

— YOUR TREATMENT GUIDE

Vagizole™

Metronidazole Vaginal Gel, 0.75%

A clear, patient-friendly companion for understanding bacterial vaginosis, your prescription, and proper use.

Rx Only



NDC 87687-002-70 | 70 g tube with 5 applicators

Your treatment, made clearer.

Vagizole is a prescription medicine containing metronidazole vaginal gel, 0.75%, indicated for the treatment of bacterial vaginosis. This guide summarizes key information in a patient-friendly format and does not replace the official FDA-approved labeling or advice from your healthcare provider.



For intravaginal use only

Not for ophthalmic, dermal, or oral use.

A balance that matters.

Bacterial vaginosis (BV) is associated with a disruption in the balance of bacteria normally present in the vagina. A healthcare provider should confirm the diagnosis and rule out other possible causes of symptoms.

— UNDERSTANDING BACTERIAL VAGINOSIS —

A Balance That Matters

Bacterial vaginosis (BV) occurs when the delicate balance of good and harmful bacteria in the vagina is disrupted. This imbalance can lead to uncomfortable symptoms.



Healthy Balance

A healthy vaginal environment is dominated by good bacteria that help protect you.



Lactobacillus Bacteria
Good Bacteria



Maintains Low pH
3.8 – 4.5



Supports Vaginal Health
Helps prevent infection



Predominantly Lactobacillus

VS.



BV Imbalance

An overgrowth of harmful bacteria can disrupt pH and lead to BV symptoms.



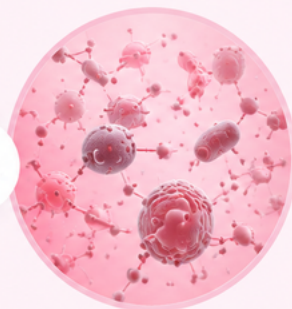
Reduced Lactobacillus
Gardnerella & anaerobes increase



Elevated Vaginal pH
Above 4.5



May Cause Symptoms
Odor, discharge, discomfort



Overgrowth of Anaerobic Bacteria



You're not alone.

Up to 1 in 3 women may experience bacterial vaginosis during their lifetime. BV is common, treatable, and is not a sign of poor hygiene.

Common signs may include

Unusual discharge, odor, irritation, burning, or discomfort. Symptoms alone cannot confirm BV.

ABOUT YOUR PRESCRIPTION

Prescription strength, targeted use.

Vagizole contains 7.5 mg of metronidazole in each gram of gel (0.75%). One full applicator contains approximately 5 grams of gel, equal to approximately 37.5 mg of metronidazole.

0.75%

Metronidazole
concentration

5 g

Approximate amount
per full applicator

70 g

Tube size



WHAT'S IN THE BOX

Everything you need, ready to go.

Each carton is supplied with one 70 g tube and five vaginal applicators.



70 g Tube

Prescription-strength metronidazole vaginal gel.

5 Applicators

Applicators supplied for administration of the gel.

Directions

Official directions for filling, inserting, and handling the applicator.

Three simple steps.

1 Fill the applicator

Remove the cap and puncture the metal seal with the pointed tip of the cap. Screw the applicator onto the tube. Gently squeeze from the bottom until the plunger stops.

2 Insert and release

Choose a comfortable position. Hold the filled applicator by the barrel, gently insert it as far as comfortable, and slowly press the plunger until it stops.

3 Follow your prescribed schedule

For once-daily dosing, administer at bedtime. For twice-daily dosing, administer morning and evening for five days, or exactly as directed by your physician.

Important

Follow the Instructions for Use supplied with the medicine. Contact your healthcare provider if you are uncertain about any step.

Use exactly as prescribed.

The recommended labeled regimen is one applicator full intravaginally once or twice daily for five days. Your healthcare provider will determine the schedule that is right for you.



*Your prescription may direct once- or twice-daily use.

Once daily

Administer one full applicator at bedtime for five days.

Twice daily

Administer one full applicator each morning and evening for five days.

Do not change your schedule or stop early unless your healthcare provider tells you to.

A few things to remember.

Alcohol

The label cautions that a possible interaction with alcohol cannot be excluded during treatment.

Intercourse

The patient information instructs patients not to engage in vaginal intercourse during treatment.

Eye contact

If gel accidentally contacts the eyes, rinse with plenty of cool tap water.

Applicator care

Follow the supplied Instructions for Use. For twice-daily dosing, the directions include cleaning and reassembly instructions.

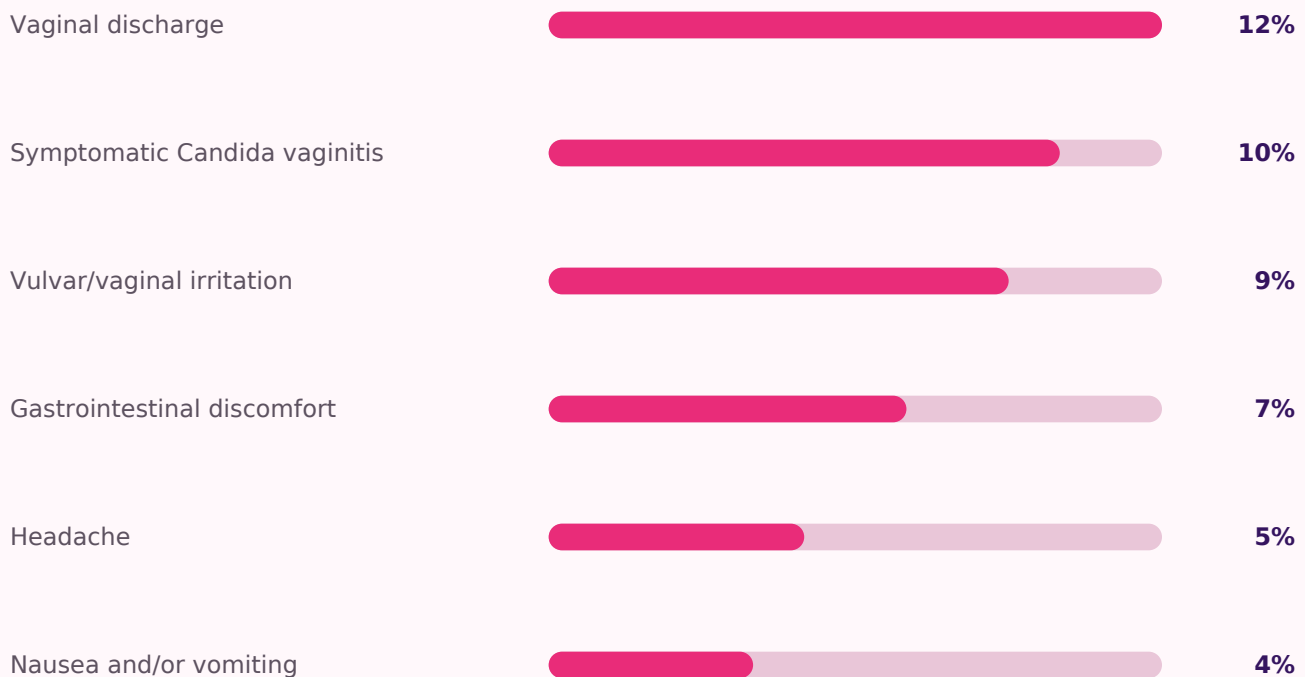
Keep your provider informed

Tell your healthcare provider about other medicines and important medical conditions.

POSSIBLE SIDE EFFECTS

Know what to watch for.

In clinical trials, reported events included vaginal discharge, symptomatic yeast infection, vaginal or vulvar irritation, gastrointestinal discomfort, headache, nausea or vomiting, dizziness, pelvic discomfort, unusual taste, and other reactions. Not everyone experiences side effects.



Contact your healthcare provider promptly

Stop treatment and seek medical advice if you develop significant irritation or abnormal neurologic symptoms such as numbness, tingling, or seizures. Call 911 for a medical emergency.

Before and during treatment.

Do not use if

You have had hypersensitivity to metronidazole, parabens, another formulation ingredient, or another nitroimidazole derivative.

Disulfiram

Do not use if you have taken disulfiram within the previous two weeks.

Pregnancy

The supplied Directions for Use state not to use during pregnancy except under a physician's supervision.

Medical conditions

Discuss treatment if you have central nervous system disease, severe liver disease, or take medicines such as warfarin, lithium, or cimetidine.

For vaginal use only

Not for the eyes, skin, or mouth. Keep this and all medicines out of reach of children.

Storage and when to call.

Storage

Store at controlled room temperature, 15° to 30°C (59° to 86°F). Protect from freezing. Check the carton or tube for the lot number and expiration date.

If you miss a dose

Contact your healthcare provider or pharmacist for individualized instructions. Do not double a dose unless specifically directed.

Symptoms persist

Contact your healthcare provider if symptoms do not improve, worsen, or return after treatment.

Unexpected reaction

Seek advice for significant irritation, new neurologic symptoms, severe allergic symptoms, or anything that concerns you.

Report suspected adverse reactions

Contact iNutrition LLC at (323) 200-5258 or report to FDA MedWatch at 1-800-FDA-1088.

Keep the official label close.

This guide is an educational companion. For complete warnings, precautions, adverse reactions, drug interactions, and directions, review the current FDA-approved labeling and speak with your healthcare provider.



Scan for the official DailyMed label

Product details

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NDC 87687-002-70

70 g tube with 5 applicators

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Manufactured for iNutrition LLC

Raleigh, NC 27617