

1.14.2.1. - *Carton VAGISTAT-1 (Final)*  
NDA 20-676/S-009  
3/18/09

Cures Most Vaginal Yeast Infections  
**VAGISTAT-1**  
I-DOSE TREATMENT  
TIOCONAZOLE OINTMENT 6.5% VAGINAL ANTIFUNGAL

Net Wt 4.6g (0.16 oz)

- 1 Pre-Filled Applicator
- Cures Most Vaginal Yeast Infections
- Odorless Formula

I-DOSE TREATMENT  
**VAGISTAT-1**  
TIOCONAZOLE OINTMENT 6.5% VAGINAL ANTIFUNGAL

I-DOSE TREATMENT

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99-0607-2090-46

I-DOSE TREATMENT  
**VAGISTAT-1**  
TIOCONAZOLE OINTMENT 6.5% VAGINAL ANTIFUNGAL



I-DOSE TREATMENT  
Vaginal Ointment In 1 Pre-Filled Applicator

Educational  
Brochure Enclosed!

**I-DOSE TREATMENT**  
Vaginal Ointment In 1 Pre-Filled Applicator



**Drug Facts**

**Active ingredient (in each applicator)**  
Tioconazole 306 mg (6.5%)

**Purpose**  
Vaginal antifungal

**Use** • treats vaginal yeast infections

**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
- 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

**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 disease (STDs).
- do not have vaginal intercourse
- mild increase in vaginal burning, itching or irritation may occur
- if you do not get complete relief, ask a doctor before using another product

**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 or hives, 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 a Poison Control Center right away.

**Drug Facts (continued)**

**Directions**

- before using this product, read the enclosed brochure and instructions on foil packet for complete directions and information
- adults and children 12 years of age and over:
  - open the foil packet just before use and remove blue cap
  - insert entire contents of applicator into the vagina at bedtime. Throw applicator away after use.
- children under 12 years of age: ask a doctor

**Other information**

- this product is a 1-dose treatment; most women do not experience complete relief of their symptoms in just one day. Most women experience some relief within one day and complete relief of symptoms within 7 days.
- if you have questions about vaginal yeast infections, consult your doctor
- store at 15°-30° C (59°-86° F)
- see end flap of carton for lot number and expiration date

**Inactive ingredients** butylated hydroxyanisole, magnesium aluminum silicate, white petrolatum

**Questions or comments?** 1-888-824-4742

For more product information call 1-888-VAGISTAT.

TAMPER-EVIDENT UNIT  
DO NOT USE IF SEALED FOIL PACKET IS  
TORN, OPEN OR INCOMPLETELY SEALED

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Parsippany, NJ 07054-0622 MADE IN USA ©2007  
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WDA 20-676/5-009

114.21 Final Content VagSTAT-1

Pouch Label

3/18/09

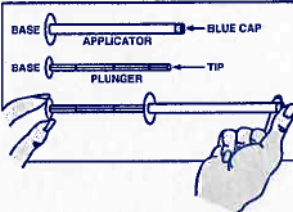
← Tear Here →  
 Do not use if sealed VAGISTAT-1 foil packet is torn, open or incompletely sealed

## I-DOSE TREATMENT VAGISTAT-1

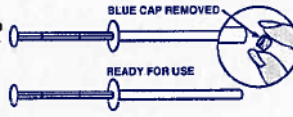
TIOCONAZOLE OINTMENT 6.5% VAGINAL ANTIFUNGAL

### DIRECTIONS FOR USING VAGISTAT-1

- Tear open foil packet just before using. It is best to use at bedtime.
- Remove applicator and plunger from packet. Applicator is pre-filled with VAGISTAT-1 vaginal ointment.
- While firmly holding the blue-capped end of the applicator, push the tip of the plunger into the base of applicator.




- **REMOVE BLUE CAP** from top of applicator with a pull-twist action.




Insert VAGISTAT-1

- Lie on your back with your knees bent. Gently insert applicator into the vagina as far as it will go comfortably.



- Push the plunger into the applicator until it will go no farther. Withdraw the applicator and plunger and dispose of it in the wastebasket. Do not flush.
- **DO NOT USE TAMPONS** while using this medicine. Use sanitary napkins instead.



PLEASE READ EDUCATIONAL BROCHURE FOR ADDITIONAL INFORMATION.

