CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-261

APPROVED DRAFT LABELING

1/4/01
1-5

21360QU10
12/13/00

MONISTAT® 3

Miconazole Nitrate Cream
Vaginal Antifungal

Active ingredient: miconazole nitrate 4% (200 mg in each applicator)

For vaginal use only

000-00-000-0

Distributed by:
Personal Products Company
Division of McNeil-PPC, Inc., Skillman, NJ 08558
MADE IN U.S.A. ©McNeil-PPC, Inc. 2001

Although applicator may not appear to be full, it has been weighed to ensure full dosage.

Contents: 1 applicator prefilled with 5g vaginal cream

000-00-000-0

200%

1/4/01
S-2

21968IL04F
1/3/01
(M3PrefildCrmCmbo)

New Combo Pack!
Includes Cream for External Relief

3 DAY TREATMENT

3 Ready-to-Use Prefilled Applicators plus Cream for External Relief

MONISTAT 3
COMBINATION PACK

If you have any questions or comments, please call 1-877-MONISTAT (1-877-666-4782) or visit our website @ www.monistat.com

MONISTAT 3
COMBINATION PACK
(Miconazole Nitrate Vaginal Cream 4% plus External Cream 2%)
Vaginal Antifungal

(Miconazole Nitrate 200 mg per applicator plus 2% external vulvar cream)

CURES MOST VAGINAL YEAST INFECTIONS
AND RELIEVES ASSOCIATED EXTERNAL ITCHING AND IRRITATION

ORTHO

3 Prefilled Applicators
plus External Cream

MONISTAT 3

MONISTAT 3

MONISTAT 3

EXPIRATION DATE
LOT #

OPEN HERE

FOR POSITION ONLY
0 00000-00000 0

10 DIGIT BAR CODE 1/2" HEIGHT

10 DIGIT BAR CODE 1/2" HEIGHT

Note:
10 point Helvetica Bold Italic Title
8 point Helvetica Bold Italic Headings
6 point Helvetica Bold Italic Subheadings
6 point Helvetica Regular Text
0.5 point Leading

2.5 point box barline
2.5 point barline
0.5 point hairline

ORTHO-McNEIL
28145.EPS
Print Side Up
16-Aug-2000

1/4/01
3-5

21360IL15B
12/14/00
(ExtrnlCrm 9g. tube)

MONISTAT®
External Vulvar Cream

Miconazole Nitrate External Vulvar Cream 2%

ORTHO

Relieves External Vulvar Itching & Irritation Due to a Vaginal 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 leaflet for complete Directions and Warnings.

Directions: To Open: Use cap to puncture seal. Squeeze a small amount of cream onto your fingertip. Apply to skin outside the vagina (vulva) that itches and is irritated. Use 2 times daily for up to 7 days, as needed.

Tamper Resistant Feature: The tube opening should be sealed. Do not use if seal has been punctured or embossed design ▽ is not visible.

Active Ingredient: miconazole nitrate 2%.

See end of tube for lot number and expiration date.

Covered under patent Number 5,514,698

Store at 20°-25°C (68°-77°F).

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Artwork Created at 200% of Actual Size

Thomas J. Paul, Inc.
[illegible] RYDAL ROAD, RYDAL, PA [illegible] • [illegible] • [illegible]

Spot Color Inks

PANTONE 300 CV | PANTONE Black | PANTONE Cl Gy 10 CV

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CONSUMER INFORMATION LEAFLET

MONISTAT® 3
COMBINATION PACK
Miconazole Vaginal Cream and External Cream
Vaginal Antifungal

Cures Most Vaginal Yeast Infections
Relieves External Vulvar Itching and Irritation Due to a Vaginal Yeast Infection

Combination Pack: MONISTAT® 3 Vaginal Cream: miconazole nitrate 4% (200 mg per applicator) plus MONISTAT® External Vulvar Cream: miconazole nitrate 2%

Use
- treats vaginal yeast infections
- relieves external itching and irritation due to a vaginal 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 MONISTAT® 3 Vaginal Cream Combination Pack may work for you. **If, however, in the past you have never had these symptoms from a vaginal yeast infection, 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: 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).

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 Combination Pack.

Warnings
- For vaginal use only. Do not use in eyes or take by mouth.
- This product is effective only in treating vaginal yeast infections and relieving vulvar itching and irritation associated with a yeast infection.
- Do not use MONISTAT® 3 Vaginal Cream Combination Pack 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 Combination Pack, 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.
- Ask a doctor or pharmacist before use if you are taking a prescription blood thinning medicine such as warfarin, because bleeding and bruising may occur.
- 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 have vaginal intercourse 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. If swallowed, get medical help or contact a Poison Control Center right away.

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How to use MONISTAT 3® Vaginal Cream Combination Pack with 3 prefilled applicators and External Vulvar Cream.

Directions For Use

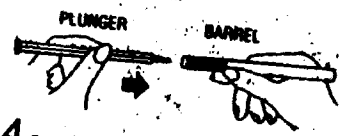
MONISTAT® 3 Vaginal Cream

Use the cream at bedtime for 3 days in a row. Read the full directions below before using.

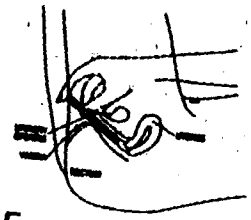
1 Remove the prefilled applicator from the wrapper.

2 Unscrew and remove blue cap from prefilled applicator.

3 Insert plunger into prefilled applicator by placing small end of plunger into the gray hole at end of the applicator.



4 Gently insert the applicator into the vagina as far 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.



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

6 Throw the applicator away after each use. Do not flush it down the toilet.

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

8 Repeat steps 1 through 7 before going to bed for the next 2 days.

You may want to use deodorant-free minipads or pantyshields to protect your clothing during the time that you are using MONISTAT® 3 Vaginal Cream Combination Pack. 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.

MONISTAT® External Vulvar Cream

Use the cream twice daily, for up to 7 days as needed.

1 Open the tube by unscrewing the cap. The first time the tube is opened, press the sharp point of the cap into the sealed end of the tube. Push down firmly until the seal is open.

2 Squeeze a small amount of cream onto your fingertip.

3 Apply the cream onto the skin outside the vagina (vulva) that itches and is irritated.

4 Screw the cap back on the tube.

5 Repeat steps 2-4 each morning and at bedtime for up to 7 days, as needed.

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 Combination Pack and consult your doctor if you have a rash, abdominal pain, or hives, or if you have severe vaginal burning, itching or irritation.

For Best Results

1. Be sure to use the prefilled applicators for the full 3 days even if your symptoms go away sooner.
2. Use one prefilled applicator at bedtime for three 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 because 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.

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, 1-877-MONISTAT (1-877-666-4782). The answer line is staffed by registered nurses between 8:00 a.m. and 5:00 p.m. Eastern Standard 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.

Active Ingredients

MONISTAT® 3 Prefilled Applicators: miconazole nitrate 4% (200 mg per applicator)
MONISTAT® External Vulvar Cream: miconazole nitrate 2%
Covered under Patent number 5,514,698.

Inactive Ingredients

Benzoic acid, cetyl alcohol, isopropyl myristate, polysorbate 60, potassium hydroxide, propylene glycol, purified water, stearyl alcohol.

Storage

Store at 20°-25°C (68°-77°F).

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