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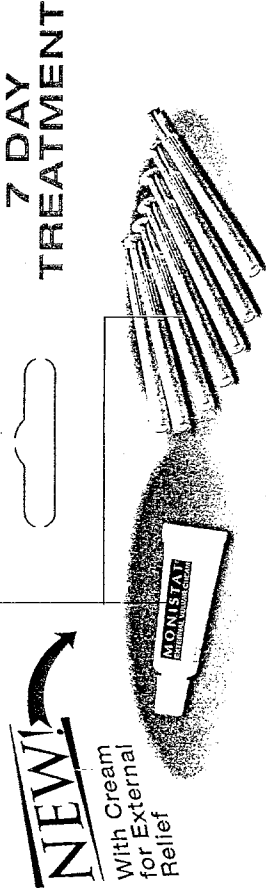
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PRODUCT AND APPLICATOR
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7 Ready-to-Use Prefilled Applicators plus Cream for External Relief

MONISTAT[®] 7
COMBINATION PACK
 Miconazole Nitrate Cream (2%) and External Cream (2%)
 Vaginal Antifungal

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

MONISTAT[®] 7
COMBINATION PACK
 Miconazole Nitrate Cream (2%) and External Cream (2%)
 Vaginal Antifungal

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

7 Prefilled Vaginal Applicators
plus External Cream

Net Wt. 0.18 oz.
 (5g) each applicator
 and (9g) tube



MONISTAT[®] 7
COMBINATION PACK
 Miconazole Nitrate Cream (2%) and External Cream (2%)
 Vaginal Antifungal

HOLD FOR LOT NUMBER
 AND EXPIRATION DATE

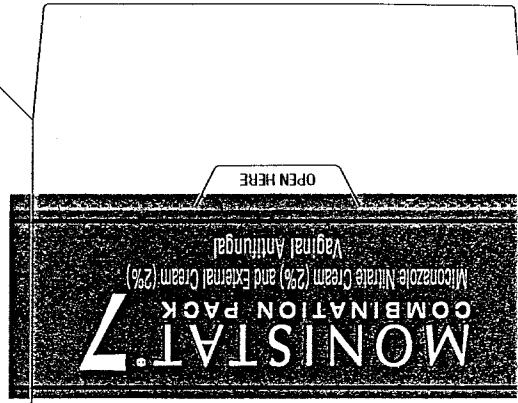
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NDA 17-450
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 6/13/02
 Custom labels
 (Drug facts)

MONISTAT 7
COMBINATION PACK
 Microzole Nitrate Cream (2%) and External Cream (2%)
 Vaginal Antifungal

visit our website @ www.monistat.com
 or visit our website @ www.monistat.com
 For more information, please call 1-877-MONISTAT (1-877-666-4782)
 Manufactured by: Personal Products Company, Division of McNeil-PPC, Inc., Skirmion, NJ 08558.
 Made in U.S.A. © McNeil-PPC, Inc. 2001 707-10-382-2 714810
 Covered under patent number 5,514,598



Drug Facts

Active Ingredients
 Microzole nitrate 2% (100 mg in each applicator)..... Vaginal antifungal
 Mononazole nitrate 2% (external cream)..... Vaginal antifungal

Purpose
 Treats vaginal yeast infections

Uses
 ■ 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
 ■ lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You may have a more serious condition.
 ■ vaginal yeast infections often (such as once a month or 3 in 6 months). You could be pregnant or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system.
 ■ been exposed to the human immunodeficiency virus (HIV) that causes AIDS

Ask a doctor or pharmacist before use if you are
 ■ taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur

When using this product
 ■ do not use tampons, douches, spermicides or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs).
 ■ do not have vaginal intercourse
 ■ mild increase in vaginal burning, itching or irritation may occur

Stop use and ask a doctor if
 ■ symptoms do not get better in 3 days
 ■ symptoms get worse, such as fever, chills, nausea, vomiting, or foul-smelling vaginal discharge

Drug Facts (continued)

Directions
 ■ before using this product, read the enclosed consumer information leaflet for complete instructions
 ■ adults and children 12 years of age and over:
 ■ applicator's insert: 1 applicatorful into the vagina at bedtime for 7 nights in a row. Throw applicator away after use.
 ■ external cream: squeeze a small amount of cream onto your fingertip. 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 of age: ask a doctor

Other information
 ■ do not use if applicator wrapper is missing or damaged (each applicator is individually wrapped)
 ■ do not use if seal over tube opening has been punctured or embossed design ("V") is not visible
 ■ do not purchase if carton is opened
 ■ store at 20°-25°C (68°-77°F)

