

Drug Class Review Monograph – GPI Class 24 – Estrogens

Review Time Frame: 05/2016 – 04/2017

Previous Class Review: 08/2016

Background:

Estrogens are a group of hormones that are synthesized mainly by the ovaries. A small amount is synthesized by the testes in males and by the adrenal cortex in both sexes. The placenta produces a fairly large amount of estrogen as well.

The three main endogenous estrogens are estradiol, estriol, and estrone. Estrogens control female sexual development, the growth and function of female sexual organs, and other secondary characteristics such as breast development. Excessive production of estrogen in men causes feminization.

Natural and synthetic estrogens are used to treat amenorrhea and menopausal symptoms. They can inhibit lactation and are also used in treatment of androgen-dependent cancers such as prostate cancer. Estrogens are given in any condition with estrogen deficiency.

New treatment guideline recommendations:

- In the 2016 revised global consensus statement on menopausal hormone therapy (MHT), the North American Menopause Society, along with other organizations, recommends MHT (e.g., tibolone, combination conjugated equine estrogens and bazedoxifene) as the most effective treatment for vasomotor symptoms associated with menopause. Benefits are likely to most outweigh risks if initiated for symptomatic women < 60 years or within 10 years after menopause. MHT is also effective for prevention of bone loss and vulvovaginal atrophy. Estrogen can be used as a single systemic agent after hysterectomy, but it should be used concurrently with progestogen if a uterus is present. Systemic MHT should not be used in breast cancer survivors.

Newly approved drugs:

- None identified

Newly approved formulations:

- None identified

Newly approved generics:

- None identified

Discontinued drugs:

- None identified

FDA Safety Alerts/black box warnings:

- None identified

Pipeline alerts:

Agents pending FDA approval include:

- None identified

References:

1. Martin KA, Barbieri RL. Preparations for menopausal hormone therapy. Snyder PJ, Crowley WF. (Ed), UpToDate. Waltham MA. Accessed April 2016.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. URL: <http://www.clinicalpharmacology-ip.com/>. Accessed April 2016.
3. US Script Oracle PBM: Medi-Span[®] Master Drug Data Base. April 2016.
4. Food and Drug Administration. [WWW.FDA.GOV](http://www.fda.gov). Accessed May 2017.
5. de Villiers TJ, Hall JE, Pinkerton JV, et al. Revised global consensus statement on menopausal hormone therapy. *Maturitas*. 2013; 74(4): 391-392.
6. Envolve Pharmacy Solutions internal pipeline database. Accessed May 2017.