





# Inside you'll find helpful information, including:

- What is bacterial vaginosis (BV)?
- What causes BV?
- Reasons why you need to see your healthcare provider
- Why treatment with SOLOSEC® is different

#### What is SOLOSEC®?

SOLOSEC® (secnidazole) 2g oral granules is a prescription medicine used to treat bacterial vaginosis in females 12 years of age and older. It is not known if SOLOSEC® is safe and effective in children under 12 years of age.

#### **Select Important Safety Information**

 You should not use SOLOSEC® if you've had an allergic reaction to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives or have Cockayne syndrome

Please see complete Important Safety Information on page 11 of this brochure.



BV is a **common bacterial infection** that results when there is an imbalance in the normal vaginal bacteria<sup>2</sup>

BV is caused by an **overgrowth of bacteria** that are naturally present in the vagina<sup>2</sup>

## BV is the most common cause of abnormal vaginal discharge<sup>2</sup>

Unlike a yeast infection, which is caused by a fungus and can be treated with over-the-counter medications, BV is caused by bacteria and must be treated with prescription antibiotics<sup>2,3</sup>



#### You should know

BV should only be treated with a prescription medication from your healthcare provider<sup>3</sup>

### Symptoms of BV include<sup>2</sup>:

- Discharge that's thin and white or light gray
- Pain, itching, or burning in or around the vagina
- A fishy odor, especially after sex

Many women with BV do not have any symptoms, or they may have discharge that comes and goes<sup>2</sup>

#### **Select Important Safety Information**

 Vaginal yeast infections may occur with SOLOSEC® and require an antifungal treatment.

Please see complete Important Safety Information on page 11 of this brochure.

## Understanding your vagina's natural balance

Healthy vaginas are naturally acidic and have a certain pH where they stay in balance<sup>2</sup>

Healthy vaginas naturally have a mix of bacteria<sup>2</sup>

Bacteria

#### Vaginal pH

It's easy for vaginal pH to become unbalanced. Your period, sex, and douching can change your vagina's pH<sup>2</sup> Changes in the pH of your vagina make it easier for some of the bacteria to overgrow, leading to BV.<sup>2</sup>

## Any woman can get BV, but research has shown that certain risk factors increase your chances:

- Douching<sup>4</sup>
- Smoking<sup>4</sup>
- Being overweight or obese<sup>5</sup>
- Having been pregnant in the past<sup>4</sup>
- Sexual activity (being sexually active, higher number of lifetime sexual partners, and same-sex sexual activity)<sup>4</sup>
  - BV is not considered a sexually transmitted infection (STI), but women who are not sexually active rarely get BV<sup>2</sup>

#### **Select Important Safety Information**

 The most common side effects of SOLOSEC® include headache, nausea, vomiting, diarrhea, abdominal pain, vaginal itching and a bad, bitter or metallic taste in your mouth (dysgeusia).

Please see complete Important Safety Information on page 11 of this brochure.



Leaving BV untreated can have **serious consequences**, so it's important to see your HCP for effective treatment<sup>2</sup>

Research has shown that untreated or improperly treated BV is associated with increased risk of:

- Developing pelvic inflammatory disease (PID), which can threaten your fertility<sup>2</sup>
- Getting sexually transmitted infections (STIs) like herpes, trichomoniasis (trich), chlamydia, gonorrhea, and HIV, and transmitting STIs to your partner<sup>2</sup>
- Complications with gynecological surgery<sup>2</sup>

If you're pregnant, it's especially important to get tested. If left untreated, BV increases the risk of complications with your pregnancy, including late term miscarriage and premature birth<sup>2,6</sup>

SOLOSEC® has no pregnancy restrictions¹

- Available data on pregnancy are limited to animal studies

#### **Select Important Safety Information**

- Before taking SOLOSEC®, tell your healthcare provider about all of your medical conditions, including if you
- Are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed. Breastfeeding is not recommended. You should not breastfeed for 96 hours (4 days) after taking SOLOSEC®.

Please see complete Important Safety Information on page 11 of this brochure.



The majority of patients treated with SOLOSEC® did not require additional treatment for BV<sup>7</sup>

For women who are treated with a common 7-day, twice-daily course of treatment, **over half (58%)** will have BV again **within 1 year**<sup>9</sup>

Research shows that not taking the full course of 7-day treatment can contribute to BV coming back<sup>10</sup>

#### Request SOLOSEC®, the one-time oral dose treatment



#### **Select Important Safety Information**

 The most common side effects of SOLOSEC® include headache, nausea, vomiting, diarrhea, abdominal pain, vaginal itching and a bad, bitter or metallic taste in your mouth (dysgeusia).

