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Single-Dose Oral Treatment Option for Bacterial Vaginosis May Improve Patient Adherence

BACKGROUND ON BACTERIAL VAGINOSIS

A vaginal infection characterized by discharge, itch, or odor will affect most women at some point during their lives.[1] Bacterial vaginosis (BV) is one such infection, and some current treatments for BV require that patients use additional or alternative birth control, avoid alcohol, or take the treatment for several days.[1]

BV is a clinical syndrome resulting from an imbalance of bacteria in the vagina. The replacement of hydrogen peroxide-producing bacteria in the vagina with high concentrations of anaerobic bacteria and other organisms leads to the development of BV.[1] Evidence from a systematic review and meta-analysis indicate that the prevalence of BV among the general population of reproductive-age women in North America is 27.4%.[2]

Treatment for BV requires prescription medication. The route of administration, cost, adverse reactions, and treatment duration of these medications can impact patient adherence.[3] Adherence rates for 5- and 7-day treatments may be as low as 50%.[4] Commonly reported reasons for nonadherence include forgetting to take or administer a dose and wanting to consume alcohol while on medication.[5] Furthermore, the application of gels or creams may be messy and interfere with daily activities, limiting their use. Some topical BV-indicated medications are oil-based and may compromise latex condoms or diaphragms.[1]

A SINGLE-DOSE ORAL TREATMENT OPTION

Solosec® (secnidazole) is a BV treatment that is administered orally as a single dose. Solosec® can be coadministered with combination oral contraceptives (such as combination ethinyl estradiol/norethindrone) and has no alcohol restriction.[6] In in vitro studies, Solosec® had no effect on the activity of aldehyde dehydrogenase, an enzyme involved in alcohol metabolism.[6] The recommended dosage of Solosec® is a single 2-gram packet of granules taken once orally.[6] It is not a topical medication. Pharmacists are ideally positioned to answer questions, educate patients, and offer support to patients prescribed Solosec® for BV.

- **Solosec® (secnidazole) 2g oral granules is a 5-nitroimidazole antimicrobial agent indicated for the treatment of BV in adult women.[6]**
- **Solosec® is contraindicated in patients with a history of hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives.[6]**
- **The most common adverse reactions observed in clinical trials (incidence ≥2%) were vulvovaginal candidiasis, headache, nausea, dysgeusia, vomiting, diarrhea, abdominal pain, and vulvovaginal pruritus.[6]**

Please see Important Safety Information for Solosec® at the end of this article and a Brief Summary of Prescribing Information for Solosec® following this article.

TABLE. CURRENT TREATMENTS FOR BACTERIAL VAGINOSIS[6-11,a,b,c]

	Solosec® (secnidazole) oral granules[6]	Flagyl ER® (metronidazole) extended-release tablets 750 mg[7]	Tindamax® (tinidazole) tablets 500 mg[8]	Clindesse® (clindamycin phosphate) Vaginal cream, 2%[9]	Metrogel® (metronidazole) Vaginal Gel, 0.75%[10]	Nuvessa™ (metronidazole) Vaginal Gel, 1.3%[11]
BV indication	✓	✓	✓	✓	✓	✓
No boxed warning	✓			✓	✓	✓
No alcohol restriction[d]	✓			✓		
Tested negative for significant interactions with a common oral contraceptive[e]	✓					
QIDP[f] designation	✓	N/A	N/A	N/A	N/A	N/A
Single dose	✓			✓		✓
Dosing	**1 dose / 1 day**	1 dose / 7 days	One 2g dose / 2 days with food OR One 1g dose / 5 days with food	1 dose / 1 day, intravaginally at any time of the day	1 dose or 2 doses / day, intravaginally, for 5 days	1 dose / 1 day, intravaginally

BV indicates bacterial vaginosis; ER, extended release; N/A, not applicable; QIDP, Qualified Infectious Disease Product.
[a]The comparative efficacy of Solosec® compared with these treatments has not been adequately studied.
[b]This is not a complete list of attributes for each product that may be important to a clinical decision. For the most updated information, consult the prescribing information for each product.
[c]Solosec® is a registered trademark owned by Lupin Inc; Flagyl® is a registered trademark of GD Searle & Co; Tindamax® is a registered trademark of Mission Pharmacal Company and is not associated with Edenbridge Pharmaceutials LLC; Clindesse® is a registered trademark of Perrigo Pharma International DAC, a Perrigo company; Metrogel® is manufactured by Teva Pharmaceuticals USA; Nuvessa™ is a trademark of Allergan Pharmaceuticals International Limited.
[d]In vitro drug alcohol studies show that Solosec® does not inhibit the enzyme that metabolizes alcohol.[6]
[e]Combination oral contraceptive ethinyl estradiol plus norethindrone.
[f]The FDA QIDP designation, established in 2012, demonstrates that the drug is an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections. Designation not applicable to or available to drugs or marketing applications approved before 2012.

