In the treatment of menopausal symptoms

Discover the Angeliq Mystique...

Model used for illustrative purposes only.

Angeliq® tablets

(Drospirenone/Estradiol)

0.5 mg/1 mg

ANGELIQ: THE ONLY HT WITH THE UNIQUE PROGESTIN drsp

- **drsp** is the same progestin as in the #1 brand of OC*
- Effective in the treatment of moderate to severe vasomotor symptoms associated with menopause[1]
  - Nearly 30% reduction by week 1[1]
  - Nearly 70% reduction by week 4[1]
  - More than 90% reduction by week 12[1]
- Established safety
  - No incidence of endometrial hyperplasia (n=227)[2]
  - **drsp** is an analog of spironolactone[3]
    - Provides AntiMineralocorticoid activity[3]
- Estrogen and progestin similar to endogenous hormones[3,4]

ANGELIQ is indicated for women who have a uterus for the treatment of moderate to severe vasomotor symptoms and/or vulvar and vaginal atrophy associated with menopause. When prescribing solely for the treatment of vulvar and vaginal atrophy, topical vaginal products should be considered.

ANGELIQ contains 0.5 mg of the progestin drospirenone that has antialdosterone activity, including the potential for hyperkalemia in high-risk patients.

ANGELIQ should not be used in patients with conditions that predispose to hyperkalemia (ie, renal insufficiency, hepatic dysfunction, and adrenal insufficiency).

Use caution when prescribing ANGELIQ to women who regularly take other medications that can increase potassium, such as NSAIDs, potassium-sparing diuretics, potassium supplements, ACE inhibitors, angiotensin-II receptor antagonists, and heparin. Consider checking serum potassium levels during the first treatment cycle in high-risk patients.

The most common side effects were: upper respiratory infection, breast pain, abdominal pain, headaches, vaginal bleeding, bloating, nausea, vomiting, and hair loss.

Estrogens with or without progestins should not be used for the prevention of cardiovascular disease or dementia. (See **WARNINGS, Cardiovascular disorders,** and **Dementia.**)

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 (CE 0.625 mg) combined with medroxyprogesterone acetate (MPA 2.5 mg) relative to placebo. (See **CLINICAL PHARMACOLOGY, Clinical Studies;** and **WARNINGS, Cardiovascular disorders,** and **Malignant neoplasms, Breast cancer.**)

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. (See **CLINICAL PHARMACOLOGY, Clinical Studies; WARNINGS, Dementia;** and **PRECAUTIONS, GERIATRIC USE.**)

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, estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

Progestogens/estrogens should not be used in individuals with any of the following conditions: undiagnosed abnormal genital bleeding; known, suspected, or history of cancer of the breast; known or suspected estrogen-dependent neoplasia; active deep vein thrombosis, pulmonary embolism, or history of these conditions; active or recent (eg, within the past year) arterial thromboembolic disease (eg, stroke, myocardial infarction); renal insufficiency; liver dysfunction or disease; or adrenal insufficiency. ANGELIQ should not be used in patients with known hypersensitivity to its ingredients, or known or suspected pregnancy. There is no indication for ANGELIQ in pregnancy. There appears to be little or no increased risk of birth defects in children born to women who have used estrogens and progestins from oral contraceptives inadvertently during early pregnancy. (See **PRECAUTIONS.**)

References: 1. Archer DF, Fischer LA, Rich D, et al. Estrace® vs Premarin® for the treatment of menopausal symptoms: dosage comparison study. *Adv Ther.* 1992;9:21-31. **2.** Archer DF, Thorneycroft IH, Foegh M, et al. Long-term safety of drospirenone–estradiol for hormone therapy: a randomized, double-blind, multicenter trial. *Menopause.* 2005;12:716-727. **3.** Krattenmacher R. Drospirenone: pharmacology and pharmacokinetics of a unique progestogen. *Contraception.* 2000;62:29-38. **4.** The North American Menopause Society. Bioidentical hormone therapy. Available at: http://www.menopause.org/bioidentical.htm. Accessed July 12, 2006.

*Data on file.

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Please see next page for brief summary of prescribing information.

The difference is drsp

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Bayer HealthCare Pharmaceuticals

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