

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number *20-676*

FINAL PRINTED LABELING

BVG-6017 — BOX w/die(2685)-A-A.2 2/6/97

Now available
without a
prescription

1-DOSE TREATMENT



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



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1 PRE-FILLED APPLICATOR

- ✓ Cures Most Vaginal Yeast Infections
- ✓ Formerly Available By Prescription
- ✓ Odorless Formula

Educational Brochure Enclosed

Bristol-Myers Squibb Company

Net wt 4.6g (0.16oz).

1-DOSE TREATMENT



CURES MOST VAGINAL YEAST INFECTIONS

VAGISTAT-1

TIOCONAZOLE 6.5% VAGINAL OINTMENT
ANTIFUNGAL

VAGISTAT-1 is a 1-dose treatment which cures most vaginal yeast infections and is now available without a prescription.

INDICATION: For the treatment of recurrent vaginal yeast infections (*candidiasis*).

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.

Before using, read the enclosed brochure and instructions on foil packet.

DIRECTIONS: Open the foil packet just before use. Insert entire contents of applicator into the vagina, preferably at bedtime (see directions on enclosed brochure). Dispose of applicator after use.

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.

WARNINGS:

- Do not use if you have abdominal pain, fever (higher than 100°F orally), chills, nausea, vomiting, diarrhea, or foul-smelling discharge. Contact your doctor immediately.
- 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.
- Do not use if you are pregnant or think you may be pregnant, have diabetes, a positive HIV test, or AIDS. Consult your doctor.
- Do not use tampons while using this medicine. Use sanitary napkins instead.

WARNINGS (continued):

- Do not rely on condoms or diaphragms to prevent sexually transmitted diseases or pregnancy while using VAGISTAT-1. This product may damage condoms and diaphragms and may cause them to fail. You should wait 3 days after treatment to resume using condoms or your diaphragm.
- Do not use in girls under 12 years of age.
- Keep this and all drugs out of the reach of children.
- VAGISTAT-1 is for vaginal use only. Do not use in eyes or take by mouth. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Store at controlled room temperature 15°-30°C (59°-86°F). See end flap and applicator foil packet for expiration date and lot number.

STRIP IN UPC:
100% MAGNIFICATION,
NO TRUNCATION.

VG6297-48-00

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Bristol-Myers Squibb Company
New York, NY 10154

If you have any questions about vaginal yeast infections, consult your doctor. If you have questions about VAGISTAT-1, call toll-free 1-888-VAGISTAT (1-888-824-4782).

Active ingredient:
Tioconazole 6.5% (300mg per applicator).
Inactive ingredients:
Butylated hydroxyanisole, magnesium aluminum silicate and white petrolatum.
IMPORTANT: Do not use if broken or incompletely sealed sealed VAGISTAT-1 foil packet is torn.

Cures Most Vaginal Yeast Infections

VAGISTAT-1

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

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EDUCATIONAL BROCHURE

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

INDICATION: For the treatment of recurrent vaginal yeast infections (*candidiasis*).

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.

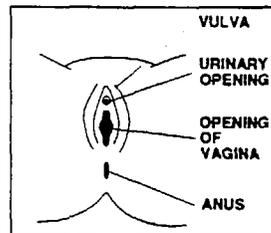
VAGISTAT-1, a vaginal ointment that contains an antifungal medicine, works to cure most recurrent vaginal yeast infections by killing the overgrowth of yeast.

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.
- **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.



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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 frequently 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

- Do not use if you have abdominal pain, fever (higher than 100°F orally), chills, nausea, vomiting, diarrhea, or foul-smelling discharge. Contact your doctor immediately.
- 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.
- Do not use if you are pregnant or think you may be pregnant, have diabetes, a positive HIV test, or AIDS. Consult your doctor.
- Do not use tampons while using this medicine. Use sanitary napkins instead.
- Do not rely on condoms or diaphragms to prevent sexually transmitted diseases or pregnancy while using VAGISTAT-1. This product may damage condoms and diaphragms and may cause them to fail. You should wait 3 days after treatment to resume using condoms or your diaphragm.
- Do not use in girls under 12 years of age.
- Keep this and all drugs out of the reach of children.
- VAGISTAT-1 is for vaginal use only. Do not use in eyes or take by mouth. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

VAGISTAT-1

1-DOSE TREATMENT
TIOCONAZOLE 6.5% VAGINAL OINTMENT
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.

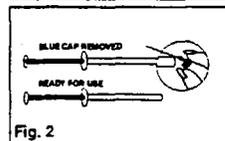
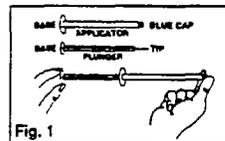
If your symptoms return within 2 months or if you think you have been exposed to the human immunodeficiency virus (HIV) that causes AIDS, consult your doctor immediately. Recurring yeast infections may be a sign of pregnancy or a serious condition, such as AIDS or diabetes.

6 HOW TO USE VAGISTAT-1

VAGISTAT-1 comes in a prefilled, single-dose applicator.

Directions for use:

- Read the full directions printed below and on the foil packet carefully before using.
- Bedtime is the best time to apply VAGISTAT-1.
- Open the foil packet just before use.
- Remove the applicator and plunger from the foil packet. The 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 until you hear it snap into place. (You shouldn't push any farther than this right now.) Fig.1
- REMOVE BLUE CAP from the top of the applicator using a pull-twist 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 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.



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8 CC YH

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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

Should I use VAGISTAT-1 while I have my period?

You can use VAGISTAT-1 while menstruating but you should not use tampons following application. Use sanitary napkins instead.

Can I have sex while using VAGISTAT-1?

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?

No. VAGISTAT-1 contains petrolatum 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?

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.

Q. Can I use feminine hygiene products (such as douche) while I have a vaginal yeast infection?

It is best not to use any vaginal preparations while you have a yeast infection including douches, feminine hygiene sprays, contraceptive foams, inserts, or jellies.

9 FOR BEST 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 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 (1-888-824-4782).

CONTENTS

Active ingredient: Tioconazole 6.5% (300mg per applicator).

Inactive ingredients: Butylated hydroxyanisole, magnesium aluminum silicate and white petrolatum.

Store at controlled room temperature 15°-30°C (59°-86°F).

Do not use if sealed VAGISTAT-1 foil packet is torn, broken, or incompletely sealed. For expiration date and lot number, see carton end flap and applicator foil packet.

 **Bristol-Myers Squibb Company**
New York, NY 10154
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VG6298-38-00

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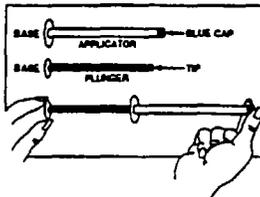
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1-DOSE TREATMENT VAGISTAT-1

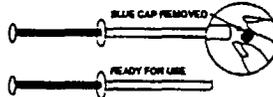
TIOCONAZOLE 0.1% VAGINAL OINTMENT
ANTIFUNGAL

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 until it snaps into place (don't push any farther yet).

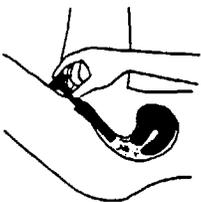
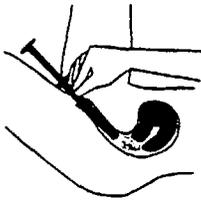


- ✓ **REMOVE BLUE CAP** from top of applicator with a pull-twist action.



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.
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PLEASE READ EDUCATIONAL BROCHURE FOR ADDITIONAL INFORMATION.

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

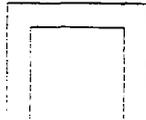
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applicator.
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