Menostar® is indicated for prevention of postmenopausal osteoporosis. Therapy should be considered only for women at significant risk of osteoporosis. Non-estrogen medications should be carefully considered.
Menostar® can be used without a daily or monthly concomitant progestin in women with a uterus. Women with irregular bleeding should be evaluated prior to and during Menostar® treatment. A 14-day course of progestin is recommended every 6 to 12 months. Endometrial sampling is recommended annually or as clinically indicated.

Close clinical surveillance of all women taking estrogens is important. 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. Endometrial sampling at yearly intervals or as clinically indicated is recommended. There is no evidence that the use of "natural" estrogens results in a different endometrial risk profile than synthetic estrogens at equivalent estrogen doses. The use of unopposed estrogen in women with a uterus can increase the risk of endometrial hyperplasia and cancer.

Estrogens with and without progestins should not be used for the prevention of cardiovascular disease.

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 during 5 years of treatment with oral conjugated estrogens (CE 0.625 mg) combined with medroxyprogesterone acetate (MPA 2.5 mg) relative to placebo. Other doses of conjugated estrogens with medroxyprogesterone acetate, and other combinations of estrogens and progestins were not studied in the WHI 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**(See CLINICAL PHARMACOLOGY, Clinical Studies, 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**.)

Estrogens and estrogen/progestin therapy 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; blood clots; stroke or myocardial infarction; known or suspected pregnancy; and liver dysfunction or disease. Menostar® should not be used in patients with known hypersensitivity to its ingredients.

Most common side effects in the clinical trial were arthralgia (12%), leukorrhea (11%), application site reactions (9%), and cervical polyps (6%).

Risk Factors include low estrogen levels, low bone mineral density (BMD), previous fracture, small frame (low body mass index), Asian or Caucasian, smoking, alcohol intake, and family history.