

NDA 20-670 MONISTAT 3® Combination Pack
Final Printed Labeling (FPI) for Supplement 014 - August 10, 2007



(b) (4)



(b) (4)



---Tear Here---

MONISTAT[®]3
Miconazole Nitrate Vaginal Insert (200mg)

FOR ORAL USE ONLY. DO NOT TAKE BY MOUTH.
Store at 20°-25°C (68°-77°F); see USP Controlled Room Temperature.

KEEP CONTENTS DRY BEFORE USE.
OPEN POIL POUCH JUST BEFORE USE.

© 2007 Monistat 3 Company
A Division of Mediatec, Inc.
Basking Ridge, NJ 08859-4115, Mediatec, Inc. 2007
MADE IN USA

NDA 20-670 MONISTAT 3® Combination Pack
Final Printed Labeling (FPL) for Supplement 014 - August 10, 2007

Consumer Information Leaflet

MONISTAT 3 COMBINATION PACK
Miconazole Nitrate Vaginal Insert (200 mg) and Miconazole Nitrate Vaginal Cream (2%)

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

Why should I use MONISTAT 3 Combination Pack?
MONISTAT 3 Combination Pack contains two OTC products that can be used for relief of itching and irritation of the vulva and the vaginal area...

What is a vaginal yeast infection?
A vaginal yeast infection is a common condition caused by an overgrowth of yeast (Candida) that normally lives in the vagina...

Why can't I get a vaginal yeast infection?
The use of a vaginal yeast infection at any age. It is not common for the following people: Women who are pregnant or diabetic...

Why can't I get a vaginal yeast infection?
The use of a vaginal yeast infection at any age. It is not common for the following people: Women who are pregnant or diabetic...

When you have a vaginal yeast infection, you may have one or more of the following symptoms:
itching/irritation of the vulva, itching and burning of the vulva, itching and burning of the vagina, itching and burning of the vulva and vagina...

How vaginal yeast infections are NOT caused:
lower abdominal, back or shoulder pain, hot, smelly vaginal discharge, or a vaginal odor that may be different from a normal vaginal odor...

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. The normal discharge may be clear or white and does not cause itching, pain or odor...

Why can't I get a vaginal yeast infection?
The use of a vaginal yeast infection at any age. It is not common for the following people: Women who are pregnant or diabetic...

Why can't I get a vaginal yeast infection?
The use of a vaginal yeast infection at any age. It is not common for the following people: Women who are pregnant or diabetic...

When you have a vaginal yeast infection, you may have one or more of the following symptoms:
itching/irritation of the vulva, itching and burning of the vulva, itching and burning of the vagina, itching and burning of the vulva and vagina...

If you get vaginal yeast infections often, you should see your doctor.
You may need to use MONISTAT 3 Combination Pack for 14 days...

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. The normal discharge may be clear or white and does not cause itching, pain or odor...

Why can't I get a vaginal yeast infection?
The use of a vaginal yeast infection at any age. It is not common for the following people: Women who are pregnant or diabetic...

Why can't I get a vaginal yeast infection?
The use of a vaginal yeast infection at any age. It is not common for the following people: Women who are pregnant or diabetic...

When you have a vaginal yeast infection, you may have one or more of the following symptoms:
itching/irritation of the vulva, itching and burning of the vulva, itching and burning of the vagina, itching and burning of the vulva and vagina...



How can I get the best results when treating my infection?
Use MONISTAT 3 Combination Pack as directed. Use during your menstrual period for 14 days...

How should I use MONISTAT 3 Combination Pack?
Directions for using 3 Applications and 3 OTC Products

Step 1: Open pouch and remove inserts.
Step 2: Place the OTC insert into the applicator...

Step 3: Insert the applicator containing the OTC insert into the vagina...

Step 4: Insert the applicator into the vagina so the OTC insert goes into the vagina...

Step 5: Wash the hand holding the applicator...

Step 6: Use the applicator after use. Do not flush in toilet.

Step 7: Use the applicator after use. Do not flush in toilet.

Step 8: Repeat steps 1-7 before bedtime for the next 2 days.

Directions for using the External Vulvar Cream
Use the cream before bed, for up to 7 days as needed.

How should I use MONISTAT 3 Combination Pack?
Directions for using 3 Applications and 3 OTC Products

Step 1: Open pouch and remove inserts.
Step 2: Place the OTC insert into the applicator...

Step 3: Insert the applicator containing the OTC insert into the vagina...

Step 4: Insert the applicator into the vagina so the OTC insert goes into the vagina...

Step 5: Wash the hand holding the applicator...

Step 6: Use the applicator after use. Do not flush in toilet.

Step 7: Use the applicator after use. Do not flush in toilet.

Step 8: Repeat steps 1-7 before bedtime for the next 2 days.

Directions for using the External Vulvar Cream
Use the cream before bed, for up to 7 days as needed.

How should I use MONISTAT 3 Combination Pack?
Directions for using 3 Applications and 3 OTC Products

Step 1: Open pouch and remove inserts.
Step 2: Place the OTC insert into the applicator...

Step 3: Insert the applicator containing the OTC insert into the vagina...

Step 4: Insert the applicator into the vagina so the OTC insert goes into the vagina...

Step 5: Wash the hand holding the applicator...

Step 6: Use the applicator after use. Do not flush in toilet.

Step 7: Use the applicator after use. Do not flush in toilet.

Step 8: Repeat steps 1-7 before bedtime for the next 2 days.