

Premarin® Horses 2019 Year in Review



JANUARY 2019

FDA denies Pfizer Petition asking for new method of assessing Premarin generics

The FDA has denied a citizen petition from Pfizer calling on the agency to use the company's method for assessing sameness in generics for its estrogen drug Premarin (conjugated "equine" estrogens).

Pfizer had appealed to the FDA to force sponsors of generics for Premarin to use the "Pfizer method" for assessing sameness rather than the method

recommended in FDA draft guidance.



Pfizer logo (uncredited image)

Pfizer claimed that the FDA's December 2014 draft guidance for establishing sameness is "fundamentally flawed". Additionally claiming that not only does it lack a critical level of sensitivity on API (Active Pharmaceutical Ingredient) steroidal composition, but also it does not account for all classes of components in the API or the non-steroidal components.

They maintained that guidance should instead use the "Pfizer Method" that the company developed at the FDA's request and with their input, which permits a determination of sameness between a proposed generic for the company's drug Premarin and the reference drug based upon the mixture as a whole, while allowing a comparison across all categories of components making up the API.

APRIL 2019

Bijuva launched for moderate to severe hot flashes in menopause

TherapeuticsMD announced the [launch of Bijuva](#) (estradiol and progesterone) capsules for use in women with a uterus for the treatment of moderate to severe vasomotor symptoms (hot flashes) due to menopause. It initially received approval from the Food and Drug Administration (FDA) in October 2018.

Bijuva is the first bio-identical hormone therapy that combines estradiol and progesterone in a single capsule. Compared with synthetic hormone products, the estradiol and progesterone found in Bijuva are structurally identical to the hormones naturally circulating in the woman's body.

Bijvua carries a Boxed Warning regarding cardiovascular disorders, breast cancer, endometrial cancer, and probable dementia. Breast tenderness, headache, vaginal bleeding, vaginal discharge, and pelvic pain were the most common adverse reactions associated with Bijuva.

JUNE 2019

PMU Ranchers feel pinch as cuts announced

Pfizer Canada's cuts to pregnant mares' urine production will force four Manitoba ranches and one Saskatchewan ranch out of the industry.



Belgian draft weanling. (uncredited image)

The reduction affects three ranches in southwestern Manitoba, one in the Interlake region of Manitoba, and one in Saskatchewan. Of those five, three producers raised registered Quarter horses, one bred purebred Percherons, and one raised sport horses.

Pfizer has initiated a review of its inventory management and determined they are able to satisfy market demand by working with fewer ranchers.

The latest reduction leaves 19 producers still involved in PMU production in Manitoba and Saskatchewan, with most ranches located in southwestern Manitoba, four each in south-central Manitoba and southeastern Saskatchewan and one in the Interlake.

JULY 2019

Pfizer's Wyeth loses bid to duck hormone-therapy lawsuit

Pfizer Inc's Wyeth unit must face a class action alleging that the drugmaker misled California women by downplaying risks including breast cancer associated with its hormone-replacement therapy products, a federal judge has ruled.

U.S. District Judge John Houston in San Diego on Monday ruled the plaintiffs presented sufficient evidence for a jury to decide whether Wyeth's alleged misrepresentations caused women to buy Prempro, Premarin and Premphase.

To read the full story on Westlaw Practitioner Insights, [click here: bit.ly/2FOpbRU](http://bit.ly/2FOpbRU) »

New Book — Flash Count Diary: Menopause and the Vindication of Natural Life, by Darcy Steinke

"What orcas can teach humans about menopause and matriarchs" — A new book argues for a sea change in the way our culture views older women.

Her research unearthed a long history of dubious "cures," from transfusions of dog's blood to vinegar sponge baths to putting a magnet in your underpants. All of which, she says, seem a little less strange once you realize that the most popular hormone replacement treatment, Premarin, is made from the urine of pregnant horses. Source: [Crosscut](#) »



Don't sweat it. Take an alternative.

AUGUST 2019

Hormone therapy during menopause raises breast cancer risk for years, study finds

New analysis adds to the evidence that many women who take hormone therapy during menopause are more likely to develop breast cancer — and remain at higher risk of cancer for more than a decade after they stop taking the drugs.

The study, [in the Lancet](#), looked at data from dozens of studies, including long-term data on more than 100,000 women who developed breast cancer after menopause. The longer women took the medicine, the more likely they were to develop breast cancer. Experts say the findings could shape how women and their health care providers decide how to manage symptoms of menopause.

For years, research has suggested a potential link between MHT and an increased risk of breast cancer. But there wasn't much information on whether that risk persisted, or how it differed based on the type of MHT a woman took. So, an international group of researchers pulled together data from dozens of studies — published and unpublished — to examine the issue more closely.

The researchers found that compared with women who never used MHT, women who did had a significantly higher risk of developing invasive breast cancer. Also, the longer women used MHT, the greater their risk of breast cancer.

OCTOBER 2019

Premarin sales figures continue to decline

The Premarin family of hormone replacement products was the 11th best seller in 2018 at \$832 million, a decline of 14.8 percent. Sales in the first six months of 2019 were \$361 million, 10 percent less than in same period of 2018.

Third quarter sales of Premarin (conjugated estrogens tablets, USP) family — \$182 million, down 11%.

Data as of 12.31.19

LEARN MORE

About Premarin Horses

Premarin®, Prempro®, Premphase® and Duavee® are examples of the Premarin® family of drugs which are made with the the estrogen rich urine of pregnant mares.

In the 'pregnant mare urine' (PMU) industry, horses are repeatedly impregnated so their urine can be collected and made into hormone replacement products.

Some of the foals are rescued. Most, however, who can not be 'repurposed' in some way are sent to slaughter — seen as a byproduct of the industry much like male calves are in the dairy industry.

Alternatives to PMU Drugs

There are many alternatives to drugs made from the urine of pregnant mares.



Visit the Fund for Horses website for alternatives to Premarin type drugs.

Talk to your doctor. Visit your local pharmacy. There are prescription free over-the-counter treatments for hot flashes, vaginal dryness and other menopausal symptoms.

See also our [Alternatives to Drugs Made with Pregnant Mare's Urine page](#).
Please share this with the women and horse lovers in your life.

Thank you.