



## *Bacterial Vaginosis:*

What you need to  
know about a common  
vaginal infection



 **VANDAZOLE™**  
(metronidazole vaginal gel, 0.75%)

*Balancing cost and treatment*



## What Is Vaginitis?

Vaginitis is a general medical term to describe an irritation, inflammation, or infection of the vagina. Vaginal irritations or infections affect millions of women each year and are among the most common reasons that women seek medical attention.<sup>1,2</sup>

Vaginitis can be caused by a variety of factors, including allergies, irritants like douches or feminine hygiene sprays, sexual activity, or even hormonal

imbalances. When vaginitis occurs for one of

2 these reasons, it is often referred to as noninfectious vaginitis, and treated by changing the probable cause.<sup>1</sup>

More often, however, vaginitis is caused by one of three types of infections<sup>2</sup>:

- 1 Bacterial vaginosis
- 2 Candidiasis
- 3 Trichomoniasis

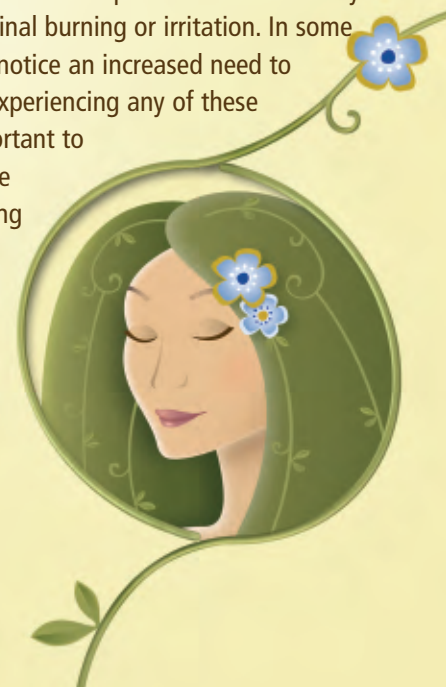
Each of these infections is caused by a different microorganism (ie, bacteria, yeast) and may produce similar symptoms or no symptoms at all. However, treatment for each condition differs greatly, which is why it is so important to see your doctor for a proper diagnosis if you suspect something is wrong.

## Vaginitis is common

Women of all ages and sexual orientations can experience vaginitis, but it occurs most often in women during their childbearing years. Chances are you will have it at least once in your life. You may even experience it more than once. The good news is that vaginitis is usually not serious if treated properly. However, it can become annoying and uncomfortable at times.<sup>2,3</sup>

## Do I have vaginitis?

3 Some of the common symptoms of vaginitis include vaginal itching and abnormal discharge. The discharge may have an unpleasant odor. You may also experience vaginal burning or irritation. In some cases, women may notice an increased need to urinate. If you are experiencing any of these symptoms it is important to determine what type of infection is causing your vaginitis.<sup>2</sup>



## Bacterial Vaginosis: A Common Form of Vaginitis

### Bacterial vaginosis

Bacterial vaginosis (BV) is the most common vaginal infection in women of childbearing age. In fact, as many as 16% of pregnant women in the United States have BV.<sup>3</sup> The cause of BV is a shift in the balance of normal healthy bacteria in the vagina.

The normal bacteria, *Lactobacillus*, are displaced through an overgrowth of unhealthy bacteria, *Gardnerella vaginalis*. *Lactobacillus* exists in the vagina to keep it slightly acidic to naturally reduce the growth of unhealthy bacteria. When you lose this protection, the natural balance—or flora—can be disturbed.<sup>4</sup>

### Symptoms of BV

The most common symptoms of BV include vaginal itching and an abnormal grayish discharge with an unpleasant fishlike odor.<sup>2</sup> This fishlike odor is often reported after intercourse.<sup>3</sup> Vaginal burning or pain during urination may also occur. However, some women who have been diagnosed with BV report no signs or symptoms at all.<sup>3</sup> If you are experiencing symptoms, it's important not to confuse your symptoms with another type of infection. Only your doctor can tell you for sure if it's BV.



