



SOLOSEC is the only single dose oral antibiotic that provides a complete course of therapy to treat both bacterial vaginosis (BV) and trichomoniasis¹

One day.
One dose.
That's it!



SOLOSEC is an effective treatment for bacterial vaginosis (BV)¹

- Single dose secnidazole 2 g efficacy comparable to 7-day BID regimen of metronidazole^{2*}
- **68%** of patients treated with SOLOSEC did not require additional treatment for BV³

SOLOSEC is an effective treatment for trichomoniasis⁴

- **92.2%** cure rate

SOLOSEC is effective for treating patients with both BV and trichomoniasis⁴

- **95.2%** microbiological cure rate in trichomoniasis patients co-infected with BV at baseline

* Secnidazole formulation may differ from SOLOSEC

Indication

SOLOSEC® (secnidazole) 2 g oral granules is an antimicrobial agent indicated for the treatment of bacterial vaginosis in adult women and trichomoniasis in adults. Since trichomoniasis is a sexually transmitted disease, treat sexual partners of infected patients with the same dose and at the same time to prevent reinfection.

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. Avoid consumption of alcoholic beverages and preparations containing ethanol or propylene glycol during treatment with SOLOSEC and for at least 2 days after completing therapy.

Select Important Safety Information

- SOLOSEC is contraindicated in patients with a history of hypersensitivity to secnidazole or other nitroimidazole derivatives.
- Vulvovaginal candidiasis may develop with SOLOSEC and require treatment with an antifungal agent.

Please see continued Important Safety Information on back and full Prescribing Information enclosed, also available at solosechcp.com.

SOLOSEC is the only single dose oral antibiotic recommended by the CDC and the American College of Obstetricians and Gynecologists (ACOG) for the treatment of BV^{5,6}

Adherence is an important consideration in treatment selection⁵

- Compliance with a multi-day metronidazole regimen is low, with documented adherence rates as low as 50.0% - 68.3%⁷
- Non-compliance to a multiple-day regimen is a contributing factor to persistent bacterial vaginosis (BV) or trichomoniasis^{8,9}

BV and trichomoniasis are associated with increased risk of:



Pelvic inflammatory disease (PID)¹⁰⁻¹²



Acquisition of STIs (gonorrhea, chlamydia, HPV and HSV)^{13,14}



Pregnancy complications (pre-term birth, premature rupture of membranes, chorioamnionitis)¹⁵⁻¹⁷



For more information about SOLOSEC, visit solosechcp.com

Select Important Safety Information (cont'd)

- Potential risk of carcinogenicity is unknown and has not been studied in patients. 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 $\geq 2\%$) were vulvovaginal candidiasis, headache, nausea, dysgeusia, vomiting, diarrhea, abdominal pain, and vulvovaginal pruritus.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch [fda.gov], or call 1-800-FDA-1088. You may also contact Lupin Pharmaceuticals, Inc. at 1-844-SOLOSEC (1-844-765-6732).

Please see full Prescribing Information enclosed, also available at www.solosechcp.com.

References: 1. SOLOSEC [prescribing information]. Baltimore, MD: Lupin Pharmaceuticals, Inc; 2021. 2. Muzny CA, Schwabke JR, Nyirjesy P, et al. Efficacy and Safety of Single Oral Dosing of Secnidazole for Trichomoniasis in Women: Results of a Phase 3, Randomized, Double-Blind, Placebo-Controlled, Delayed-Treatment Study. *Clin Infect Dis* 2021. 3. Bohbot JM, Vicaut E, Fagnen D, Brauman M. Treatment of bacterial vaginosis: a multi-center, double-dummy, randomized phase III study comparing secnidazole and metronidazole. *Infect Dis Obstet Gynecol* 2010;2010:1-6. 4. Schwabke 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. 5. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin: Clinical Management Guidelines for Obstetricians-Gynecologists, Number 215. *Obstet Gynecol* 2020;135(1):e1-e17. 6. Centers for Disease Control and Prevention (CDC). 2021 STI Treatment Guidelines Update Webinar Transcript and Video Recording. 18 December 2020. 7. 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. 8. Marrazzo JM, Thomas KK, Fiedler 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. 9. Kissinger P. *Trichomonas vaginalis*: a review of epidemiologic, clinical and treatment issues. *BMC Infect Dis* 2015;15(307):1-8. 10. Ness RB, Kip KE, Hillier SL et al. A Cluster Analysis of Bacterial Vaginosis-Associated Microflora and Pelvic Inflammatory Disease. *Am J Epidemiol* 2005;162(6):585-590. 11. Smart S, Singal A, Mindel A. Social and sexual risk factors for bacterial vaginosis. *Sex Transm Infect* 2004;80:58-62. 12. Wiringa AE, Ness RB, Darville T et al. *Trichomonas vaginalis*, endometritis and sequelae among women with clinically suspected pelvic inflammatory disease. *Sex Transm Infect* 2020;96:436-438. 13. Chavoustie SE, Maribona AS, Hanna M. Bacterial Vaginosis and the Risk for Sexually Transmitted Infections. *Contemp Ob Gyn* 2020. Educational Supplement. 14. Allsworth JE, Ratner JA, Peipert JF. Trichomoniasis and other sexually transmitted infections: results from the 2001-2004 National Health and Nutrition Examination Surveys. *Sex Transm Dis* 2009;36(12):738-44. 15. Leitch 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. 16. Svare JA, Schmidt H, Hansen BB, Lose G. Bacterial vaginosis in a cohort of Danish pregnant women: prevalence and relationship with preterm delivery, low birthweight and perinatal infections *BJOG* 2006;113(12):1419-1425. 17. Van Gerwen OT, Craig-Kuhn MC, Jones AT et al. Trichomoniasis and adverse birth outcomes: a systematic review and meta-analysis. *BJOG* 2021.