

Solosec™ (secnidazole) 2g Oral Granules

The First and Only Single-Dose Oral Therapy
FDA Approved for Adult Women with Bacterial Vaginosis



Solosec™ is a potent, next-generation, 5-nitroimidazole antibiotic with enhanced pharmacokinetic properties that enable delivery in a single dose that's been shown to be efficacious and well tolerated. Solosec™ is the first and only single-dose oral therapy for bacterial vaginosis (BV), the most common gynecologic infection in the U.S.^{1,2}

Solosec™ is designed to offer an effective single-dose treatment option that adult women can take any time of day, with or without a meal. It is clinically proven to normalize BV symptoms, odor and discharge, without the use of creams or week-long oral regimens. Solosec™ should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.¹

The most common side effects of Solosec™ include yeast infection, headache, nausea, dysgeusia, vomiting, diarrhea, abdominal pain, and vaginal itching. Please see complete **Important Safety Information** below and [click here](#) for full Prescribing Information.¹

How does Solosec™ work?

Solosec™ is clinically proven to treat BV in a single-dose oral therapy, normalizing symptoms, odor and discharge, without creams or week-long oral regimens.¹

Solosec™ can be administered by sprinkling onto applesauce, yogurt or pudding. The granules will not dissolve, and should be consumed within 30 minutes without chewing or crunching the granules.¹

Who should use Solosec™?



Solosec™ is an effective single-dose oral antibiotic therapy to treat adult women with BV.¹ The Solosec™ pivotal trials included both frequent and infrequent BV patients.^{3,4}

Solosec™ should not be prescribed to patients with a history of hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives.¹

Does Solosec™ require a prescription?

BV can only be treated with a prescription antibiotic. Solosec™ must be prescribed by a healthcare professional. Women who experience signs and symptoms of BV should visit their healthcare provider.

How long does a patient have to take Solosec™?

Solosec™ is designed to offer an effective single-dose treatment option that adult women can take any time of day, with or without a meal.¹

How is Solosec™ different from other available treatment options?



Solosec™ is the only complete course of antibiotic therapy for BV in a single, oral dose. The most commonly prescribed oral BV treatment regimen requires twice-a-day dosing for seven days. Adherence with the current leading therapies for the treatment of BV has been shown to be only approximately 50 percent.^{1,5}

What data were submitted in support of the FDA approval of Solosec™?

The FDA approval was supported by a comprehensive set of studies, including two pivotal trials in BV and an open label safety study, which found efficacy for single-dose secnidazole 2g. All treatment-emergent adverse events were mild or moderate in intensity; no serious adverse events were reported, and no patients discontinued treatment due to adverse events.^{3,4}

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When will Solosec™ be available?

2018

Solosec™ received FDA approval in September 2017 and is expected to be available to patients the first quarter of 2018.

Where can women learn more information about Solosec™?

For more information, visit www.solosec.com and **click here for full Prescribing Information.**

Indication & Important Safety Information

Indication

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

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 in patients taking single-dose of SOLOSEC to treat bacterial vaginosis is unclear. Chronic use should be avoided.
- SOLOSEC may pass into breast milk. Patients should discontinue breastfeeding for 96 hours after administration of SOLOSEC.
- 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.
- In clinical studies, the most common adverse events occurring in (≥2%) of patients receiving SOLOSEC 2g oral granules were vulvovaginal candidiasis (9.6%), headache (3.6%), nausea (3.6%), dysgeusia (3.4%), vomiting (2.5%), diarrhea (2.5%), abdominal pain (2.0%), and vulvovaginal pruritus (2.0%).

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

Please click [here](#) for full Prescribing Information.

1. Solosec [Package Insert]. Newark, NJ: Symbiomix Therapeutics, LLC 2. Koumans E.H., Sternberg M, Bruce C, et al. (2007). "The Prevalence of Bacterial Vaginosis in the United States, 2001-2004: Associations with Symptoms, Sexual Behaviors, and Reproductive Health." Sex Transm Dis. 34(11): 864-869. 3. Hillier, S.L., et al. (2017). "Secnidazole Treatment of Bacterial Vaginosis: A Randomized Controlled Trial." Obstetrics & Gynecology 130(2): http://journals.lww.com/greenjournal/Abstract/publishahead/Secnidazole_Treatment_of_Bacterial_Vaginosis__A.98347.aspx. 4. Schwebke, J.R., et al. (2017). "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." Retrieved from: [http://www.ajog.org/article/S0002-9378\(17\)30964-X/fulltext](http://www.ajog.org/article/S0002-9378(17)30964-X/fulltext) 5. IMS Health, 2014