Solosec® (secnidazole) – New indication

- On July 1, 2021, Lupin Pharmaceuticals announced the FDA approval of Solosec (secnidazole), for the treatment of trichomoniasis caused by *Trichomonas vaginalis* (*T. vaginalis*) in adults.
    - Because trichomoniasis is a sexually transmitted disease with potentially serious sequelae, treat partners of infected patients simultaneously in order to prevent reinfection.
- Solosec is also approved for the treatment of bacterial vaginosis in adult women.
- The approval of Solosec for the new indication was based on a randomized, placebo-controlled, delayed treatment, double-blind study in 147 female patients with trichomoniasis. Patients received a single dose of Solosec or placebo. The modified intent-to-treat (mITT) population included all randomized patients who were culture positive for *T. vaginalis* and negative for other sexually transmitted infections. The primary endpoint was microbiological cure at the test of cure visit (occurred 6 to 12 days after initial dosing), defined as testing negative for *T. vaginalis*.
    - In the mITT population (N = 131), microbiological cure was achieved in 92.2% of patients receiving Solosec vs. 1.5% of patients receiving placebo (treatment difference: 90.7, 95% CI: 80.7, 96.5; $p < 0.001$).
- Solosec was also evaluated in four open-label studies in males. Reported cure rates ranged from 91.7% (165/180) to 100% (30/30) at time points ranging from 2 to 20 days.
- The most common adverse reaction (≥ 2%) with Solosec use was vulvovaginal candidiasis.
- The recommended dose of Solosec for the treatment of bacterial vaginosis and trichomoniasis is a single 2-gram packet of granules taken once orally.
- Since trichomoniasis is a sexually transmitted disease, treat sexual partners with the same dose and at the same time.