IMPORTANT SAFETY INFORMATION AND INDICATIONS (continued on next page)

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.

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 with daily oral conjugated estrogens (CE) alone. The WHI estrogen plus progestin substudy reported increased risks of DVT, pulmonary embolism, stroke, and myocardial infarction in postmenopausal women with daily oral CE combined with medroxyprogesterone acetate (MPA). In the absence of comparable data, these risks should be assumed to be similar for other dosage forms of estrogens.

The WHI Memory Study (WHIMS) reported an increased risk of developing probable dementia in postmenopausal women 65 years of age or older, in both the estrogen alone and estrogen plus progestin arms. It is unknown whether these findings apply to younger postmenopausal women.

The WHI estrogen plus progestin substudy demonstrated an increased risk of invasive breast cancer.

Please see accompanying Full Prescribing Information, including BOXED WARNING.
IMPORTANT SAFETY INFORMATION (continued)

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

PREMARIN VAGINAL CREAM should not be used in women with any of the following conditions: undiagnosed abnormal genital bleeding; known, suspected, or a history of breast cancer; known or suspected estrogen-dependent neoplasia; active deep vein thrombosis, pulmonary embolism, or a history of these conditions; active arterial thromboembolic disease (eg, stroke, myocardial infarction), or a history of these conditions; anaphylactic reaction or angioedema to Premarin Vaginal Cream; liver dysfunction or disease; thrombophilic disorders; pregnancy.

Estrogens increase the risk of gallbladder disease. Discontinue estrogen if loss of vision, severe hypertriglyceridemia or cholestatic jaundice occurs. Monitor thyroid function in women on thyroid replacement therapy, because estrogens may be associated with increased thyroid binding globulin (TBG) levels.

In a prospective, randomized, placebo-controlled, double-blind study, the most common adverse reactions (≥2%) were headache, pelvic pain, vasodilation, breast pain, leucorrhea, metrorrhagia, vaginitis, and vulvovaginal disorder.

INDICATIONS

Premarin Vaginal Cream is indicated for the treatment of atrophic vaginitis and kraurosis vulvae; and for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

For more information, visit www.premarinvaginalcreamhcp.com.

STUDY DESCRIPTION

Bachmann: Results from a 12-week, randomized, double-blind, placebo-controlled trial that evaluated the efficacy and safety of Premarin Vaginal Cream 0.5 g for the treatment of vulvovaginal atrophy in generally healthy postmenopausal women aged 44 to 77 years (N=423). Premarin Vaginal Cream was administered using 2 dosing regimens: twice weekly and once daily (21 days on/7 days off). The study consisted of an initial 12-week trial followed by an open-label extension to assess endometrial safety through week 52 (n=155). Primary endpoints were the changes from baseline in Vaginal Maturation Index, vaginal pH, and severity of patient-reported most bothersome symptom (vaginal dryness, itching, burning, or dyspareunia) at week 12. Participants defined the severity of their most bothersome symptom on the following scale: 1=mild, 2=moderate, 3=severe; and at least 1 symptom had to be moderate to severe. For most women, dyspareunia was identified as the most bothersome symptom at baseline. Weekly severity score is an average of the daily scores.1-3


Please see accompanying Full Prescribing Information, including BOXED WARNING.