Solosec (secnidazole)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Solosec
- **Generic name:** Secnidazole
- **Pharmacological class:** Nitroimidazole
- **Strength and Formulation:** 2g; per packet; oral granules
- **Manufacturer:** Symbiomix Therapeutics
- **How supplied:** Packet—1
- **Legal Classification:** Rx

Indications

- Bacterial vaginosis

Solosec


To open:
Fold corner and tear
This packet is contained within
CARTON NDC 27437-051-01
LOT 51422 EXP 03/2020
solosec™
secnidazole
2g
Oral Granules
Rx Only
LUPIN
PHARMACEUTICALS, INC.

Dosage & Administration

- Do not dissolve in liquid
- Sprinkle contents onto applesauce, yogurt or pudding; consume within 30mins without chewing or crunching; may follow with a glass of water
- **≥18yrs:** give single 2g packet once orally

Considerations for Special Populations

- **Pregnancy:** Insufficient data to inform a drug-associated risk
- **Nursing mothers:** Not recommended during treatment and for 96hrs after dose or, may pump and discard milk during this time period
- **Pediatric:** <18yrs: not established
- **Elderly:** Insufficient number studied

Contraindications

- Hypersensitivity to other nitroimidazole derivatives

Warnings/Precautions

- Avoid chronic use
- Treat with antifungal if vulvo-vaginal candidiasis occurs

Adverse Reactions

- Vulvo-vaginal candidiasis
- Headache
- Nausea
- Dysgeusia
- Vomiting
- Diarrhea
- Abdominal pain
- Vulvo-vaginal pruritus

Mechanism of Action

- **Secnidazole** enters the bacterial cell as an inactive prodrug where the nitro group is reduced by bacterial enzymes to radical anions
- The radical anions are thought to interfere with bacterial DNA synthesis of susceptible isolate

Clinical Studies

- **Trial 1** (N=144) and **Trial 2** (N=189) evaluated the efficacy of Solosec 2g for the treatment of bacterial vaginosis in non-pregnant females
- A **clinical responder** was defined as “normal” vaginal discharge, negative “whiff” test, and clue cells <20%

Clinical Studies

- In both trials, a **statistically significantly greater percentage of patients** experienced clinical response, Nugent score cure, and therapeutic response at 21 to 30 days after a single dose of Solosec vs placebo

Clinical Studies

- **In Trial 1,** 67.7% of the Solosec group were clinical responders vs 17.7% of the placebo group
  - Difference 50% (95% CI, 33.4, 66.7; *P* <.001) at 21 to 30 days
- **In Trial 2,** 53.3% of the Solosec group were clinical responders vs 19.3% of the placebo group
  - Difference 34% (95% CI, 18.7, 49.3; *P* <.001) at 21 to 30 days

Clinical Studies

- **In Trial 2,** 57.9% of the Solosec group were clinical responders vs 24.6% of the placebo group
  - Difference 33.3% (95% CI, 17.4, 49.2; *P* <.001) at 7 to 14 days

Clinical Studies

- The percentage of patients with clinical response was also consistently higher in both trials in the Solosec arm vs placebo among **all subgroups**:
  - Number of episodes of bacterial vaginosis (≤3 and ≥4 in past 12 months)
  - Baseline Nugent score (4-6 and 7-10)
  - Race (Black/African American and White)

Clinical Studies

- **In Trial 1,** 40.3% of the Solosec group achieved Nugent score cure vs 6.5% of the placebo group
  - Difference 33.8% (95% CI, 18.5, 49.1; *P* <.001) at 21 to 30 days
- **In Trial 2,** 43.9% of the Solosec group achieved Nugent score cure vs 5.3% of the placebo group
  - Difference 38.6% (95% CI, 26.2, 51.0; *P* <.001) at 21 to 30 days

Clinical Studies

- **In Trial 2,** 45.8% of the Solosec group achieved Nugent score cure vs 3.5% of the placebo group
  - Difference 42.3% (95% CI, 30.4, 54.2; *P* <.001) at 7 to 14 days

- For more clinical data info, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/solosec/drug/34784/