SAFETY AND EFFICACY OF SOLOSEC®

Efficacy for Solosec® was established based on 2 randomized placebo-controlled trials in women aged 18 to 54 years. Both trials demonstrated a higher percentage of clinical response, Nugent score cure, and therapeutic response with Solosec® compared with placebo.[6]

One trial demonstrated clinical outcome responder rates for Solosec® of 53.3% versus 19.3% for placebo (P <.001). Clinical cure rates were 64.0% and 26.4% for Solosec® versus placebo, respectively. In addition, at the test-of-cure/end-of-study visit, significantly more patients receiving Solosec® versus placebo required no additional treatment for BV (68.0% vs 29.6%; P <.001).[12]

Solosec® has been shown to be generally well tolerated.[12,13] The most commonly reported adverse reactions, with incidence ≥2%, were vulvovaginal candidiasis, headache, nausea, diarrhea, abdominal pain, and vulvovaginal pruritus.[6]

ROLE OF THE PHARMACIST

Pharmacists play a crucial role in educating patients on the appropriate use of Solosec®. Patients should be counseled to talk to their health care providers to share their medical history prior to using Solosec®. The medication should be taken once, as a single dose, orally. Patients should be counseled to sprinkle and mix the entire contents of the packet with applesauce, pudding, or yogurt. Once combined, the patient should consume the entire mixture within 30 minutes and be instructed not to crush, chew, or crunch the granules. The contents of the packet are not intended to be dissolved in liquid.[6]

The most common adverse reaction reported by patients taking Solosec® is vulvovaginal candidiasis (yeast infection). The incidence of yeast infection in clinical trials was 9.6%.[6] Symptoms of a vaginal yeast infection include vaginal itching and white or yellowish discharge with a texture that may resemble cottage cheese. Women should be advised to contact their health care provider if they experience a change in vaginal discharge or odor, or any adverse reactions, while taking Solosec®.[6]

SAVINGS PROGRAM

A copay card is available to help reduce the out-of-pocket cost of the medication for eligible patients. The card can be utilized as a secondary insurance in patients with primary commercial insurance. Patients who are enrolled in Medicare, Medicaid, a state pharmaceutical assistance program, or any other federal or state healthcare program are not eligible. Terms and conditions apply, and can be found at solosechcp.com/savings.[14]

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INDICATION

SOLOSEC® (secnidazole) 2g oral granules is a 5-nitroimidazole antimicrobial agent indicated for the treatment of bacterial vaginosis in adult women.

DOSAGE AND ADMINISTRATION

SOLOSEC is a single-dose therapy for oral use. The entire contents of SOLOSEC packet should be sprinkled onto applesauce, yogurt or pudding and consumed once within 30 minutes without chewing or crunching the granules. SOLOSEC is not intended to be dissolved in any liquid.

IMPORTANT SAFETY INFORMATION

- SOLOSEC is contraindicated in patients with a history of hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives.
- Vulvo-vaginal candidiasis may develop with SOLOSEC and require treatment with an antifungal agent.
- Potential risk of carcinogenicity is unknown and has not been studied. Carcinogenicity has been seen in rodents chronically treated with nitroimidazole derivatives, which are structurally related to secnidazole. Chronic use should be avoided.
- Breastfeeding is not recommended. Patients should discontinue breastfeeding for 96 hours after administration of SOLOSEC.
- Most common adverse reactions observed in clinical trials (incidence ≥2%) were vulvovaginal candidiasis, headache, nausea, dysgeusia, vomiting, diarrhea, abdominal pain, and vulvovaginal pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact Lupin Pharmaceuticals, Inc. at 1-844-SOLOSEC (1-844-765-6732) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Please note this information is not complete.
Visit solosechcp.com for full Prescribing Information.