

# PharmaNavigator

## PharmPix Clinical Department

*At PharmPix, we help you navigate your way through informed education.*

### FDA Removes Boxed Warnings from Select Hormone Replacement Therapy (HRT)

On February 12, 2026, the U.S. Food and Drug Administration (FDA) approved labeling updates removing boxed warning statements related to cardiovascular disease, breast cancer, and probable dementia from six hormone replacement therapy (HRT) products. The FDA initiated this process in November 2025 following a comprehensive review of the scientific literature, and 29 manufacturers submitted proposed labeling revisions at the agency's request. The first six products with approved changes represent all four major HRT categories for menopausal women: systemic combination therapy with Bijuva, systemic estrogen-alone therapies including Divigel, Cenestin, and Enjuvia, systemic progestogen therapy with Prometrium, and topical vaginal estrogen therapy with Estring.

HRT is FDA-approved for the treatment of moderate-to-severe menopausal symptoms, including vasomotor symptoms (hot flashes and night sweats) and genitourinary syndrome of menopause (vulvovaginal atrophy). Certain products are also approved for the prevention of osteoporosis. Contemporary evidence supports that initiating systemic HRT within 10 years of menopause onset, generally before the age of 60, provides benefits that for most women outweigh potential risks. An analysis of 30 trials involving 26,708 women found no association between HRT and increased cancer mortality, and women who initiate

therapy before age 60 appear to have decreased overall mortality. Randomized trials and pooled analyses not only demonstrate reductions in all-cause mortality, but also cardiovascular risk reductions of up to 50%, decreased Alzheimer's disease risk of approximately 35%, reduced cognitive decline by as much as 64%, and bone fractures reduced by approximately 50-60%.

The updated labeling reflects growing evidence that the benefits and risks of HRT vary by age and timing of initiation, with systemic therapy recommended within 10 years of menopause onset or before age 60 when appropriate. Decisions on initiation, formulation, and duration remain individualized between clinician and patient. This change has the potential to transform patient care by improving access to effective menopausal symptom relief and osteoporosis prevention.

#### REFERENCES:

1. U.S. Food and Drug Administration. (2026, February 12). *FDA Approves Labeling Changes to Menopausal Hormone Therapy Products*. <https://www.fda.gov/news-events/press-announcements/fda-approves-labeling-changes-menopausal-hormone-therapy-products>
2. U.S. Food and Drug Administration. (2025, November 10). *HHS advances women's health, removes misleading FDA warnings on hormone replacement therapy*. <https://www.fda.gov/news-events/press-announcements/hhs-advances-womens-health-removes-misleading-fda-warnings-hormone-replacement-therapy>
3. Salpeter, S. R., Walsh, J. M., Greyber, E., Ormiston, T. M., & Salpeter, E. E. (2004). Mortality associated with hormone replacement therapy in younger and older women: a meta-analysis. *Journal of general internal medicine*, 19(7), 791–804. <https://doi.org/10.1111/j.1525-1497.2004.30281.x>

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252-ext.219. Our pharmacists will help you. In addition, know that you can access our recent communications at our providers' portal: <https://www.pharmpix.com/providers/>.