

1.14.2-1- Canton VAGISTAT-1 (Final)
 NDA 20-67675-009
 3/18/09

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

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

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

NDC 0067-2090-46

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

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



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 300 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? 1-888-824-4782

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/S-009

1.14.2.1 Final Container VagSTAT-1

Pouch Lab

3/18/09

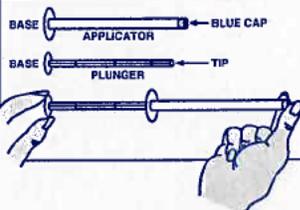
← Tear Here →
Do not use if sealed VAGISTAT-1 foil packet is torn, open or incompletely sealed

I-DOSE TREATMENT VAGISTAT-1

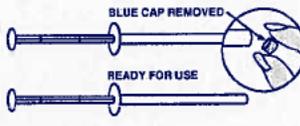
TIOCONAZOLE OINTMENT 6.5% VAGINAL ANTIFUNGAL

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 prefilled 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.

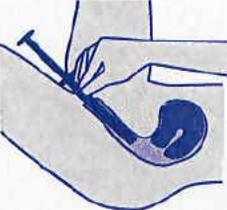
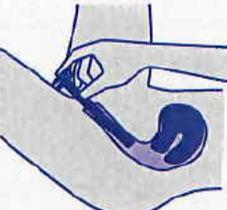


- **REMOVE BLUE CAP** from top of applicator with a pull-twist action.



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
Active ingredient (in each applicator) Tioconazole 300 mg (6.5%)	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.	
Directions	
• 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"> • 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 left side of foil package for lot number and expiration date	
Inactive ingredients butylated hydroxyanisole, magnesium aluminum silicate, white petrolatum	
Questions or comments? 1-888-824-4782	

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1-DOSE TREATMENT VAGISTAT-1

TRICHOZOLE OINTMENT 0.5% VAGINAL ANTIFUNGAL

EDUCATIONAL BROCHURE

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

USE: treats vaginal yeast infections



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 A 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.

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VAGISTAT-1

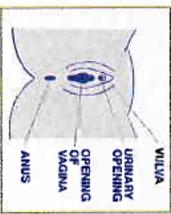
3/18/09
NDA 20-676/5009

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 the 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 severe.
- **Vaginal discharge** - This discharge may be thick like peels 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.
- **Rash or redness** - Rash or redness may occur around the vagina (vulvar irritation).

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. 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 other 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), 1-800-544-7432 (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 foul-smelling vaginal discharge. You may have a more serious condition.
- **Vaginal yeast infections often recur** (such as once a month or 2 in 6 months). You could be pregnant or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system. You should see your doctor if you have a vaginal yeast infection that has 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 diseases (STDs), do not have vaginal intercourse until the yeast infection has cleared up. 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 or symptoms last more than 7 days or 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.

1-DOSE TREATMENT VAGISTAT-1

TRICHOZOLE OINTMENT 0.5% VAGINAL ANTIFUNGAL

5 WHEN CAN YOU EXPECT SYMPTOM 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.

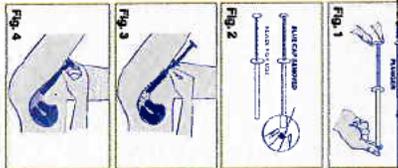
If your symptoms do not improve in 3 days or if you still have symptoms after 7 days, consult your doctor. Your doctor may recommend other treatment, or you may have a condition other than a yeast infection.

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 are:

- **Insert the applicator into the vagina as far as it will go comfortably.** Fig. 1
- **REMOVE BLUE CAP** from the top of the applicator using a push-pull 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 into the applicator until it will go no further.** 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 swelling or redness; difficulty or burning on urination; headache; abdominal pain/cramping 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 I have my period?
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 parabens which may damage the latex from 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 BETT RESULTS...

