

## Estrogens and Progestins Combined

**DROSPIRENONE/ESTRADIOL**Rx **Angeliq**  
(Berlex)**Tablets:** 0.5 mg drospirenone and 1 mg estradiol

Lactose. (CK). Pink. Film coated. In blister pack 28s.

**DROSPIRENONE/ESTRADIOL****WARNING**

Do not use estrogens with or without progestins for the prevention of cardiovascular disease or dementia.

**Cardiovascular risks** – The Women’s Health Initiative (WHI) study reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis in postmenopausal women (50 to 79 years of age) during 5 years of treatment with oral conjugated equine estrogens (0.625 mg) combined with medroxyprogesterone acetate (2.5 mg) relative to placebo.

**Dementia** – The Women’s Health Initiative Memory Study (WHIMS), a substudy of WHI, reported increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 5.2 years of treatment with conjugated estrogens alone and during 4 years of treatment with oral conjugated estrogens plus medroxyprogesterone acetate, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women.

Other doses of oral conjugated estrogens with medroxyprogesterone acetate, and other combinations and dosage forms of estrogens and progestins were not studied in the WHI clinical trials, and, in the absence of comparable data, these risks should be assumed to be similar. Because of these risks, prescribe estrogens with or without progestins at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

**Indications**

Drospirenone/Estradiol is indicated in women who have a uterus for:

► **Moderate to severe vasomotor symptoms:** Treatment of moderate to severe vasomotor symptoms associated with menopause.

► **Moderate to severe vulvar and vaginal atrophy:** Treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause. When prescribing solely for the treatment of symptoms of vulvar and vaginal atrophy, consider topical vaginal products.

**Administration and Dosage**

► **Moderate to severe vasomotor symptoms and moderate to severe vulvar and vaginal atrophy:** Dosage is 1 tablet daily. Women who are already using a product containing estrogen should stop taking that product before starting drospirenone/estradiol.

Use of estrogen alone or in combination with a progestin should be limited to the lowest effective dose available and for the shortest duration consistent with treatment goals and risks for the individual woman.

Patients should be reevaluated periodically as clinically appropriate (eg, 3- to 6-month intervals) to determine if treatment is still necessary (see Black Box Warning). For women who have a uterus, adequate diagnostic measures such as endometrial sampling, when indicated, should be undertaken to rule out malignancy in cases of undiagnosed persistent or recurring abnormal vaginal bleeding.

The lowest effective dose has not been determined.

► **Storage/Stability:** Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).