## I-DOSE TREATMENT VAGISTAT-1

TIOCONAZOLE OINTMENT 6.5% VAGINAL ANTIFUNGAL

Drug Facts	Purpose
<b>Active ingredient (in each applicator)</b> Tioconazole 300 mg (6.5%)	Vaginal antifungal
<b>Use</b>	
• treats vaginal yeast infections	
<b>Warnings</b>	
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	
• 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	
<b>When using this product</b>	
• do not use tampons, douches, spermicides, or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted disease (STDs).	
• do not have vaginal intercourse	
• mild increase in vaginal burning, itching or irritation may occur	
• if you do not get complete relief, ask a doctor before using another product	
<b>Stop use and ask a doctor if</b>	
• symptoms do not get better after 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	
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.	
<b>Directions</b>	
• before using this product read the enclosed brochure and instructions on foil packet for complete directions and information	
• adults and children 12 years and over: <ul style="list-style-type: none"> <li>• open the foil packet just before use and remove blue cap</li> <li>• insert entire contents of applicator into the vagina at bedtime. Throw applicator away after use.</li> </ul>	
• children under 12 years of age: ask a doctor	
<b>Other information</b>	
• this product is a 1-dose treatment; most women do not experience complete relief of their symptoms in just one day. Most women experience some relief within one day and complete relief of symptoms within 7 days.	
• if you have questions about vaginal yeast infections, consult your doctor	
• store at 15°-30° C (59°-86° F)	
• see left side of foil package for lot number and expiration date	
<b>Inactive Ingredients</b> butylated hydroxyanisole, magnesium aluminum silicate, white petrolatum	
<b>Questions or comments?</b> 1-888-824-4782	

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Bioclure  
VAGISTAT-1  
3/18/09  
NDA 20-676/5009

# 1-DOSE TREATMENT VAGISTAT-1

TIOCONAZOLE OINTMENT 0.5% VAGINAL ANTIMYCNAL

EDUCATIONAL BROCHURE

Please read this educational brochure completely before using VAGISTAT-1.

**1** VAGISTAT-1 CURES MOST RECURRENT VAGINAL YEAST INFECTIONS



IF THIS IS THE FIRST TIME YOU HAVE HAD VAGINAL ITCH AND DISCOMFORT, CONSULT YOUR DOCTOR. IF YOU HAVE HAD A DOCTOR DIAGNOSE VAGINAL YEAST INFECTION BEFORE AND HAVE THE SAME SYMPTOMS NOW, USE THIS OINTMENT AS DIRECTED. VAGISTAT-1 IS FOR THE TREATMENT OF RECURRENT VAGINAL YEAST INFECTIONS ONLY. IT DOES NOT TREAT OTHER INFECTIONS AND DOES NOT PREVENT PREGNANCY.

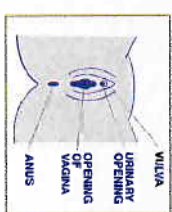
VAGISTAT-1, a vaginal ointment that contains an antifungal medicine, works to cure most recurrent vaginal yeast infections by killing the overgrowth of yeast.

## 2 WHAT IS A VAGINAL YEAST INFECTION (CANDIDIASIS)?

A yeast infection is caused by an organism called *Candida*, which is a type of yeast. Healthy women usually have this yeast in the vagina. Either an overgrowth or rapid growth of this yeast can cause a vaginal yeast infection. The symptoms of a vaginal yeast infection can include any or all of the following:

- Vaginal itching - Itching can range from mild to intense.
- Vaginal discharge - This discharge may be thick like paste or lumpy like cottage cheese.
- Vaginal soreness, burning or irritation - The vagina can feel sore inside or there can be a burning sensation, particularly during vaginal intercourse.
- Redness or redness - Redness or redness may occur around the vagina (vulva irritation).

**NOTE:** Vaginal discharge that is different from the above, for example, a yellow/green discharge or a discharge that smells "fishy" (fish-smelling), may indicate that you have something other than a yeast infection. If this is the case, you should consult your doctor before using VAGISTAT-1.