Inactive ingredients
 benzoic acid, cetyl alcohol, isopropyl myristate, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, stearic alcohol

Questions? If you have any questions or comments, please call 1-877-666-4782

Note:
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 6 point Helvetica Bold Italic Subheadings
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 June 10, 2002
 JJ1002, Monistat 7 Combo.M1.1, 6/5/02
 Adobe Illustrator 8.0, Photoshop 6.0

Kristen Juegster
 Xavier, Malta
 Kara Denniston
 JR, XM, ck
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Consumer Information Leaflet

MONISTAT[®] 7 COMBINATION PACK Miconazole Nitrate Cream (2%) and External Cream (2%)

VAGINAL ANTIFUNGAL

Cures Most Vaginal Yeast Infections Relieves External Vulvar Itching and Irritation Associated With a Yeast Infection

Why should I use MONISTAT[®] 7 Vaginal Cream Combination Pack?

MONISTAT[®] 7 Vaginal Cream Combination Pack contains vaginal cream that cures most vaginal yeast infections, plus an external cream that can be used for relief of itching and irritation on the skin outside the vagina (vulva) due to a yeast infection. **Do not use MONISTAT[®] 7 Vaginal Cream Combination Pack if this is the first time you have vaginal discharge, itching, burning and 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 vaginal yeast infection and you have the same symptoms now (such as vaginal discharge, itching or burning), then MONISTAT[®] 7 Vaginal Cream Combination Pack 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 numbers are: 1-800-342-AIDS (English), 1-800-344-7432 (Spanish), or 1-800-243-7889 (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 likely 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[®] 7 Vaginal Cream Combination Pack.

How can I prevent repeated vaginal yeast infections?

- To lower your chances of getting another yeast infection:
 - Try 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[®] 7 Vaginal Cream Combination Pack 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[®] 7 Vaginal Cream Combination Pack 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[®] 7 Vaginal Cream Combination Pack?

- This drug should not be used with other vaginal products.
- Douches and tampons may remove some of the drug from the vagina.
 - Spermicides may interfere with MONISTAT[®] 7 Vaginal Cream Combination Pack.
 - Condoms and diaphragms may be damaged by this product and fail to prevent pregnancy or sexually transmitted diseases (STDs).



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NDA 17-450
SCP 052 BL
6/13/02
Consumer Information Leaflet
(front)

How Should I Use MONISTAT[®] 7 Vaginal Cream Combination Pack?

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 Prefilled Applicators
Begin treatment for going to bed:

- 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.

Directions for using the 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 seated 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.

When using this product:

- do not use tampons, douches, spermicides, or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse
- mild increase in vaginal burning, itching or irritation may occur

Stop use and ask your doctor if:

- symptoms do not get better in 3 days
- symptoms last more than 7 days
- you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge.

These may be signs that this product is not working, or you may have a more serious condition or an allergic reaction.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

What side effects may occur with MONISTAT[®] 7 Vaginal Cream Combination Pack?

A mild increase in vaginal burning, itching, or irritation may occur when the MONISTAT[®] 7 Vaginal Cream is inserted. Abdominal cramping has also been reported.

Stop using MONISTAT[®] 7 Vaginal Cream Combination Pack 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[®] 7 Vaginal Cream Combination Pack?

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 8:00 AM and 5:00 PM Eastern time, Monday through Friday. A nurse will gladly answer your questions. Our toll-free number is 1-877-MONISTAT (1-877-666-4782).

Other information:

- do not use if applicator wrapper is missing or damaged (each applicator is individually wrapped).
- do not use if tube seal has been punctured or embossed design symbol is not visible.
- store at 20° - 25° C (68° - 77° F)

Active Ingredients
MONISTAT[®] 7 Prefilled Applicators: miconazole nitrate 2% (100 mg per applicator)
MONISTAT[®] External Vulvar Cream: miconazole nitrate 2%

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

XXX-XX-XXXX-X

How Should I Use MONISTAT[®] 7 Vaginal Cream Combination Pack?

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 Prefilled Applicators
Begin treatment for going to bed:

- 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.

Directions for using the 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 seated 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.

When using this product:

- do not use tampons, douches, spermicides, or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse
- mild increase in vaginal burning, itching or irritation may occur

Stop use and ask your doctor if:

- symptoms do not get better in 3 days
- symptoms last more than 7 days
- you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge.

