FDA Approves New Drug for Vasomotor Symptoms, Osteoporosis Prevention

By Jamie Habib [2]

The FDA has approved Duavee, the first medication to combine estrogen with bazedoxifene, for the treatment of hot flashes and the prevention of osteoporosis after menopause.

Earlier this month, the FDA approved the first medication that combines estrogen with bazedoxifene, an estrogen agonist/antagonist, for the treatment of moderate to severe hot flashes and for the prevention of osteoporosis after menopause.

Marketed as Duavee by Wyeth Pharmaceuticals, Inc, a subsidiary of Pfizer Inc, this conjugated estrogens-bazedoxifene combination product is intended only for women with a uterus that remains intact. Duavee should be used for the shortest duration necessary to achieve treatment goals. The component bazedoxifene, a selective estrogen-receptor modulator that behaves as an estrogen agonist in some tissues and an antagonist in others, has been shown to reduce the risk of endometrial hyperplasia that can occur with the use of conjugated estrogens.

When used to prevent osteoporosis, it is intended only for women at high risk for the condition. According to the product labeling, the need for continued treatment should be reassessed periodically, and an adequate daily intake of calcium and vitamin D must be maintained throughout treatment.

In clinical trials, the most commonly reported adverse events were muscle spasms, nausea, diarrhea, dyspepsia, upper abdominal pain, oropharyngeal pain, dizziness, and neck pain. The product comes with a boxed warning stating that estrogen therapy should not be used for the prevention of cardiovascular disease and dementia, a common warning for all drugs containing estrogen. The boxed warning also states an increased risk of endometrial cancer, thromboembolic events, and dementia in postmenopausal women who use unopposed estrogens.

Women with undiagnosed abnormal uterine bleeding, a history or suspicion of breast cancer or estrogen-dependent neoplasia, any history of venous or arterial thromboembolism, or sensitivity to any product ingredient should not use Duavee, according to the product labeling. The recommended oral dosage of Duavee is 1 tablet daily, swallowed whole, taken with or without food. Each tablet of Duavee contains 0.45 mg of conjugated estrogens and 20 mg of bazedoxifene. Duavee is expected to be available for use in the first quarter of 2014.

Source URL:

Links: