



## Solosec™ (secnidazole) – New drug approval

- On September 18, 2017, [Symbiomix Therapeutics announced](#) the [FDA approval](#) of [Solosec \(secnidazole\)](#), for the treatment of bacterial vaginosis (BV) in adult women.
- BV is the most prevalent gynecologic infection in the U.S., affecting 21 million women ages 14 to 49 annually. If left untreated, BV can increase the risk of contracting sexually transmitted diseases, including chlamydia, gonorrhea, herpes, trichomaniasis and HIV, and can also increase the risk of pre-term birth and low birth weight.
- Solosec is a 5-nitroimidazole antibiotic and the first single-dose oral antibiotic for BV.
- The efficacy of Solosec was demonstrated in 2 placebo-controlled studies in 333 patients with BV. Efficacy was assessed by clinical outcome evaluated 21 - 30 days following a single dose of Solosec. A clinical responder was defined as “normal” vaginal discharge, negative “whiff” test, and clue cells < 20%.
  - In study 1, 67.7% of Solosec-treated patients were clinical responders vs. 17.7% of placebo-treated patients ( $p < 0.001$ ).
  - In study 2, 53.3% of Solosec-treated patients were clinical responders vs. 19.3% of placebo-treated patients ( $p < 0.001$ ).
- Warnings and precautions of Solosec include vulvo-vaginal candidiasis, potential risk for carcinogenicity, and drug resistance.
- The most common adverse reactions ( $\geq 2\%$ ) with Solosec use were vulvo-vaginal candidiasis, headache, nausea, dysgeusia, vomiting, diarrhea, abdominal pain, and vulvovaginal pruritus.
- The recommended dosage of Solosec is a single 2-gram packet of granules taken once orally, without regard to the timing of meals.
  - The entire contents of the Solosec packet should be sprinkled onto applesauce, yogurt or pudding. The granules will not dissolve. All of the mixture should be consumed within 30 minutes without chewing or crunching the granules. A glass of water may be taken after the administration of Solosec to aid in swallowing.
  - The granules are not intended to be dissolved in any liquid.
- Ipsen plans to launch Solosec in the first quarter of 2018. Solosec will be available as 2 gram oral granules in a foil packet.



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