COMMUNICATION

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PLEASE REVIEW

Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

Drug Information

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

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FDA Requests Labeling Changes for Menopausal Hormones Therapy (MHT/HRT)

In November 2025, the FDA requested updates to the labeling of menopausal hormone therapy (MHT) products, including estrogen only and estrogen/progestin formulations. These changes aim to better reflect the true benefit/risk profile, correct misconceptions from older data, and ensure appropiate use in women who may benefit from therapy.

Why is the FDA updating the labeling?

MHT is commonly used to manage vasomotor symptoms, genitourinary syndrome of menopause (GSM), and in some cases to prevent osteoporosis. The current boxed warnings are largely based on findings from the Women's Health Initiative (WHI), a study of women whose average age was approximately 63 years, many years beyond the menopausal transition. This has contributed to an overestimation of risk younger, newly menopausal women and has led to underuse of therapy in appropiate candidates. The FDA reviewed more recent evidence on cardiovascular, breast cancer, and cognitive outcomes and concluded that risks vary significantly by age, timing of therapy, formulation, dose, and route of administration.

Requested Changes and Pharmacy Implications

As a result, the FDA is requesting updates to the boxed warning and other labeling sections to clarify how risks differ by patient characteristics, to reflect limitations of applying WHI data to younger women, and to distinguish systemic products from low dose vaginal estrogen.

For pharmacy practice, these changes highlight the importance of individualized counseling. Many women under 60 with moderate to severe symptoms may be appropriate candidates for MHT when used correctly. Pharmacists should confirm whether a patient has a uterus to determine the need for progestin, understand that transdermal options may have lower clot and stroke risks, and recognize that low dose vaginal estrogen has minimal systemic exposure.

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/.

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REFERENCES:

1. Center for Drug Evaluation and Research. (2025, November 10). *FDA requests labeling changes related to HRT*. U.S. Food and Drug Administration. https://www.fda.gov/drugs/drug-safety-and-availability/fda-requests-labeling-changes-related-safety-information-clarify-benefitrisk-considerations

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