These may be signs that this product is not working, or you may have a more serious condition or an allergic reaction.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

What side effects may occur with MONISTAT[®] 7 Vaginal Cream Combination Pack?

A mild increase in vaginal burning, itching, or irritation may occur when the MONISTAT[®] 7 Vaginal Cream is inserted. Abdominal cramping has also been reported.

Stop using MONISTAT[®] 7 Vaginal Cream Combination Pack 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[®] 7 Vaginal Cream Combination Pack?

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MONISTAT[®] External Vulvar Cream: miconazole nitrate 2%

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

XXX-XX-XXXX-X

How Should I Use MONISTAT[®] 7 Vaginal Cream Combination Pack?

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 Prefilled Applicators
Begin treatment for going to bed:

- 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.

Directions for using the 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 seated 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.

When using this product:

- do not use tampons, douches, spermicides, or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse
- mild increase in vaginal burning, itching or irritation may occur

Stop use and ask your doctor if:

- symptoms do not get better in 3 days
- symptoms last more than 7 days
- you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge.

These may be signs that this product is not working, or you may have a more serious condition or an allergic reaction.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

What side effects may occur with MONISTAT[®] 7 Vaginal Cream Combination Pack?

A mild increase in vaginal burning, itching, or irritation may occur when the MONISTAT[®] 7 Vaginal Cream is inserted. Abdominal cramping has also been reported.

Stop using MONISTAT[®] 7 Vaginal Cream Combination Pack and consult your doctor if you have abdominal pain, hives, skin rash, or if you have severe vaginal burning, itching, or irritation or swelling.

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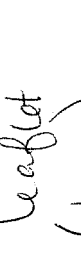
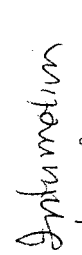
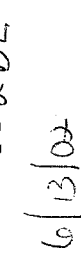
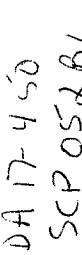
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MONISTAT[®] External Vulvar Cream: miconazole nitrate 2%

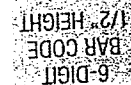
Inactive Ingredients
Benzoic acid, cetyl alcohol, isopropyl myristate, polysorbate 60, potassium hydroxide, propylene glycol, purified water, stearyl alcohol.

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NDA 17-450
SCP 052BL
6/13/02

Consumer
Information
leaflet
(back)



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Covered under Patent number 5,514,698.

Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine, warfarin (Coumadin), because bleeding or bruising may occur.

- vaginal yeast infections often (such as once a month or 3 in 6 months). You could be pregnant or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system.
- been exposed to the human immunodeficiency virus (HIV) that causes AIDS.

What warnings should I know about when using MONISTAT[®] 7 Vaginal Cream Combination Pack?
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. You may need a different treatment.
- lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You could have a more serious condition.

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.

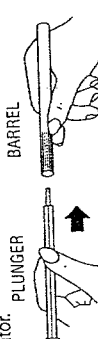
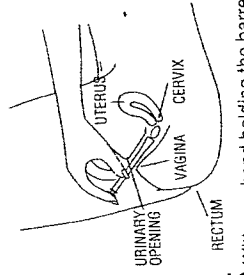
If you have any other medical questions or concerns about vaginal yeast infections, call your doctor.

What warnings should I know about when using MONISTAT[®] 7 Vaginal Cream Combination Pack?
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:

- lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You could have a more serious condition.
- vaginal yeast infections often (such as once a month or 3 in 6 months). You could be pregnant or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system.
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What warnings should I know about when using MONISTAT[®] 7 Vaginal Cream Combination Pack?
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:

- lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You could have a more serious condition.
- vaginal yeast infections often (such as once a month or 3 in 6 months). You could be pregnant or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system.
- been exposed to the human immunodeficiency virus (HIV) that causes AIDS.



- 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 all the way in to place the cream as far back in the vagina as possible. Then remove both parts of the applicator from the vagina.

6 Throw the applicator away after use. Do not flush in toilet.

7 Lie down as soon as possible after inserting the cream. This will reduce leakage.

8 Repeat steps 1 through 7 before going to bed for the next 6 days.

You may want to use deodorant-free pads or pantyliners to protect your clothing during the time that you are using MONISTAT[®] 7 Vaginal Cream Combination Pack. This is because the cream can leak or you may get some discharge. Do not use tampons, douches, spermicides, condoms or diaphragms until after you have completed treatment and your symptoms are gone.

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this page is the manifestation of the electronic signature.**

/s/

Linda Katz
8/7/02 11:10:17 AM