

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**20-827**

**DRAFT PRINTED LABELING**

**FOLDING CARTON**

**MONISTAT® 3 Vaginal Cream in Prefilled Applicators**

**FLAG IN CORNER OF PACKAGE** (Note: Flag will be removed in 6 months.)

**New! Three Day Cream**

**FRONT PANEL**

**MONISTAT® 3  
Miconazole Nitrate Cream  
Vaginal Cream**

**Cures Most Vaginal Yeast Infections**

**Ortho  
Logo**

**3 Day Vaginal Cream  
In Prefilled Applicators**

**3 Prefilled Applicators  
Net wt. 0.18 oz (5g) each**

**TOP PANEL**

**MONISTAT® 3  
Miconazole Nitrate Cream  
Vaginal Cream**

**3 Prefilled Applicators (200 mg miconazole nitrate per applicator)**



**If you have questions or comments, please call 1-800-782-4051.**

**BOTTOM PANEL**

**MONISTAT® 3  
Miconazole Nitrate Cream  
Vaginal Cream**

**3 Prefilled Applicators (200 mg miconazole nitrate per applicator)**



**If you have questions or comments, please call 1-800-782-4051.**

**SIDE PANELS**

**MONISTAT® 3  
Miconazole Nitrate Cream  
Vaginal Cream**

**3 Prefilled Applicators (200 mg miconazole nitrate per applicator)**

**00-000003**

## **FOLDING CARTON**

### **MONISTAT® 3 Vaginal Cream in Prefilled Applicators**

#### **BACK PANEL**

**MONISTAT® 3**  
**Miconazole Nitrate Cream**  
**Vaginal Cream**

MONISTAT® 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:** miconazole nitrate (200 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 MONISTAT 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 MONISTAT 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 two 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.**
- **In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.**

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## **FOLDING CARTON**

### **MONISTAT® 3 Vaginal Cream in Prefilled Applicators**

#### **BACK PANEL** (con't)

**Directions:** Insert one prefilled applicator into the vagina at bedtime for 3 days in a row. Before using, read the enclosed brochure for complete instructions.

**Inactive Ingredients:** benzoic acid, cetyl alcohol, isopropyl myristate, polysorbate 60, potassium hydroxide, propylene glycol, purified water, stearyl alcohol.

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

**Important:** Do not purchase if carton is opened. Each applicator is individually wrapped. If wrapper is missing or damaged, do not use. 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 24 hour automated response system at 1-800-782-4051. Nurses are available between the hours of 8am to 5pm EST, Monday through Friday. You can also visit our website at [www.monistat.com](http://www.monistat.com)

#### **ADVANCED CARE PRODUCTS**

Manufactured by: Ortho-McNeil Pharmaceutical, Inc., Raritan, New Jersey 08869  
For: Advanced Care Products, Personal Products Co., Division of McNeil-PPC, Inc.  
© OMPI 1998 MADE IN U.S.A.  
Covered under Patent number 5,514,698.

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## **EDUCATIONAL BROCHURE**

### **MONISTAT® 3 Vaginal Cream in Prefilled Applicators**

#### **Educational Brochure**

**MONISTAT® 3**  
**Miconazole Nitrate Cream**  
**Vaginal Cream**

**Prefilled Applicators (200 mg miconazole nitrate per applicator)**

#### **Cures Most Vaginal Yeast Infections**

#### **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 MONISTAT 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: (at) 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).

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## **EDUCATIONAL BROCHURE (cont'd)**

### **MONISTAT<sup>®</sup> 3 Miconazole Nitrate Vaginal Cream (4%)**

**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 MONISTAT 3 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 MONISTAT 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 MONISTAT 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 two 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.
- In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

#### **Adverse Reactions (Side Effects)**

A mild increase in vaginal burning, itching, or irritation may occur when MONISTAT 3 Vaginal Cream is inserted. Abdominal cramping has also been reported. Stop using MONISTAT 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 all three prefilled applicators even if your symptoms go away before three days.
2. Use one prefilled applicator at bedtime for three days in a row, even during your menstrual period.

## **EDUCATIONAL BROCHURE (cont'd)**

### **MONISTAT<sup>®</sup> 3 Miconazole Nitrate Vaginal Cream (4%)**

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, 1-800-782-4051**. The answer line is staffed by registered nurses between 8:00 a.m. and 5:00 p.m. Eastern Time, Monday through Friday. After business hours, our automated response system can provide helpful information and answer many of your questions. You can also visit our website at [www.monistat.com](http://www.monistat.com)

#### **Active Ingredient**

miconazole nitrate (200 mg per applicator).

Covered under Patent number 5,514,698.

#### **Storage**

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

#### **ADVANCED CARE PRODUCTS**

Manufactured by: Ortho-McNeil Pharmaceutical, Inc., Raritan, New Jersey 08869

For: Advanced Care Products, Personal Products Co., Division of McNeil-PPC, Inc.

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## **EDUCATIONAL BROCHURE**

### **MONISTAT® 3 Vaginal Cream in Prefilled Applicators**

The following are the instructions for use for MONISTAT 3 Vaginal Cream in Prefilled Applicators.

#### **Directions For Use**

Begin treatment before going to bed:

1. Unscrew and remove blue cap from prefilled applicator.
2. Insert plunger into prefilled applicator by placing small end of plunger into the grey hole at the end of the applicator.

(Illustration) [*Label plunger and barrel*]

3. 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.

(Illustration) [*Label vagina, uterus, and rectum.*]

With one hand holding the barrel use the other hand to push the plunger all the way in to place all the cream as far back in the vagina as possible. Then remove both parts of the applicator from the vagina. Throw away applicator after each use. Do not flush in toilet.

4. You should lie down as soon as possible after inserting the cream. This will reduce leakage.
5. Repeat steps 1 through 4 before going to bed for the next two days.

You may want to use deodorant-free minipads or pantyshields during the time that you are using MONISTAT 3 Vaginal Cream. This is because the cream can leak or you may see some discharge. Do not use tampons, douches, or spermicides until after you have completed treatment and your symptoms are gone.



**OVERWRAP**

**MONISTAT<sup>®</sup> 3 Vaginal Cream in Prefilled Applicators**

OVERWRAP for MONISTAT 3

**MONISTAT<sup>®</sup> 3**

**Miconazole Nitrate Cream  
Vaginal Cream**

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Active ingredient: 200 mg miconazole nitrate per applicator

For vaginal use only **ADVANCED CARE PRODUCTS**

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**ALTHOUGH APPLICATOR MAY NOT APPEAR TO BE FULL,  
IT HAS BEEN WEIGHED TO ENSURE FULL DOSAGE.**

Contents: 1 applicator prefilled with 5g vaginal cream

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