Important Information about Product Availability

Potential Retail Stocking Issue with Estradiol Transdermal Spray

Attention Pharmacists-

Recently you may have learned of a notice of supply problems for Evamist (estradiol transdermal spray). If your patients are affected, please contact their health care provider about considering EstroGel® 0.06% (estradiol gel), NDC# 17139-617-40, as a suitable and convenient option.

EstroGel is the only non-patch transdermal estrogen indicated in the treatment of both moderate to severe vasomotor symptoms due to menopause and moderate to severe symptoms of vulvar and vaginal atrophy due to menopause. When prescribing solely for the treatment of symptoms of vulvar and vaginal atrophy, topical vaginal products should be considered.

Key features of EstroGel include:

- Provides timely, effective relief of menopausal symptoms such as hot flashes, night sweats, or vaginal dryness and itching
- Easy-to-use (1 pump, 1 arm, once-a-day) estrogen therapy in a topical gel application
- A natural, low-dose transdermal estrogen therapy

ASCEND Therapeutics, Inc. the marketer of EstroGel 0.06%, is committed to maintaining adequate inventory levels of EstroGel 0.06%.

Also, please remind your patients using EstroGel to visit www.estrogel.com for money-saving coupons to help reduce out-of pocket expenses at the pharmacy.

Please click here for full EstroGel Prescribing Information and boxed warning.

In clinical studies, the most commonly reported adverse events for EstroGel were headache, infection, breast pain, vaginitis, abdominal pain, pain, and rash.

EstroGel® is indicated in the treatment of moderate to severe vasomotor symptoms associated with menopause and in the 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, topical vaginal products should be considered.

For more information on EstroGel for pharmacists or physicians, please visit www.estrogel.com

IMPORTANT SAFETY INFORMATION[1]

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 or recent arterial thromboembolic disease; known liver dysfunction or disease; known hypersensitivity to any of the ingredients in EstroGel; known or suspected pregnancy.

Because of the risk of endometrial cancer, adequate diagnostic measures, including endometrial sampling when indicated, should be undertaken to rule out malignancy in all cases of undiagnosed persistent or recurring abnormal vaginal bleeding.

Estrogens with or without progestIns 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 (50-79 years of age) during 6.8 and 7.1 years, respectively, of treatment with daily oral conjugated estrogens (CE 0.625 mg), relative to placebo.

The estrogen plus progestin WHI substudy reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and DVT in postmenopausal women (50-79 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 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 daily CE 0.625 mg alone and 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.

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. 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.

Increase in the risk of breast cancer, gallbladder disease, severe hypercalcemia in patients with breast cancer and bone metastases, and retinal vascular thrombosis have been reported in patients receiving estrogens. The risk of ovarian cancer may also be increased.

In clinical studies, the most commonly reported adverse events for EstroGel were headache, infection, breast pain, vaginitis, abdominal pain, pain, and rash.

Blood pressure should be monitored with estrogen use. Precautions should be taken when administering to patients over 65 years of age and in patients with hypertriglyceridemia, impaired liver function and past history of cholestatic jaundice, hypothyroidism, conditions that might be influenced by fluid retention, severe hypocalcemia, endometriosis, asthma, diabetes mellitus, epilepsy, migraine, porphyria, systemic lupus erythematosus, and hepatic hemangiomas. EstroGel should not be used during lactation and is not indicated for pediatric use. Alcohol-based gels are flammable. Avoid fire, flame, or smoking until the gel has dried.

Please click here for full EstroGel Prescribing Information and boxed warning.

References: 1. EstroGel 0.06% [package insert]. Herndon, VA: ASCEND Therapeutics, Inc; 2008.