INSERT FRONT

## 3 WHAT ARE THE REASONS YOU GET VAGINAL YEAST INFECTIONS?

There are several conditions that can cause too much yeast to grow inside the vagina such as:

- Hormonal changes - Changes in hormonal levels can occur during pregnancy, with the use of some birth control pills, and just before a woman's menstrual period.
- Antibiotics - Because antibiotics can kill the normal bacteria in the vagina, yeast may grow very quickly.
- Diabetes - Diabetes can also make a woman more likely to get a vaginal yeast infection.
- Human Immunodeficiency Virus (HIV) - 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). Infection with HIV causes the body to be more susceptible to infections, including vaginal yeast infections. Women with HIV infection may have frequent vaginal yeast infections or especially vaginal yeast infections that do not clear up easily with proper treatment. If you may have been exposed to HIV and are experiencing either frequent recurring vaginal yeast infections or, especially, vaginal yeast infections that do not clear up easily with proper treatment, you should see your doctor promptly. If you wish further information on risk factors for HIV infection or on the relationship between recurrent or persistent vaginal yeast infections and HIV infection, please contact your doctor or the CDC National AIDS Hotline at 1-800-342-AIDS (English), 1-800-344-7432 (Spanish), or 1-800-243-7889 (hearing impaired, TDD).

## 4 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; lower abdominal, back, or shoulder pain, fever, chills, nausea, vomiting, or food-smelling vaginal discharge; you may have a more serious condition; vaginal yeast infections often (such as once a month or 3 to 6 months); you could be pregnant or have a serious underlying immune system; your symptoms, including diabetes or a weakened immune system, have been exposed to the human immunodeficiency virus (HIV) that causes AIDS. 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 disease (STD). Do not have vaginal intercourse if you do not get complete relief, ask a doctor before using another product.

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 or hives, abdominal pain, fever, chills, nausea, vomiting, or food-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 a Poison Control Center right away.

# 1-DOSE TREATMENT VAGISTAT-1

TIOCONAZOLE OINTMENT 0.5% VAGINAL ANTIMYCNAL

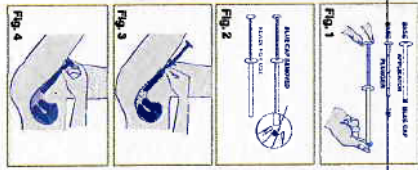
## 5 WHEN CAN YOU EXPECT SWAYTOM RELIEF?

While VAGISTAT-1 is a 1-dose treatment, most women do not experience complete relief of their symptoms in just 1 day. Most women experience some improvement within 1 day and complete relief of symptoms within 7 days. If your symptoms do not improve in 3 days or if you still have symptoms after 7 days, consult your doctor. Your doctor may recommend other treatment, or you may have a condition other than a yeast infection. If your symptoms return within 2 months or if you think you have been exposed to the human immunodeficiency virus (HIV) that causes AIDS, consult your doctor immediately. Recurring yeast infections may be a sign of pregnancy or a serious condition, such as AIDS or diabetes.

## 6 HOW TO USE VAGISTAT-1

VAGISTAT-1 comes in a pre-filled, single-dose applicator. Directions for use:

- Read the full directions printed below and on the foil packet carefully before using.
- Position is the best time to apply VAGISTAT-1.
- Open the foil packet just before use.
- Remove the applicator cap/plunger from the foil packet. The applicator is pre-filled with VAGISTAT-1 vaginal ointment.
- While firmly holding the blue-capped end of the applicator, push the tip of the plunger into the base of applicator (Fig. 1).
- REMOVE BLUE CAP from the top of the applicator using a push-in action, Fig. 2.
- Lie on your back with your knees bent. Gently insert applicator into the vagina as far as it will go comfortably, Fig. 3.
- Push the plunger until the applicator until it will go no farther. Withdraw the applicator and plunger and dispose of it in the wastebasket. Do not flush, Fig. 4.
- DO NOT USE TAMPONS while using this medicine. Use sanitary napkins instead.



## 7 ADVERSE REACTIONS (SIDE EFFECTS)

A temporary increase in vaginal burning, itching and/or irritation may be experienced upon insertion of VAGISTAT-1 ointment. These reactions, in addition to vaginal itching or redness, difficulty or burning on urination, headache, abdominal pain/aching and upper respiratory infection have been reported with the use of VAGISTAT-1. If you experience any of these, consult your doctor.

## 8 COMMON QUESTIONS ABOUT VAGINAL YEAST INFECTIONS AND VAGISTAT-1

- Q. Should I use VAGISTAT-1 while menstruating?
- A. You should use VAGISTAT-1 while menstruating but you should not use tampons following application. Use sanitary napkins instead.
- Q. Can I have sex while using VAGISTAT-1?
- A. It is generally recommended not to have vaginal intercourse the first few nights after treatment with VAGISTAT-1.
- Q. Can I use a condom or diaphragm while using VAGISTAT-1?
- A. No, VAGISTAT-1 contains petroleum which may damage the latex form which condoms and diaphragms are made and may cause them to fail. This may reduce their effectiveness in preventing sexually transmitted diseases and pregnancy. You should wait 3 days after treatment to resume using condoms or your diaphragm.
- Q. Does my partner need to be treated?
- A. Yeast infections occur less frequently in men than in women. However, if your partner has any of the following symptoms: itching, redness or discomfort in the genital area, he should see a doctor and mention that you are treating a vaginal yeast infection.

## 9 FOR BEST RESULTS...

- Use cotton underwear and loose-fitting clothes - Yeast grow in warm, moist environments. Wearing loose-fitting, cotton clothes helps create a cooler environment, which makes it more difficult for yeast to grow.
  - Change out of a wet bathing suit quickly - Dampness is more likely to encourage the growth of yeast.
  - Use proper hygiene - Wipe from front to rear (away from vagina) after a bowel movement or urination.
  - Discuss with your doctor any medication you are now taking - Certain types of medication can make your vagina more prone to infection. If you have any other questions or concerns about vaginal yeast infections or of a medical nature, don't hesitate to consult your doctor.
  - If you have questions or comments about VAGISTAT-1, call toll-free 1-888-VAGISTAT-1 (1-888-824-4752).
- CONTENTS**  
Active ingredient: Tioconazole 300mg (0.5% per applicator).  
Inactive ingredients: Butylated hydroxyanisole, magnesium aluminum silicate and white petrolatum.
- Do not use if sealed VAGISTAT-1 foil packet is torn, open, or incompletely sealed. For expiration date and lot number, see carton end flap and applicator foil packet.

**1-DAY™**  
 Tioconazole Ointment 6.5%  
 Vaginal Antifungal

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 Personal Products Company  
 Division of McNeil-PPC, Inc., Skillman, NJ 08568  
 MADE IN U.S.A. ©McNeil-PPC, Inc. 2008  
 734291 30740A



**?** If you have questions or comments please call 1-877-MONISTAT (1-877-666-4782) or visit our website @ [www.monistat.com](http://www.monistat.com)

**TAMPER-EVIDENT UNIT**  
 DO NOT USE IF SEALED FOIL PACKET IS  
 TORN, OPEN OR INCOMPLETELY SEALED

NET WT 4.5 g (0.16 oz)

1 Prefilled Applicator



CURES MOST VAGINAL YEAST INFECTIONS

**1-DAY™**  
 Tioconazole Ointment 6.5%  
 Vaginal Antifungal

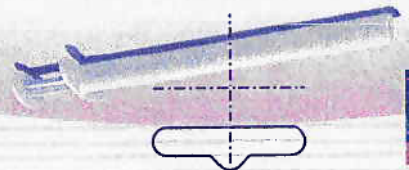
NDC 62341-4100-1

**1-Dose Treatment**

**?** If you have questions or comments please call 1-877-MONISTAT (1-877-666-4782) or visit our website @ [www.monistat.com](http://www.monistat.com)

**1-DAY™**  
 Tioconazole Ointment 6.5%  
 Vaginal Antifungal

1 Ready-to-Use Prefilled Applicator



FROM THE MAKERS OF  
**MONISTAT®**

**1-DAY™**  
 Tioconazole Ointment 6.5%  
 Vaginal Antifungal

**1 - DOSE TREATMENT**  
 CURES MOST VAGINAL YEAST INFECTIONS

FROM THE MAKERS OF  
**MONISTAT®**

Drug Facts	Purpose
<b>Active ingredient (in each applicator)</b> Tioconazole 300 mg (6.5%)	Vaginal antifungal
<b>Use</b> • treats vaginal yeast infections	
<b>Warnings</b> 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 • 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 human immunodeficiency virus (HIV) that causes AIDS. 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 disease (STDs). • do not have vaginal intercourse. • mild increase in vaginal burning, itching or irritation may occur. • if you do not get complete relief, ask a doctor before using another product.	
<b>Stop use and ask a doctor if</b> • symptoms do not get better after 7 days • symptoms last more than 7 days • you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge	
<b>Directions</b> Before using this product read the enclosed brochure and instructions on foil packet for complete directions and information. • adults and children 12 years and over: • open the foil packet just before use and remove blue cap • insert entire contents of applicator into the vagina at bedtime. Throw applicator away after use. • children under 12 years of age: ask a doctor.	
<b>Other information</b> • this product is a 1-dose treatment, most women do not experience complete relief of their symptoms in just one day. Most women experience some relief within one day and complete relief of symptoms within 7 days. • if you have questions about vaginal yeast infections, consult your doctor. • store at 15°-30°C (59°-86°F) • see and flap of carton for lot number and expiration date	
<b>Inactive ingredients</b> butylated hydroxyanisole, magnesium aluminum silicate, white petrolatum	
<b>Questions or comments?</b> 1-877-666-4782	



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 3/18/2009

NDA 20-67615-009

1.14.21, Final Container - 1-DAY  
 Patch label



<b>Drug Facts</b>	
<b>Active ingredient (in each applicator)</b>	<b>Purpose</b>
Tioconazole 300 mg (6.5%)	Vaginal antifungal
<b>Use</b> • treats vaginal yeast infections	
<b>Warnings</b>	
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	
<ul style="list-style-type: none"> <li>vaginal itching and discomfort for the first time</li> <li>lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You may have a more serious condition.</li> <li>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.</li> <li>been exposed to human immunodeficiency virus (HIV) that causes AIDS</li> </ul>	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>do not use tampons, douches, spermicides, or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted disease (STDs).</li> <li>do not have vaginal intercourse</li> <li>mild increase in vaginal burning, itching or irritation may occur</li> <li>if you do not get complete relief, ask a doctor before using another product</li> </ul>	
<b>Stop use and ask a doctor if</b>	
<ul style="list-style-type: none"> <li>symptoms do not get better after 3 days</li> <li>symptoms last more than 7 days</li> <li>you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge</li> </ul>	
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.	
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<b>Other information</b>	
<ul style="list-style-type: none"> <li>this product is a 1-dose treatment, most women do not experience complete relief of their symptoms in just one day. Most women experience some relief within one day and complete relief of symptoms within 7 days.</li> <li>if you have questions about vaginal yeast infections, consult your doctor</li> <li>store at 15° - 30°C (59° - 86°F)</li> <li>see end flap of carton for lot number and expiration date</li> </ul>	
<b>Inactive ingredients</b>	
butylated hydroxyanisole, magnesium aluminum silicate, white petrolatum	
<b>Questions or comments?</b> 1-877-666-4782	

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Tear Here  
 Do not use if sealed 1-DAY™ foil packet is torn, open or incompletely sealed.

**1-Dose Treatment**

# 1

-DAY™  
 TIOCONAZOLE OINTMENT 6.5%  
 VAGINAL ANTIFUNGAL

**DIRECTIONS FOR USING 1-DAY™ Vaginal Antifungal**

- Tear open foil packet just before using. It is best to use at bedtime.
- Remove applicator and plunger from packet. Applicator is prefilled with 1-DAY™ vaginal ointment.
- While firmly holding the blue-capped end of the applicator, push the tip of the plunger into the base of applicator.

- REMOVE BLUE CAP** from top of applicator with a pull-twist action.

Insert 1-DAY™ Vaginal Antifungal

- Lie on your back with your knees bent. Gently insert applicator into the vagina as far as it will go comfortably.
- Push the plunger into the applicator until it will go no farther. Withdraw the applicator and plunger and dispose of it in the wastebasket. Do not flush.
- DO NOT USE TAMPONS** while using this medicine. Use sanitary napkins instead.

PLEASE READ EDUCATIONAL BROCHURE FOR ADDITIONAL INFORMATION.

# 1-DAY™ TIOCONAZOLE OINTMENT 6.5% VAGINAL ANTIMYCNAL

## EDUCATIONAL BROCHURE

Please read this educational brochure carefully before using 1-DAY™ Vaginal Antimycnal. Use 1-DAY™ Vaginal Antimycnal to treat vaginal yeast infections.



### 1-DAY™ VAGINAL ANTIMYCNAL CURES MOST RECURRENT VAGINAL YEAST INFECTIONS

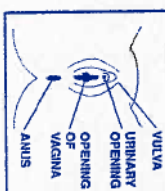
IF THIS IS THE FIRST TIME YOU HAVE HAD VAGINAL ITCH AND DISCOMFORT, CONSULT YOUR DOCTOR. IF YOU HAVE HAD A DOCTOR DIAGNOSE A VAGINAL YEAST INFECTION BEFORE AND HAVE THE SAME SYMPTOMS NOW, USE THIS OINTMENT AS DIRECTED. 1-DAY™ VAGINAL ANTIMYCNAL IS FOR THE TREATMENT OF RECURRENT VAGINAL YEAST INFECTIONS ONLY. IT DOES NOT TREAT OTHER INFECTIONS AND DOES NOT PREVENT PREGNANCY.

1-DAY™, a vaginal ointment that contains an antifungal medicine, works to cure most recurrent vaginal yeast infections by killing the overgrowth of yeast.

### 2 WHAT IS A VAGINAL YEAST INFECTION (CANDIDIASIS)?

Vaginal yeast infections are caused by an organism called Candida, which is a type of yeast. Healthy women usually have the yeast in the vagina. Either an overgrowth or rapid growth of the yeast can cause a vaginal yeast infection. The symptoms of a vaginal yeast infection can include any or all of the following:

- 1. Vaginal itching, itching, or burning, even mild to moderate.
- 2. Vaginal discharge - The discharge may be thick like paste or lumpy like cottage cheese.
- 3. Vaginal soreness, burning or irritation - The vagina can feel sore inside or there can be a burning sensation, particularly during vaginal intercourse.
- 4. Rash or redness - Rash or redness may occur around the vagina (outer infection).



**NOTE:** Vaginal discharge that is different from the above, for example, a yellow-green discharge or a discharge that smells "fishy" (foul-smelling), may indicate that you have something other than a yeast infection. In this case, you should consult your doctor before using 1-DAY™ Vaginal Antimycnal.

### 3 WHAT ARE THE REASONS YOU GET VAGINAL YEAST INFECTIONS?

There are several conditions that can cause too much yeast to grow inside the vagina such as:

- 1. Hormonal changes - Changes in hormonal levels can occur during pregnancy, with the use of some birth control pills, and just before a woman's menstrual period.
- 2. Antibiotics - Because antibiotics can kill the normal bacteria in the vagina, yeast may grow very quickly.
- 3. Diabetes - Diabetes can also make a woman more likely to get a vaginal yeast infection.
- 4. Highest Immuno-deficiency Virus (HIV) - Various medical conditions can damage the body's normal defenses against infection. One of the most serious of these conditions is AIDS. Infection with the human immunodeficiency virus (HIV) is the virus that causes AIDS. Infection with HIV causes the body to be more susceptible to infections, including vaginal yeast infections. Women with HIV infection may have frequent vaginal yeast infections as well as other vaginal yeast infections that do not respond to antifungal treatment. If you may have been exposed to HIV and are experiencing either frequent vaginal yeast infections or, respectively, vaginal yeast infections that do not clear up easily with proper treatment, you should see your doctor promptly. If you wish further information on risk factors for HIV infection or on the relationship between recurrent or persistent vaginal yeast infections and HIV infection, please contact your doctor or the CDC National AIDS Hotline at 1-800-342-AIDS (English), 1-800-342-7432 (Spanish), or 1-800-243-7889 (hearing impaired, TDD).

### 4 WARNINGS

For vaginal use only.  
Do not use if you have ever had a vaginal yeast infection diagnosed by a doctor.  
Ask a doctor before use if you have:  
- recurrent itching and discharge for the first time  
- vaginal itching at the back of the shoulder, groin, lower thighs, nape, navel, or fold-creasing vaginal discharge, you may have a more serious condition.  
- vaginal yeast infections often (such as once a month or 3 or 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.  
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 disease (STDs).  
- do not have vaginal intercourse.  
- do not increase vaginal burning, itching or irritation may occur.  
- if you do not get complete relief, see a doctor before using another product.  
Stop use and ask a doctor if:  
- symptoms do not get better after 7 days  
- you get a rash or have 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 a Poison Control Center right away.

VDA 20-676/5009  
Brochure  
3/18/09

BACK

# 1-DAY™ TIOCONAZOLE OINTMENT 6.5% VAGINAL ANTIMYCNAL

### 5 WHEN CAN YOU EXPECT SYMPTOM RELIEF?

While 1-DAY™ Vaginal Antimycnal is a 1-dose treatment, most women do not experience complete relief of their symptoms in just one day. Most women experience some improvement within one day and complete relief of symptoms within 7 days.  
If your symptoms do not improve in 3 days or if you still have symptoms after 7 days, consult your doctor. Your doctor may recommend other treatment, or you may have a condition other than a yeast infection.