- **Wear 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 vaginal more prone to infection.
- **If you have any other questions or concerns about vaginal yeast infections or 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 (1-888-824-4782).**

ACTIVE INGREDIENT: Trichazole 300mg (0.5% per applicator).
Inactive ingredients: Butylated Hydroxytoluene, magnesium aluminum silicate and white petrolatum.
Store at 15-30°C (59-86°F)
Do not use if sealed VAGISTAT-1 kit packet is torn, open, or incompletely sealed. For expiration date and lot number, see carton and bag and applicator kit packet.

1-DAY™
 Tioconazole Ointment 6.5%
 Vaginal Antifungal

Distributed by:
Personal Products Company
 Division of McNeil-PPC, Inc., Skillman, NJ 08568
 MADE IN U.S.A. ©McNeil-PPC, Inc. 2008
 734991 30740A



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

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

Net Wt 4.6 g (0.16 oz)

1 Prefilled Applicator



CURES MOST VAGINAL YEAST INFECTIONS

1-DAY™
 Tioconazole Ointment 6.5%
 Vaginal Antifungal

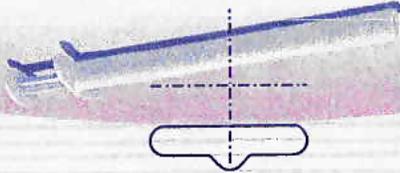
1-Dose Treatment

NDC 623414100-1

2 If you have questions or comments please call 1-877-MONISTAT (1-877-666-4782) or visit our website @ 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



FROM THE MAKERS OF
MONISTAT®

1 - DOSE TREATMENT
 CURES MOST VAGINAL YEAST INFECTIONS

Drug Facts	Purpose
Active ingredient (in each applicator) Tioconazole 300 mg (6.5%)	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 (recur at 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	
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.	
Directions • 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	
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 and flip of carton for lot number and expiration date	
Inactive ingredients butylated hydroxyanisole, magnesium aluminum silicate, white petrolatum	
Questions or comments? 1-877-666-4782	

Carton label
 NDA 20-676/5009

1.14.2 1 Unit Carton + Dose
 3/18/2009

OPEN HERE

FPO



Drug Facts	
Active ingredient (in each applicator)	Purpose
Tioconazole 300 mg (6.5%)	Vaginal antifungal
Use • treats vaginal yeast infections	
Warnings	
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Do not use if you have never had a vaginal yeast infection diagnosed by a doctor	
Ask a doctor before use if you have	
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Questions or comments? 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 ANTIFUNGAL

1-DOSE TREATMENT

EDUCATIONAL BROCHURE

Directions and this educational brochure are available at www.1dayvaginal.com.



1-DOSE™ VAGINAL ANTIFUNGAL CURES MOST RECURRENT VAGINAL YEAST INFECTIONS

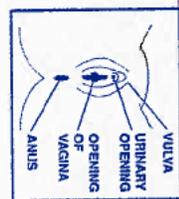
IF THIS IS THE FIRST TIME YOU HAVE HAD VAGINAL ITCH AND DISCOMFORT, CONSULT YOUR DOCTOR. IF YOU HAVE HAD A DOCTOR DIAGNOSE A VAGINAL YEAST INFECTION BEFORE AND HAVE THE SAME SYMPTOMS NOW, USE THIS OINTMENT AS DIRECTED. 1-DAY™ VAGINAL ANTIFUNGAL IS FOR THE TREATMENT OF RECURRENT VAGINAL YEAST INFECTIONS 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)?

Most 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 this 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 can range from mild to intense.
- 2. Vaginal discharge - The discharge may be thick like white or lumpy 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" (bacterial), may indicate that you have something other than a yeast infection. If this is the case, you should consult your doctor before using 1-DAY™ Vaginal Antifungal.

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 - Broad-spectrum antibiotics can kill the beneficial 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. 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 infections that recur more often than do in other people who do not have HIV infection. 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 ever 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. You may be exposed to the human immunodeficiency virus (HIV) that causes AIDS.