### What if I think I might have BV?

If you suspect you have a vaginal infection of any kind, here are some tips that may help:

- 1 It might be a yeast infection, but don't self-diagnose the situation. You need to know for sure. Medications for yeast infections will not cure BV.<sup>4</sup>
- 2 Monitor your symptoms carefully and write down what you are experiencing so you can talk honestly to your doctor.
- 3 Make sure you see your doctor for a proper diagnosis and a prescription for BV medication if necessary. Do not use an over-the-counter medication unless you know for sure you have a yeast infection.



## How do you get BV?

While BV is caused by an imbalance of normal and unhealthy bacteria in the vagina, no one fully understands what causes this shift. Some activities or behaviors are known to upset the normal balance of vaginal bacteria and can put a woman at greater risk for BV. These behaviors include having a new sex partner or multiple sex partners, vaginal douching, or using an intrauterine device (IUD) for birth control.<sup>3</sup>

You cannot get BV from toilet seats, bedding, or swimming pools. And women who have never had sexual intercourse are not commonly affected.<sup>3</sup>

## Diagnosing BV

Your doctor must examine your vagina for signs of BV and perform laboratory tests on a sample of your vaginal fluid to look for the bacteria that causes BV. Your annual Pap smear does not typically test for BV.

Diagnosis is commonly determined after a thorough examination that includes these components.<sup>4</sup>

### Criteria for diagnosing BV<sup>1,4</sup>

#### Evaluate vaginal discharge

thin, milky white discharge that may be fishy smelling

#### Measure vaginal acidity

vaginal pH is often greater than 4.5

#### Look for the presence of clue cells

these vaginal epithelial cells have a distinct appearance due to the presence of harmful bacteria which may indicate BV

#### Perform a "whiff test"

a test in which potassium hydroxide solution is added to vaginal secretions to see if a fishy odor results

## Treatment for BV

BV can only be treated with antibiotics prescribed by a doctor. The most common antibacterial medication used to treat BV is metronidazole. Metronidazole is available in both an oral (tablet) form and as a gel or cream. Over-the-counter yeast infection preparations will not be effective in curing BV. Metronidazole vaginal gel, 0.75%, is the #1 prescribed treatment for BV.<sup>5</sup>

It is important to be treated for BV to avoid any potential complications that may result from nontreatment, such as pelvic inflammatory disease (PID).<sup>3</sup> Male partners generally do not need to be treated, but BV can be spread between female sex partners. Remember, it is not uncommon for BV to recur once you have experienced it.<sup>2,3</sup>

## Preventing BV

While there is no sure way to prevent BV from recurring, there are some things you can do to help prevent it. Since BV may be associated with sexual activity, taking the following steps may help you reduce your risk of disrupting the natural balance of bacteria in your vagina<sup>1-3</sup>:

- Limit your number of sex partners or remain abstinent altogether
- Do not use vaginal douches
- Practice good hygiene but do not use perfumed soaps or feminine hygiene sprays
- Use other forms of birth control instead of an IUD, such as a condom
- If diagnosed with BV, use all of the prescribed medication, even if your signs and symptoms go away right away

## Complications of BV

BV is usually considered a mild condition and in most cases does not cause any further health-related problems for women. However, there are some serious risks for women who have had BV before, including<sup>3</sup>:

- An increased risk of contracting HIV infection if you are exposed to HIV
- An increased chance that an HIV-infected woman can pass HIV to her sex partner
- An increased risk in the development of PID following surgical procedures such as a hysterectomy or an abortion
- BV during pregnancy may put a woman at increased risk for pregnancy complications
- An increased susceptibility to sexually transmitted diseases such as chlamydia and gonorrhea

## BV complications during pregnancy

Pregnant women who get BV often deliver premature babies or babies with a low birth weight (less than 5 pounds).<sup>3</sup>

The bacteria that cause BV, *Gardnerella vaginalis*, can sometimes also infect the uterus or fallopian tubes, leading to PID. PID can cause infertility by damaging the fallopian tubes or increasing the risk for an ectopic (tubal) pregnancy. For these reasons, it is extremely important for women who are pregnant or thinking of becoming pregnant to be treated for BV.<sup>3</sup>

## Other Infections That Cause Vaginitis



### Candidiasis (Yeast Infection)

Candidiasis, commonly known as a yeast infection, is an infection of the vagina caused by the yeast *Candida*. Yeast is found in the mouth and intestines, and in the vagina. Overgrowth of yeast in the vagina is caused by a number of factors including certain antibiotics, the disease diabetes, drugs that slow the immune system, immune deficiencies, hormonal changes, and pregnancy.<sup>2</sup>

