STEPS
New Drug Reviews

Conjugated Estrogens/Bazedoxifene (Duavee) for Menopausal Symptoms

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STEPS new drug reviews cover Safety, Tolerability, Effectiveness, Price, and Simplicity. Each independent review is provided by authors who have no financial association with the drug manufacturer.

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Conjugated estrogens/bazedoxifene (Duavee) combines conjugated estrogen with bazedoxifene, a selective estrogen receptor modulator. Bazedoxifene stimulates estrogen receptors in bone and has antagonistic effects in the breast and uterus.[1] Conjugated estrogens/bazedoxifene is labeled for the treatment of moderate to severe vasomotor symptoms associated with menopause and prevention of postmenopausal osteoporosis.[2]

Drug	*Dosage*	*Dose form*	*Cost**
Conjugated estrogens/bazedoxifene (Duavee)	0.45 mg/20 mg once daily	0.45-mg/20-mg tablet	$145

**—Estimated retail price of one month's treatment based on information obtained at http://www.goodrx.com (accessed December 14, 2015).*

SAFETY

As with other estrogen therapies, conjugated estrogens/bazedoxifene includes a boxed warning of increased risk of dementia in women older than 65 years, endometrial cancer, stroke, and deep venous thrombosis.[2] However, in studies of 7,487 patients, there was no increase in endometrial hyperplasia. There is not enough research to directly evaluate the effect of conjugated estrogens/bazedoxifene on thrombotic or cardiovascular events.[1,3,4] Because of established risks of estrogen agonists/antagonists, conjugated estrogens/bazedoxifene should not be used with other estrogen preparations or in patients with abnormal uterine bleeding, breast cancer, estrogen-dependent neoplasia, venous or arterial thromboembolism, liver disease, or thrombophilic disorders. It has not been studied in patients with renal impairment, obesity (body mass index greater than 34 kg per m^2), or in women older than 75 years. Conjugated estrogens/bazedoxifene is a U.S. Food and Drug Administration pregnancy category X drug and should not be used by lactating women.[2]

TOLERABILITY

Conjugated estrogens/bazedoxifene is generally well tolerated. About one in 12 patients (8%) will stop taking the medication in the first year because of adverse effects.[4,5] When compared with conjugated estrogens/medroxyprogesterone, conjugated estrogens/bazedoxifene results in less vaginal bleeding, and in head-to-head trials it has lower dropout rates due to adverse effects (8% vs. 13%; $P < .05$).[4,5]

EFFECTIVENESS

Conjugated estrogens/bazedoxifene reduces the number and severity of hot flashes, decreases pain with intercourse, and reduces vaginal dryness vs. placebo.[1,3,6] Also, use of conjugated estrogens/bazedoxifene results in statistically significant improvements in sexual functioning, menopause-related quality of life, sleep quality, and satisfaction with treatment.[7-9] Improvements in sleep quality and quality of life are similar to those seen with conjugated estrogens/medroxyprogesterone.[9] ▶

For the prevention of postmenopausal osteoporosis, conjugated estrogens/bazedoxifene will maintain or slightly increase bone mineral density in the lumbar spine and hip. Its effect on vertebral, hip, or overall fracture rate is not known.[4,5,10] Although conjugated estrogens/bazedoxifene does not affect breast density, studies have not examined its use for the prevention of breast cancer.[11]

PRICE

A one-month supply of conjugated estrogens/bazedoxifene costs approximately $145. In comparison, a one-month supply of conjugated estrogens/medroxyprogesterone costs approximately $148. Cyclical combined hormone replacement with separate tablets of estradiol and medroxyprogesterone costs about $10 per month.

SIMPLICITY

Conjugated estrogens/bazedoxifene is taken once daily without regard to meals.

Bottom Line

Conjugated estrogens/bazedoxifene is effective for the treatment of menopausal symptoms and may be better tolerated than conjugated estrogens/medroxyprogesterone. It will maintain bone mineral density in the lumbar spine and hip, but its effect on fractures is not known. Cardiovascular safety beyond two years is not known.

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