

# The Medical Letter®

## On Drugs and Therapeutics

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### **Addendum: Ospemifene (*Osphena*) for Dyspareunia (Med Lett Drugs Ther 2013; 55:55)**

Some readers have objected to our recommendation that postmenopausal women with an intact uterus who take the oral estrogen agonist/antagonist ospemifene (*Osphena*) to reduce the severity of dyspareunia should also take a progestin.<sup>1</sup> Ospemifene has agonistic effects on the endometrium, and the *Osphena* package insert says: "Generally, when a product with estrogen agonistic effects on the endometrium is prescribed for a postmenopausal woman with a uterus, a progestin should be considered to reduce the risk of endometrial cancer."

Endometrial hyperplasia has been reported in more than 20% of women taking unopposed systemic estrogen for more than one year; the risk is closely related to the dose and duration of treatment. Adding a progestin to estrogen therapy in women with a uterus reduces the risk of endometrial hyperplasia and cancer, but has been associated with an increased risk of invasive breast cancer and thromboembolic events.<sup>2</sup>

In ospemifene clinical trials, the drug was taken without a progestin and at 1 year there were no cases of endometrial hyperplasia or carcinoma, but only a small number of women took the drug for more than 12 weeks. These studies excluded women with an endometrial thickness of  $\geq 4$  mm detected by transvaginal ultrasound, pathological findings on endometrial biopsy or Pap test, or any other clinically significant gynecological abnormality. They also excluded women who were obese or had hypertension, among many other exclusions.

It is possible that the estrogenic effects of ospemifene on the endometrium will prove to be similar to those of the estrogen agonist/antagonist raloxifene (*Evista*), which has not increased the incidence of endometrial

cancer.<sup>3</sup> For now, it would not be unreasonable for postmenopausal women with an intact uterus who can be followed closely for vaginal bleeding or spotting and do not have risk factors for endometrial cancer (obesity, hypertension, diabetes, nulliparity) to take ospemifene without a progestin. For all others, a progestin should be considered.

1. Ospemifene (*Osphena*) for dyspareunia. Med Lett Drugs Ther 2013; 55:55.
2. JE Manson et al. Menopausal hormone therapy and health outcomes during the intervention and extended poststopping phases of the Women's Health Initiative randomized trials. JAMA 2013; 310:1353.
3. SR Goldstein. Postmenopausal dyspareunia: has the Food and Drug Administration really helped? Menopause 2013; 20:596.

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