Symptoms of a yeast infection can be similar to symptoms of BV and may include itching, irritation and redness of the vulva or vagina, and painful intercourse. However, unlike the vaginal discharge of BV, vaginal discharge with a yeast infection is thick, white, and odorless.<sup>2</sup>

Diagnosis is made by examination of the vagina and vaginal discharge. A number of over-the-counter preparations, including creams, suppositories, and tablets, are available to treat yeast infections.<sup>2</sup>

### Trichomoniasis

Trichomoniasis, or trich, is a sexually transmitted disease caused by the microorganism called *Trichomonas*. It is one of the most common sexually transmitted diseases and is spread by exchanging bodily fluids.<sup>2</sup>

Many women experience no symptoms, or it may take years for symptoms to appear. Symptoms can include a frothy, musty-smelling vaginal discharge, itching in and around the vagina, spotty bleeding in the discharge, and increased urination. Oral antibiotics are used to treat both partners, which is important as you may become infected again if your partner isn't treated.<sup>2</sup>



## Signs and Symptoms of the 3 Types of Vaginitis

The following chart outlines the most common causes of vaginitis and compares the symptoms and treatment for each.<sup>1-4</sup>

Bacterial Vaginosis (BV)	Yeast Infection	Trichomoniasis
<b>Cause</b>		
Bacteria	Yeast	Protozoa trichomonas
<b>Occurrence</b>		
Most common	Common	Common
<b>Vaginal Odor</b>		
Fishy or unpleasant smelling	None	Musty or unpleasant smelling
<b>Vaginal Itching or Irritation</b>		
Sometimes	Usually	Usually intense
<b>Vaginal Discharge</b>		
Thin Milky white or gray	Thick and white Cottage cheese-like	Frothy Yellow-greenish
<b>Treatment</b>		
Rx antibiotic medication prescribed by physician	OTC preparations if previously diagnosed by physician	Rx antibiotic medication prescribed by physician



## Vandazole™ — Balancing cost and treatment

Vandazole™ contains metronidazole vaginal gel, 0.75%, the #1 prescribed intravaginal treatment for BV.<sup>5</sup> Metronidazole gel, 0.75%, is proven to cure BV and restore the natural balance, or flora, of the vagina.<sup>6</sup>

Vandazole™ vaginal gel works directly at the site of infection, which minimizes any interaction with other medications you may be taking. It also minimizes any potential side effects that might occur with an oral treatment. Vandazole™ is a cost-effective alternative to other brands of metronidazole gel and can save you money at the pharmacy.\*<sup>7</sup> If your doctor diagnoses BV, ask for Vandazole™ vaginal gel.

### Convenient dosing

Metronidazole vaginal gel, 0.75%, is the shortest course of therapy for BV for nonpregnant women recommended by the Centers for Disease Control and Prevention.<sup>4</sup> You should use one Vandazole™ applicator once daily at bedtime for 5 days to cure your BV. Make sure you finish the entire course of therapy to help prevent a recurrence. There is a low incidence of systemic side effects with Vandazole™.<sup>8</sup>

\*May vary based on health plan.

The most commonly reported side effects for Vandazole™ are fungal infection, headache, pruritus, and abdominal pain. Vandazole™ is contraindicated in patients with a prior history of hypersensitivity to metronidazole, parabens, other ingredients of the formulation, or other nitroimidazole derivatives. Vandazole™ should not be administered to

patients who have taken disulfiram within the last two weeks. Patients should be cautioned about drinking alcohol and instructed not to engage in vaginal intercourse or use vaginal products during treatment.

**Please see accompanying full prescribing information.**

# VANAZOLE™ (metronidazole vaginal gel, 0.75%) NOT FOR INTRAVAGINAL USE ONLY FOR TOP OPHTHALMIC, DERMAL, OR ORAL USE

Rx only

**Brief Summary** - For more information consult Full Prescribing Information.  
**INDICATIONS AND USAGE**

VANAZOLE™ is indicated in the treatment of bacterial vaginosis (formerly referred to as *Haemophilus* vaginitis, *Gardnerella* vaginitis, nonspecific vaginitis, *Corynebacterium* vaginitis, or anaerobic vaginosis) in non-pregnant women. There are no adequate and well-controlled studies of metronidazole vaginal gel in pregnant women.