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SOLOSEC® is the **only single dose oral** antibiotic that's FDA-approved to treat bacterial vaginosis (BV)<sup>1</sup>

SOLOSEC® lets you complete treatment with **one oral dose**, **one time**—not several pills over multiple days<sup>1,13,14</sup>

#### **SOLOSEC®**

- ✓ Is an effective antibiotic medication that treats BV with just one oral dose¹
- ✓ Is rapidly absorbed by your body and goes to work quickly to treat BV¹¹
- ✓ Keeps working in the body to treat BV for several days after one dose<sup>11</sup>
- ✓ Was effective in clinical studies; most women treated with SOLOSEC® needed no additional treatment for BV<sup>7,12</sup>
- ✓ Isn't a pill. It's different¹
- SOLOSEC is also approved to treat trichomoniasis, a common sexually transmitted infection (STI)<sup>1</sup>

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SOLOSEC® does not interfere with a common birth control pill\*, condoms or diaphragms¹

\*Combination ethinyl estradiol and norethindrone



With SOLOSEC®, you can continue to use your vaginal products (tampons)

### **Complete Treatment with One Oral Dose**



#### **Select Important Safety Information**

 Vaginal yeast infections may occur with SOLOSEC® and require an antifungal treatment.

Please see complete Important Safety Information on page 11 of this brochure.





How do I take SOLOSEC®?



One day. One dose. That's it!



SOLOSEC® is easy to take1

In fact, the American College of Obstetricians and Gynecologist (ACOG) and the Centers for Disease Control (CDC) include SOLOSEC® as a treatment for BV in their guidelines to healthcare providers.<sup>2,13</sup>

SOLOSEC® is the only single dose oral antibiotic to treat BV











#### **Select Important Safety Information**

• The most common side effects of SOLOSEC® include headache, nausea, vomiting, diarrhea, abdominal pain, vaginal itching and a bad, bitter or metallic taste in your mouth (dysgeusia).

Please see complete Important Safety Information on page 11 of this brochure.





Open the packet and sprinkle the entire contents of the packet onto applesauce, yogurt or pudding





Stir and mix





Consume all of the mixture within 30 minutes. DO NOT CHEW OR CRUNCH THE GRANULES



You can drink a glass of water after taking SOLOSEC® to help with swallowing, if needed. Do not try to dissolve the medication in water or any other liquid

#### **Select Important Safety Information**

• Take SOLOSEC® exactly as your healthcare provider tells you to. Do not take SOLOSEC® more often than it is prescribed.

Please see complete Important Safety Information on page 11 of this brochure.



There are multiple ways to access a co-pay card that may help you save money on your SOLOSEC® prescription\*



If commercially insured, most eligible patients may pay **as little as \$25** for SOLOSEC<sup>®</sup>.\* If you don't have insurance or are paying cash, you may still pay as little as \$75

- Visit solosec.com/savings-card to text a card to your mobile device, get a card emailed to you, or download a card onto your computer
- Alternatively, get a physical card from your HCP
- Using your mobile device, scan the QR code on this brochure below



\*Per fill. Not valid for any person eligible for reimbursement of prescriptions, in whole or in part, by any state- or federally funded program, including Medicare, Medigap, or Medicaid, or where prohibited, taxed or otherwise restricted by law. Cash-pay patients may pay as little as \$75. Eligibility requirements and terms and conditions apply. See Terms and Conditions at solosec.com for full details.



#### What is SOLOSEC®?

SOLOSEC® (secnidazole) 2g oral granules is a prescription medicine used to treat bacterial vaginosis in females 12 years of age and older. SOLOSEC® is used to treat Trichomoniasis, a common sexually transmitted infection (STI), in people 12 years of age and older. People taking SOLOSEC® for Trichomoniasis should avoid having sex until they and their sex partners are treated with the same dose and at the same time, to prevent reinfection. It is not known if SOLOSEC® is safe and effective in children under 12 years of age.

#### How should I take SOLOSEC®?

SOLOSEC® is a single-dose therapy for oral use. Use SOLOSEC® by sprinkling an entire packet of SOLOSEC® onto applesauce, yogurt, or pudding. The entire dose should be taken at once, and finished within 30 minutes. Avoid chewing or crunching the granules. SOLOSEC® should not be taken by dissolving the granules in any liquid. Avoid drinking alcohol during treatment with SOLOSEC® and for 2 days (48 hours) after you take SOLOSEC®.

