ESTROGel® 0.06%
(estradiol gel)
The *Modern* Classic

Provides the lowest, effective dose of transdermal estrogen therapy to help meet your patients' treatment goals[1]

In the 2017 North American Menopause Society (NAMS) Position Statement, NAMS recommends first-line treatment of VMS with the most appropriate, often lowest effective dose, of estrogen therapy consistent with treatment goals[2]

- The dose of estradiol in EstroGel has been proven to be the lowest effective dose for the treatment of symptomatic postmenopausal women[1]
- EstroGel follows cGMP regulations as required by the FDA so you can be confident your patients are receiving a product regulated for safety and efficacy
- EstroGel is a non-patch transdermal gel. According to NAMS, nonoral routes of administration may offer advantages over oral routes by bypassing first-pass hepatic metabolism. [2*]

2 INDICATIONS 1 COPAY

When you prescribe EstroGel, your patients receive effective and FDA-approved transdermal therapy for both moderate to severe VMS and VVA[†] – all with one copay.[3]

*No head to head randomly controlled trials have been conducted to validate this supposition.

†When prescribing solely for the treatment of moderate to severe vulvar/vaginal atrophy due to menopause, topical vaginal products should be considered.

Please see Important Risk Information and complete boxed warning on back relating to estrogen, such as estrogen with progestin may increase the risks of deep vein thrombosis, pulmonary embolism, stroke, and myocardial infarction.

Please see full Prescribing Information at www.estrogel.com

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2 INDICATIONS 1 COPAY

The *Modern* Classic

- The only non-patch transdermal estrogen therapy that provides relief of both moderate to severe vasomotor symptoms and moderate to severe vulvar/vaginal atrophy due to menopause[3†]
- The long half-life of EstroGel (36 hours) allows steady state to be reached in 3 days[3‡]
- Once steady state is achieved, most women have baseline values of approximately 30 pg/mL, a normal physiologic level during the premenopausal follicular phase[4]

† When prescribing solely for the treatment of moderate to severe vulvar/vaginal atrophy due to menopause, topical vaginal products should be considered.

‡ Steady state achieved after the third daily application of a 2.5-g dose of EstroGel (1.25-g on each arm).

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IMPORTANT RISK INFORMATION about EstroGel[3]

WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER AND PROBABLE DEMENTIA

There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens. Adding a progestin to estrogen therapy has been shown to reduce the risk of endometrial hyperplasia, which may be a precursor to endometrial cancer. Adequate diagnostic measures including directed or random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed, persistent or recurring abnormal genital bleeding.

Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia. The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 7.1 years of treatment with daily oral conjugated estrogens (CE) [0.625 mg]-alone, relative to placebo.

The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 5.2 years of treatment with daily CE (0.625 mg)-alone, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women.

In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and other dosage forms of estrogens. 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.

Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia. The WHI estrogen plus progestin substudy reported increased risks of DVT, pulmonary embolism (PE), stroke and myocardial infarction (MI) in postmenopausal women (50 to 79 years of age) during 5.6 years of treatment with daily oral CE (0.625 mg) combined with medroxyprogesterone acetate (MPA) [2.5 mg], relative to placebo.

The WHIMS estrogen plus progestin ancillary study of WHI reported an increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 4 years of treatment with daily CE (0.625 mg) combined with MPA (2.5 mg), relative to placebo. It is unknown whether this finding applies to younger postmenopausal women.

The WHI estrogen plus progestin substudy also demonstrated an increased risk of invasive breast cancer. In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and MPA and other combinations and dosage forms of estrogens and progestins.

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.

EstroGel is contraindicated in women with any of the following conditions: undiagnosed abnormal genital bleeding; known, suspected, or history of breast cancer; known or suspected estrogen-dependent neoplasia; active deep vein thrombosis, pulmonary embolism, or history of these conditions; active arterial thromboembolic disease, or a history of these conditions; known anaphylactic reaction or angioedema to EstroGel; known liver impairment or disease; known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders; known or suspected pregnancy.

Increase in the risk of breast cancer, ovarian cancer, gallbladder disease, severe hypercalcemia in patients with breast cancer and bone metastases, visual abnormalities such as retinal vascular thrombosis, elevated blood pressure, hypertriglyceridemia, hypothyroidism, fluid retention, and hypocalcemia have been reported in patients receiving estrogens.

Estrogens may cause an exacerbation of endometriosis, angioedema in women with hereditary angioedema, asthma, diabetes mellitus, epilepsy, migraine, porphyria, systemic lupus erythematosus, and hepatic hemangiomas and should be used with caution in women with these conditions. Use with caution in women with hepatic impairment and/or past history of cholestatic jaundice, and in the case of recurrence, medication should be discontinued. Moisturizer lotion application 1 hour after EstroGel application significantly increased estradiol absorption. Alcohol-based gels are flammable. Avoid fire, flame, or smoking until the gel has dried.

In clinical studies, the most commonly reported adverse events for EstroGel were breast pain, headache, and flatulence.

Please see full Prescribing Information and boxed warning at www.estrogel.com

REFERENCES: 1. Archer DF, Pickar JH, MacAllister DC, Warren MP. Transdermal estradiol gel for the treatment of symptomatic postmenopausal women. *Menopause*. 2012;19(6):622-629. **2.** The North American Menopause Society. The 2017 hormone therapy position statement of The North American Menopause Society [published online June 22, 2017]. *Menopause*. 2017. doi: 10.1097/GME.0000000000000921. **3.** EstroGel 0.06% [package insert]. Herndon, VA: ASCEND Therapeutics; 2014. **4.** Data on File. ASCEND Therapeutics.

ASCEND THERAPEUTICS

This promotional material may be reportable under state and/or federal law.

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