**NOTE:** For purposes of this indication, a clinical diagnosis of bacterial vaginosis is usually defined by the presence of a homogeneous vaginal discharge that (a) has a pH of greater than 4.5, (b) emits a "fishy" amine odor when mixed with a 10% KOH solution, and (c) contains clue cells on microscopic examination. Gram's stain results consistent with a diagnosis of bacterial vaginosis include (a) markedly reduced or absent *Lactobacillus* morphology, (b) predominance of *Gardnerella* morphotype, and (c) absent or few white blood cells.

Other pathogens commonly associated with vulvovaginitis, e.g., *Trichomonas vaginalis*, *Chlamydia trachomatis*, *N. gonorrhoeae*, *Candida albicans*, and *Herpes simplex virus* should be ruled out.

## CONTRAINDICATIONS

VANAZOLE™ is contraindicated in patients with a prior history of hypersensitivity to metronidazole, parabens, other ingredients of the formulation, or other nitroimidazole derivatives.

## WARNINGS

### Convulsive Seizures and Peripheral Neuropathy

Convulsive seizures and peripheral neuropathy, the latter characterized mainly by numbness or paresthesia of an extremity, have been reported in patients treated with oral or intravenous metronidazole. The appearance of abnormal neurologic signs demands the prompt discontinuation of metronidazole vaginal gel therapy. Metronidazole vaginal gel should be administered with caution to patients with central nervous system diseases.

### Psychotic Reactions

Psychotic reactions have been reported in alcoholic patients who were using oral metronidazole and disulfiram concurrently. Metronidazole vaginal gel should not be administered to patients who have taken disulfiram within the last two weeks.

## PRECAUTIONS

Metronidazole vaginal gel results in minimal peak serum levels and systemic exposure (AUCs) of metronidazole compared to 500 mg oral metronidazole dosing. Although these lower levels of exposure are less likely to produce the common reactions seen with oral metronidazole, the possibility of these and other reactions, cannot be excluded presently. Data from well-controlled trials directly comparing metronidazole administered orally to metronidazole administered vaginally are not available.

## General

Patients with severe hepatic disease metabolize metronidazole slowly. This results in the accumulation of metronidazole and its metabolites in the plasma. Accordingly, for such patients, metronidazole vaginal gel should be administered cautiously.

Known or previously unrecognized vaginal candidiasis may present more prominent symptoms during therapy with metronidazole vaginal gel. Approximately 10% of patients treated with metronidazole vaginal gel developed symptomatic *Candida* vaginitis during or immediately after therapy.

Disulfiram-like reaction to alcohol has been reported with oral metronidazole, thus the possibility of such a reaction occurring while on metronidazole vaginal gel therapy cannot be excluded.

Metronidazole vaginal gel contains ingredients that may cause burning and irritation of the eye. In the event of accidental contact with the eye, rinse the eye with copious amounts of cool tap water.

## Information for the Patient

The patient should be cautioned about drinking alcohol while being treated with metronidazole vaginal gel. While blood levels are significantly lower with VANAZOLE™ than with usual doses of oral metronidazole, a possible interaction with alcohol cannot be excluded.

The patient should be instructed not to engage in vaginal intercourse, or use other vaginal products (such as tampons or douches) during treatment with this product.

VANAZOLE™ (metronidazole vaginal gel, 0.75%) is supplied with 5 vaginal applicators. For once daily dosing, one applicator should be used per dose. For twice-daily dosing, the applicator should be washed, rinsed, and dried following the morning application, and re-used for the evening dose. After the evening dose, the applicator should be discarded and a new applicator used for the next day's dose. See **DIRECTIONS FOR USE** for complete instructions on how to use the product and the vaginal applicator.

## Drug Interactions

The intravaginal administration of metronidazole vaginal gel, results in relatively lower systemic metronidazole concentrations compared to that following a 500 mg metronidazole oral dose (see **CLINICAL PHARMACOLOGY**). The following drug interactions were reported for oral metronidazole.