If your symptoms return within 2 months of your treatment, begin exposed to the human immunodeficiency virus (HIV) that causes AIDS, consult your doctor immediately. Recurrent yeast infections may be a sign of pregnancy or a serious condition, such as AIDS or diabetes.

### 6 HOW TO USE 1-DAY™ VAGINAL ANTIMYCNAL

1-DAY™ Vaginal Antimycnal comes in a pre-filled, single-dose applicator. Directions for use:  
- Read the full directions printed below and on the foil packet carefully before use.  
- Bedtime is the best time to apply 1-DAY™ Vaginal Antimycnal.



### 7 ADVERSE REACTIONS (SIDE EFFECTS)

A temporary increase in vaginal burning, itching, and/or irritation may be expected upon insertion of 1-DAY™ Vaginal Antimycnal. These reactions, in addition to vaginal swelling or redness, difficulty or burning on urination, headache, abdominal pain/irritation, or other respiratory infection have been reported with the use of 1-DAY™ Vaginal Antimycnal. If you experience any of these, consult your doctor.

### 8 COMMON QUESTIONS ABOUT VAGINAL YEAST INFECTIONS AND 1-DAY™ VAGINAL ANTIMYCNAL

**Q: Should I use 1-DAY™ Vaginal Antimycnal while I have my period?**  
You should use 1-DAY™ Vaginal Antimycnal while menstruating but you should not use tampons following application. Use sanitary napkins instead.  
**Q: Can I have sex while using 1-DAY™ Vaginal Antimycnal?**  
It is generally recommended not to have vaginal intercourse the first few nights after treatment with 1-DAY™ Vaginal Antimycnal.  
**Q: Can I use a condom or diaphragm while using 1-DAY™ Vaginal Antimycnal?**  
The 1-DAY™ Vaginal Antimycnal ointment may weaken latex condoms, which conditions that may reduce their effectiveness in preventing sexually transmitted diseases and pregnancy. You should wait 3 days after treatment to resume using condoms or your diaphragm.  
**Q: Does my partner need to be treated?**  
Yeast infections occur less frequently in men than in women. However, if your partner has any of the following symptoms: itching, redness or discomfort in the genital area, he should see a doctor and mention that you are treating a vaginal yeast infection.

### 9 FOR BEST RESULTS...

**Q: Can I use feminine hygiene products (such as douches) while I have a vaginal yeast infection?**  
It is best not to use any vaginal products while you have a yeast infection, such as douches, feminine hygiene sprays, contraceptive foam, pads, or pills.  
**Q: Wear cotton underwear and loose-fitting clothes.** -Wash your groin, most environments. Washing your groin may help to create a more favorable environment for healthy yeast growth.  
**Q: Change your underwear frequently.** -Change your underwear frequently to change the growth of yeast.  
**Q: Use proper hygiene.** -Wipe from front to rear (away from vagina) after a bowel movement or urination.  
**Q: Discuss with your doctor any medication you are now taking.** -Certain types of medication can make your vagina more prone to infection.  
**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. Call between 8:00 AM and 5:00 PM, Eastern time, Monday through Friday. A health care specialist will gladly answer your questions. Our toll-free number is 1-877-466-4783.

**CONTRAINS**  
Active ingredient: Tioconazole 6.5% (per application), inactive ingredients: Polyethylene glycol, polyethylene glycol, magnesium aluminum silicate and white petrolatum.  
**NOTE: THE ACTIVE INGREDIENT IN THIS PRODUCT (TIOCONAZOLE 6.5%) IS NOT THE SAME ACTIVE INGREDIENT FOUND IN MONISTAT™, MONISTAT™ 3 OR MONISTAT™ 1.**  
Store at 15-30°C (59-86°F).  
Do not use if sealed 1-DAY™ foil packet is torn, open, or incompletely sealed. For expiration date and lot number, see carton and foil packet and applicator foil packet.  
Patent of Midepharm, Inc., Stillpoint, NJ 07865-2416  
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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20676	SUPPL-9	NOVARTIS CONSUMER HEALTH INC	VAGISTAT-1 (TIOCONAZOLE 6.5%) VAGINAL OI

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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JOEL SCHIFFENBAUER  
09/15/2009