When using this product:

- do not use tampons, douches, spermicide, 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 reactions in vaginal itching, 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 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, use a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact Dr. Poison Control Center right away.

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

BACK

1-DAY™

TIOCONAZOLE OINTMENT 6.5%
VAGINAL ANTIFUNGAL

5 WHEN CAN YOU EXPECT SYMPTOM RELIEF?

While 1-DAY™ Vaginal Antifungal 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.

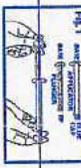
If your symptoms do not improve in 3 days or if you still have symptoms after 7 days, consult your doctor. Your doctor may recommend other treatment, or you may have a condition other than a yeast infection.

IF YOUR SYMPTOMS RETURN WITHIN 2 MONTHS OF YOUR TREATMENT, YOU MAY BE AT RISK FOR A RECURRENT VAGINAL YEAST INFECTION. YOU SHOULD 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 ANTIFUNGAL

1-DAY™ Vaginal Antifungal comes in a pre-filled, single-dose applicator. Directions for use:

- 1. Read the full directions printed below and on the foil packet carefully before using.
- 2. Bedtime is the best time to apply 1-DAY™ Vaginal Antifungal.
- 3. Open the foil packet just before use.
- 4. Remove the applicator and plunger from the foil packet. The applicator is pre-filled with 1-DAY™ vaginal antifungal.
- 5. While firmly holding the blue-colored end of the applicator, push the tip of the plunger into the base of applicator, Fig. 1
- 6. REMOVE BLUE CAP from the top of the applicator using a quick-twist action, Fig. 2
- 7. Use on your back with your knees bent. Gently insert applicator into the vagina as far as it will go comfortably, Fig. 3
- 8. Push the plunger into the applicator until it will go no further. Withdraw the applicator and plunger and dispose of it in the wastebasket. Do not flush, Fig. 4
- 9. 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 1-DAY™ Vaginal Antifungal. These reactions, in addition to vaginal itching or redness, difficulty or burning on insertion, irritation, abdominal pain, discomfort and upper respiratory infection have been reported with the use of 1-DAY™ Vaginal Antifungal. If you experience any of these, consult your doctor.

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

Q. Should I use 1-DAY™ Vaginal Antifungal while I have my period?
You should use 1-DAY™ Vaginal Antifungal while menstruating but you should not use tampons following application. Use sanitary napkins instead.

Q. Can I have sex while using 1-DAY™ Vaginal Antifungal?
It is generally recommended not to have vaginal intercourse the first few nights after treatment with 1-DAY™ Vaginal Antifungal.

Q. Can I use a condom or diaphragm while using 1-DAY™ Vaginal Antifungal?
Use a condom or diaphragm while using 1-DAY™ Vaginal Antifungal. Do not use tampons, douches, spermicide, or other vaginal products. Condoms and diaphragms may be damaged 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?
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...

- 1. Wear 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.
- 2. Change out of wet clothing and towels as soon as possible - Dampness is more likely to encourage the growth of yeast.
- 3. Use proper hygiene - Wipe from front to rear (away from vagina) after a bowel movement or urination.
- 4. 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. Health care specialists will gladly answer your questions. Our toll-free number is 1-877-666-4782.

CONTENTS: Tioconazole 90mg (6.5% per applicator), Inactive ingredients: dimethyl hydrosynthetic, magnesium stearate

NOTE: THE ACTIVE INGREDIENT IN THIS PRODUCT (TIOCONAZOLE 6.5%) IS NOT THE SAME ACTIVE INGREDIENT FOUND IN MONISTAT™ 7.

MONISTAT™ 7 OR MONISTAT™ 1.
Shown 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 flip and applicator foil packet.

Manufactured by: Fortaseal Products Company
Division of Wyeth-Pfizer Inc., Skillman, NJ 08558-2418
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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

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

/s/

JOEL SCHIFFENBAUER
09/15/2009