#### **Important Safety Information**

- You should not use SOLOSEC® if you've had an allergic reaction to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives or have Cockayne syndrome.
- Before taking SOLOSEC®, tell your healthcare provider about all of your medical conditions, including if you
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed. Breastfeeding is not recommended. You should not breastfeed for 96 hours (4 days) after taking SOLOSEC®.
- Vaginal yeast infections may occur with SOLOSEC® and require an antifungal treatment.
- The most common side effects of SOLOSEC® include headache, nausea, vomiting, diarrhea, abdominal pain, vaginal itching and a bad, bitter or metallic taste in your mouth (dysgeusia).
- Take SOLOSEC® exactly as your healthcare provider tells you to. Do not take SOLOSEC® more often than it is prescribed.

Call your doctor for medical advice on side effects. You are encouraged to report suspected side effects of prescription drugs to FDA at www.fda.gov/MedWatch also at 1-800-FDA-1088 or contact Lupin Pharmaceuticals, Inc. at 1-844-SOLOSEC (1-844-765-6732).

Please see full Prescribing Information for SOLOSEC®, available at www.solosec.com.

References: 1. SOLOSEC® [prescribing information]. Baltimore, MD: Lupin Pharmaceuticals, Inc; 2022. 2. Workowski KA, Bachmann LH, Chan PA, et al. CDC Sexually Transmitted Diseases Treatment Guidelines, 2021. MMWR Recomm Rep 2021;70(RR-04):1-192. 3. CDC. Bacterial Vaginosis Fact Sheet. Updated Jun 2017. Accessed 26 Jul 2021. 4. Koumans EH, Sternberg M, Bruce C, et al. The prevalence of bacterial vaginosis in the United States, 2001-2004; associations with symptoms, sexual behaviors, and reproductive health. Sex Transm Dis. 2007; 34(11):864-869. 5. Brookheart RT, Lewis WG, Peipert JF, Lewis  $\dot{AL}$ , Allsworth JE. Association between obesity and bacterial vaginosis as assessed by Nugent Score. Am J Obstet Gynecol. 2019;220(5):476.e1-476.e11. 6. Leitich H, Bodner-Adler B, Brunbauer M, et al. Bacterial vaginosis as a risk factor for preterm delivery; a meta-analysis Am J Obstet Gynecol 2003;189(1):139-147. **7.** Schwebke JR, Morgan FG Jr, Koltun W, Nyirjesy P. A phase-3, double-blind, placebo-controlled study of the effectiveness and safety of single oral doses of secnidazole 2 g for the treatment of women with bacterial vaginosis [published correction appears in Am J Obstet Gynecol 2018;219(1):110]. Am J Obstet Gynecol 2017;217(6):678.e1-678.e9. 8. Bartley JB, Ferris DG, Allmond LM, Dickman ED, Dias JK, Lambert J. Personal digital assistants used to document compliance of bacterial vaginosis treatment. Sex Transm Dis 2004;31(8):488-491. 9. Bradshaw CS, Morton AN, Hocking J, et al. High recurrence rates of bacterial vaginosis over the course of 12 months after oral metronidazole therapy and factors associated with recurrence. J Infect Dis 2006; 193:1478-89. 10. Marrazzo JM, Thomas KK, Fledler TL, Ringwood K, Fredricks DN. Relationship of Specific Vaginal Bacteria and Bacterial Vaginosis Treatment Failure in Women Who Have Sex with Women. Ann Intern Med 2008;149:20-28 11. Nyirjesy P, Schwebke JR. Secnidazole: Next generation antimicrobial agent for bacterial vaginosis treatment. Future Microbiol 2018;13:507-524. 12. Hillier SL, Nyirjesy P, Waldbaum AS, et al. Secnidazole treatment of bacterial vaginosis: a randomized controlled trial. Obstet Gynecol 2017;130(2):379-386. 13. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin: Clinical Management Guidelines for Obstetricians-Gynecologists, Number 215. Obstet Gynecol 2020:135(1):e1-e174. 14. U of Illinois-Chicago Drug Information Group. How to Use Vaginal Suppositories. Healthline.com. Updated 22 May 2017.



Ask your healthcare provider if SOLOSEC® is right for you.

One day. One dose. That's it!



For more information about SOLOSEC®, visit Solosec.com

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