Oral metronidazole has been reported to potentiate the anticoagulant effect of warfarin and other coumarin anticoagulants, resulting in a prolongation of prothrombin time. This possible drug interaction should be considered when metronidazole vaginal gel is prescribed for patients on this type of anticoagulant therapy.

In patients stabilized on relatively high doses of lithium, short-term oral metronidazole therapy has been associated with elevation of serum lithium levels and, in a few cases, signs of lithium toxicity.

Use of cimetidine with oral metronidazole may prolong the half-life and decrease plasma clearance of metronidazole.

## Drug/Laboratory Test Interactions

Metronidazole may interfere with certain types of determinations of serum chemistry values, such as aspartate aminotransferase (AST, SGOT), alanine aminotransferase (ALT, SGPT), lactate dehydrogenase (LDH), triglycerides, and glucose hexokinase. Values of zero may be observed. All of the assays in which interference has been reported involve enzymatic coupling of the assay to oxidation-reduction of nicotinamide-adenine dinucleotides (NAD + NADH). Interference is due to the similarity in absorbance peaks of NADH (340 nm) and metronidazole (322 nm) at pH 7.

## Carcinogenesis, Mutagenesis, Impairment of Fertility

Metronidazole has shown evidence of carcinogenic activity after chronic oral administration in mice and rats. Pulmonary tumors and lymphomas were reported in several oral mouse studies in which mice were dosed at 75 mg/kg and above (about 5 times the clinical human dose based on body surface area comparison). Malignant liver tumors were reported in male mice dosed at doses equivalent to a human dose of 41 mg/kg/day (3.9 times the recommended clinical dose based on body surface area comparisons). Chronic oral dosing of metronidazole in rats at doses above 150 mg/kg (about 120 times the clinical human dose based on body surface area comparison) has resulted in mammary and hepatic tumors. Two lifetime tumorigenicity studies in hamsters have been performed and reported to be negative. No life-time studies were performed to evaluate the carcinogenic potential of VANAZOLE™ (metronidazole vaginal gel, 0.75%).

Metronidazole has shown mutagenic activity in a number of *in vitro* assay systems. In addition, a dose dependent increase in the frequency of micronuclei was observed in mice after intraperitoneal injections. An increase in chromosome aberrations has been reported in one study of patients with Crohn's disease who were treated with 200 to 1200 mg/day of metronidazole for 1 to 24 months. However, in a second study, no increase in chromosome aberrations was reported in patients with Crohn's disease who were treated with metronidazole for 8 months.

Fertility studies have been performed in mice up to six times the recommended human oral dose (based on mg/m<sup>2</sup>) and have revealed no evidence of impaired fertility.

## Pregnancy

### Teratogenic Effects

### Pregnancy category B

There is no data available regarding the use of VANAZOLE™ in pregnant women and therefore, no adequate and well-controlled studies in pregnant women. Oral reproductive toxicity studies have been performed in mice at doses up to six times the recommended human dose based on body surface area comparisons and have revealed no evidence of impaired fertility or harm to the fetus. However, in a single small study where the drug was administered intraperitoneally, some intrauterine deaths were observed.

Animal studies have shown that metronidazole crosses the placental barrier and enters the fetal circulation rapidly. Because animal reproduction studies are not always predictive of human response, and because metronidazole crosses the placental barrier and is a carcinogen in rodents, this drug should be used during pregnancy only if clearly needed.

### Nursing Mothers

Specific studies of metronidazole levels in human milk following intravaginally administered metronidazole have not been performed. However, metronidazole is secreted in human milk in concentrations similar to those found in plasma following oral administration of metronidazole.

Because of the potential for tumorigenicity shown for metronidazole in mouse and rat studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

### Pediatric Use

The safety and efficacy of VANAZOLE™ in the treatment of bacterial vaginosis in post-menarchal females has been established on the extrapolation of clinical trial data from adult women. The safety and efficacy of VANAZOLE™ in pre-menarchal females have not been established.

### Geriatric Use

Clinical studies with VANAZOLE™ did not include sufficient numbers of subjects 65 years of age or older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients.

## ADVERSE EVENTS

### Clinical Trials

There were no deaths or serious adverse events related to drug therapy in a clinical trial involving 220 non-pregnant women who received VANAZOLE™ once daily at bedtime for 5 days. VANAZOLE™ was discontinued in 5 patients (2.3%) due to adverse events. Adverse events judged definitely or probably related to drug occurred in 25 patients (11.4%).

The incidence of all adverse events was 42% (92/220). Events occurring in ≥ 1% of patients were: fungal infection (12%), headache (7%), pruritus (6%), abdominal pain (5%), nausea (3%), dysmenorrhea (3%), pharyngitis (2%), rash (1%), infection (1%), diarrhea (1%), breast pain (1%), and metrorrhagia (1%).

Adverse events judged to be definitely related or probably related to study medication occurring in ≥ 1% of patients were: fungal infection (9.1%).

Additional uncommon events, not necessarily related to VANAZOLE™, but reported by < 1% of those women treated included:

<b>General:</b>	allergic reaction, back pain, flu syndrome, mucous membrane disorder, pain
<b>Gastrointestinal:</b>	anorexia, constipation, dyspepsia, flatulence, gingivitis, vomiting
<b>Nervous System:</b>	depression, dizziness, insomnia
<b>Respiratory System:</b>	asthma, rhinitis
<b>Skin and Appendages:</b>	acne, sweating, urticaria
<b>Urogenital System:</b>	breast enlargement, dysuria, female lactation, labial edema, leucorrhea, menorrhagia, pyelonephritis, salpingitis, urinary frequency, urinary tract infection, vaginitis, vulvovaginal disorder

## Other Metronidazole Formulations

### Other Vaginal Formulations

Other effects that have been reported in association with the use of other formulations of metronidazole vaginal gel include: unusual taste and decreased appetite.

### Topical (dermal) Formulations

Other effects that have been reported in association with the use of topical (dermal) formulations of metronidazole include skin irritation, transient skin erythema, and mild skin dryness and burning. None of these adverse events exceeded an incidence of 2% of patients.

### Oral and Parenteral Formulations

Metronidazole vaginal gel results in minimal peak serum levels and systemic exposure (AUC) of metronidazole compared to 500 mg oral metronidazole dosing. Although these lower levels of exposure are less likely to produce the common reactions seen with oral metronidazole, the possibility of these and other reactions cannot be excluded presently. Data from well-controlled trials directly comparing metronidazole administered orally to metronidazole administered vaginally are not available.

The following adverse reactions and altered laboratory tests have been reported with the oral or parenteral use of metronidazole:

**Cardiovascular:** Flattening of the T-wave may be seen in electrocardiographic tracings.

**Central Nervous System:** (See **WARNINGS**.) Headache, dizziness, syncope, ataxia, confusion, convulsive seizures, peripheral neuropathy, vertigo, incoordination, irritability, depression, weakness, insomnia.

**Gastrointestinal:** Abdominal discomfort, nausea, vomiting, diarrhea, an unpleasant metallic taste, anorexia, epigastric distress, abdominal cramping, constipation, "furry" tongue, glossitis, stomatitis, pancreatitis, and modification of taste of alcoholic beverages.

**Genitourinary:** Overgrowth of *Candida* in the vagina, dyspareunia, decreased libido, proctitis.

**Hematopoietic:** Reversible neutropenia, reversible thrombocytopenia.

**Hypersensitivity Reactions:** Urticaria, erythematous rash, flushing; nasal congestion, dryness of the mouth, vagina, or vulva; fever; pruritus; fleeting joint pains.

**Renal:** Dysuria, cystitis, polyuria, incontinence, a sense of pelvic pressure, darkened urine.

## OVERDOSAGE

There is no human experience with overdosage of metronidazole vaginal gel. Vaginally applied metronidazole gel, 0.75% could be absorbed in sufficient amounts to produce systemic effects. (See **WARNINGS**.)

## DOSAGE AND ADMINISTRATION

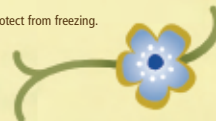
See full prescribing information.


Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from freezing.

Manufactured for  
UPSHER-SMITH LABORATORIES, INC.  
Minneapolis, MN 55447


VABS01

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For more information about Vandazole™ visit  
[www.upsher-smith.com/products/vandazole.html](http://www.upsher-smith.com/products/vandazole.html)



# VANDAZOLE™

(metronidazole vaginal gel, 0.75%)

## *Balancing cost and treatment*

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