Pfizer Premarin® (conjugated estrogens tablets, USP) DKSH

Dear healthcare professionals,

Menopause, which marks the end of reproductive life, characterizes the penultimate stage in a woman's life. However, this does not signal the end of sexual and social activities.[1] In Malaysia, median age at menopause was reported **50.7**[1].

The menopause transition is experienced by **1.5 million** women each year and often involves troublesome symptoms, including vasomotor symptoms, vaginal dryness, decreased libido, insomnia, fatigue, and joint pain.[2] Approximately **85%** of menopausal women experience hot flushes[2]. Risk for the development of a major depressive episode is increased by **3-fold** during perimenopause[2]. Bone Mineral Density (BMD) decrease by about **10%** during menopausal transition.[3] Up to **60%** of women reported moderate to severe symptoms of vaginal dryness due to menopause[2]

Hormone therapy (HT) **remains the most effective** treatment for vasomotor symptoms (VMS) and the genitourinary syndrome of menopause (GSM) and has been shown to prevent bone loss and fracture.[4] Find out more from the video clip.

References:

1. Nik et al. Menopause and HRT in Malaysia. First Consensus Meeting on Menopause in the East Asian Region. Menopause and HRT in Malaysia. https://www.gfmer.ch/Books/bookmp/197.htm. Accessed 13 May 2020.
2. Santoro et al. Menopausal Symptoms and Their Management. Endocrinol Metab Clin North Am. 2015 September ; 44(3): 497–515
3. Gallagher JC, et al. Prevention and treatment of postmenopausal osteoporosis. *J Steroid Biochem Mol Biol* 2014;142:155-170.
4. The 2017 hormone therapy position statement of The North American Menopause Society Menopause: The Journal of The North American Menopause Society. Vol. 24, No. 7, pp. 728-753

Premarin Vaginal Cream Abbreviated Prescribing Information

Presentation: Premarin vaginal cream (0.625mg conjugated estrogens, USP). 14g cream formulation. **Indications and dosages**: 1. Treatment of atrophic vaginitis and kraurosis vulvae: Administer intravaginally in a cyclic regimen (daily for 21 days and then off for 7 days) with starting dose at 0.5g dosage strength. Dosage adjustments (0.5 to 2g) may be made based on individual response. 2. Treatment of Dyspareunia: 0.5g is administered intravaginally twice weekly continuously or in a cyclic regimen of 21 days of therapy followed by 7 days off of therapy. Use of Premarin Vaginal Cream, alone or in combination with a progestin, should be with the lowest effective dose and for the shortest duration consistent with treatment goals and risks for the individual woman. **Contraindications**: Known or suspected pregnancy. Undiagnosed abnormal uterine bleeding. Known, suspected or history of breast cancer. Known or suspected estrogen- dependent neoplasia. Active or history or arterial thromboembolic disease or venous thromboembolism. Active or chronic liver dysfunction or disease. Known thrombophilic disorders. Hypersensitivity to any component of medication. **Adverse reactions**: Reproductive system and breast disorders, gastrointestinal disorders, nervous system disorders, musculoskeletal, connective tissue and bone disorders, psychiatric disorders, vascular disorders, general disorders and administration site conditions, skin and subcutaneous tissue disorders, hepato-biliary disorders, infections and infestations, neoplasms benign and malignant, immune system disorders, metabolism and nutrition disorders, eye disorders, cardiac disorders, endocrine disorders. **Special precautions**: Systemic absorption may occur with the use of CE vaginal cream. Additional and/or increased risks that may be associated with the use of combination estrogen-plus-progestin therapy compared with using estrogen-alone regimens. Increased risk of myocardial infarction, pulmonary embolism, invasive breast cancer and ovarian cancer. Cardiovascular risk, stroke, venous thromboembolism, malignant neoplasms (endometrial cancer, breast cancer, ovarian cancer), dementia, gallbladder disease, hypercalcemia, immune (angioedema), fluid retention, hypertrigylceridemia, impaired liver function and history of cholestatic jaundice, elevated blood pressure, exacerbation of other conditions like asthma, epilepsy, migraine with or without aura, otosclerosis, porphyria, systemic lupus erythematosus, and hepatic hemangiomas, and should be used with caution in women with these conditions, Hypocalcemia, hypothyroidism, use of latex condoms.

API-PREMARIN VAGINAL CREAM-EN-1118

Full prescribing information available upon request.

Reference: Malaysia Premarin Vaginal Cream Package Insert, PREMARIN VAGINAL CREAM-1118

Premarin Tablets Abbreviated Prescribing Information

Presentation: Premarin Tablets (0.3mg and 0.625mg of conjugated estrogens). Blisters pack of 28's. **Indications and dosages**: 1.Moderate to severe vasomotor symptoms associated with estrogen deficiency: 0.3mg - 1.25mg daily. 2. Prevention and management of osteoporosis associated with estrogen deficiency: Generally, women should be started at 0.3mg daily and subsequent dosage adjustment may be based upon individual clinical and bone mineral density responses which should be periodically reassessed by healthcare provider. When prescribing solely for the prevention of post-menopausal osteoporosis, therapy should only be considered for women at significant risk of osteoporosis and for whom non-estrogen medications are not considered appropriate. When prescribing solely for the management of post-menopausal osteoporosis, non-estrogen medications should be first considered. 3. Atrophic vaginitis and atrophic urethritis: 0.3mg - 1.25mg daily. When prescribing solely for the treatment of symptoms of vulvar and vaginal atrophy, topical vaginal products should be considered.4. Female hypoestrogenism: 0.3mg - 1.25mg daily, administered cyclically (e.g., three weeks on and one week off). Doses are adjusted depending on the severity of symptoms and responsiveness of the endometrium. ERT and HRT should not be initiated or continued to prevent coronary heart disease. **Contraindications**: Known or suspected or history of breast cancer. Known or suspected estrogen-dependent neoplasia. Known or suspected pregnancy. Undiagnosed abnormal uterine bleeding. Active or history of confirmed arterial thromboembolic disease or venous thromboembolic. Known or suspected hypersensitivity to any component of this medication. Active or chronic liver dysfunction or disease. Known thrombophilic disorders. **Adverse reactions**: Abnormal uterine bleeding; breast pain, tenderness, enlargement, discharge; leukorrhea; arthralgias; leg cramps; alopecia; changes in weight (increase or decrease); increased triglycerides. **Special precautions**: There are additional and/or increased risks that may be associated with the use of combination estrogen-plus-progestin therapy compared with using estrogen-alone regimens. Increased risk of myocardial infarction, pulmonary embolism, invasive breast cancer and ovarian cancer. Cardiovascular risk, stroke, venous thromboembolism, endometrial cancer, breast cancer, ovarian cancer, dementia, gallbladder disease, hypercalcemia, palliative therapy in men, angioedema, fluid retention, hypertriglyceridemia, impaired liver function and history of cholestatic jaundice, elevated blood pressure, exacerbation of other conditions, hypocalcemia, hypothyroidism.

Full prescribing information available upon request.

Reference: Malaysia Premarin Package Insert, PREMARIN TABLETS-0516

For Healthcare Professionals Only

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