

Drug Class Review Monograph – GPI Class 55 – Vaginal Products

Review Time Frame: 02/2016 – 01/2017

Previous Class Review: 05/2016

Background:

Vaginal anti-infectives are available as creams, tablets, gels, or solutions to treat ~~either~~ bacterial or fungal vaginal infections. Vaginal antifungal products are used to treat vaginal thrush as well as bacterial infections such as bacterial vaginosis.

New treatment guideline recommendations:

- None identified

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Newly approved drugs:

- None identified

Newly approved formulations:

- None identified

Newly approved generics:

- ~~Estradiol vaginal inserts 10mcg May 29, 2015.~~ None identified

Discontinued drugs:

- None identified

FDA Safety Alerts/black box warnings:

- None identified

Pipeline alerts:

Agents pending FDA approval include:

- ~~None identified~~ Solosec (secnidazole), a 5-nitroimidazole antibiotic for the treatment of bacterial vaginosis (PDUFA: 09/19/2017).

References:

1. Sobel JD. Approach to women with vaginitis. Barbieri RL, Eckler K (Eds.), UpToDate. Waltham, MA. Accessed January 2017.
2. ~~Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2015. URL: <http://www.clinicalpharmacology-ip.com/>. Updated January 2016.~~
3. ~~US Script Oracle PBM: Medi-Span® Master Drug Data Base. January -2017.~~ [WWW.FDA.GOV](http://www.fda.gov).
4. Symbiomix Therapeutics submits new drug application for US FDA for Solosec for the treatment of BV. Symbiomix Therapeutics. Available at: <https://symbiomix.com/symbiomix-therapeutics-submits-new-drug-application-us-fda-solosec-treatment-bv/>. Published January 19, 2017. Accessed January 27, 2017.