 28092 USA

FORM NO. 0730-63
Rev. R/08
VC3335
**MICONAZOLE 7**
miconazole nitrate cream

### Product Information

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### Product Characteristics

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**Labeler** - Actavis Mid Atlantic LLC (809515898)

Revised: 9/2011