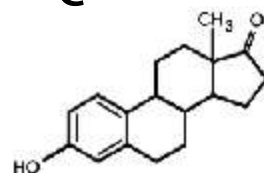


R^x ESTROGEN

(Conjugated estrogens are used for treating the symptoms of menopause including hot flashes)



100 % EXPORT QUALITY MEDICINE



GENERIC NAME: conjugated estrogens

DRUG CLASS AND MECHANISM

Estrogens are one of the two major classes of female hormones. (Progestins comprise the second major class). Estrogens are used primarily to treat the symptoms of menopause and states in which there is a deficiency of estrogen, for example, in women who have had their ovaries removed.

Conjugated estrogens are a mixture of several different estrogens (estrogen salts) that are derived from natural sources and blended to the approximate composition of estrogens in the urine of pregnant mares. The main components are sodium estrone sulphate and sodium equilin sulfate. Estrogens have widespread effects on many tissues in the body. Estrogens cause growth and development of the female sexual organs and maintain female sexual characteristics such as the growth of underarm and pubic hair, body contours and skeleton. Estrogens also increase secretions from the cervix and growth of the inner lining of the uterus (endometrium).

PRESCRIPTION: Yes.

GENERIC AVAILABLE: No.

PREPARATIONS: **Tablets:** 0.3, 0.45, 0.625, 0.9, and 1.25 mg. Vaginal cream: 0.625 mg per gm of cream. Injection: 25 mg

PRESCRIBED FOR

Conjugated estrogens are used for treating the symptoms of menopause including hot flashes, vaginal dryness, and vaginal atrophy. They also are used as therapy when the body does not produce enough estrogen due to castration (removal of the ovaries), ovarian failure or underdevelopment of hormone-secreting organs (hypogonadism). Conjugated estrogens also may be beneficial in treating advanced prostate and breast cancer. Although estrogens are approved for preventing osteoporosis, other drugs are more commonly prescribed for this purpose. Intravenous conjugated estrogens are used for treating abnormal uterine bleeding due to hormonal imbalance.

DOSING

To minimize side effects, the lowest effective oral dose of conjugated estrogens is used. The usual starting dose for treating symptoms associated with menopause and for preventing postmenopausal osteoporosis is 0.3 mg/day. The dose should be increased based on response. Conjugated estrogens may be administered in a continuous or cyclical interval (i.e., 25 days on treatment then 5 days off treatment).

Hypogonadism is treated with doses of 0.3 mg or 0.625 mg daily with a cyclical interval of 25 days on treatment followed by 5 days off treatment. The dose for women who have been castrated or have ovarian failure is 1.25 mg daily in a cyclical interval of three weeks on treatment and one week off treatment. In reality, most women take estrogens continuously since during the week off treatment, symptoms return because of the lack of estrogen. For treatment of breast cancer, the recommended dose is 10 mg daily for three months.

Abnormal uterine bleeding due to hormonal imbalance is treated with one 25 mg intravenous or intramuscular injection. Another injection may be given in 6-12 hours if needed.

The vaginal cream is used for treating vulvar and vaginal atrophy, and the recommended dose is ½ to 2 g daily.

DRUG INTERACTIONS

Estrogens increase the liver's ability to manufacture factors that promote the clotting of blood. Because of this, patients receiving warfarin (Coumadin), a drug that thins the blood and prevents clotting by reducing clotting factors, need to be monitored for loss of the blood thinning effect if treatment with an estrogen is begun.

Rifampin (Rifadin), barbiturates, carbamazepine (Tegretol), griseofulvin (Grifulvin), phenytoin (Dilantin), St. John's wort and primidone all increase the elimination of estrogen by enhancing the liver's ability to eliminate estrogens. Use of any of these medications with estrogens may result in a reduction of the beneficial effects of estrogens. Conversely, drugs such as erythromycin, ketoconazole (Nizoral), itraconazole (Sporanox), and ritonavir (Norvir) may reduce the elimination of estrogens by the liver as and lead to increased levels of estrogens in the blood. Grapefruit juice also may increase

levels of estrogen by increasing the absorption of estrogens from the intestine. Increased levels of estrogens in the blood may result in more estrogen-related side effects.

USES

This medication is a female hormone and is usually given to women who no longer produce the proper amount. It is used to reduce menopause symptoms (e.g., hot flashes, vaginal dryness), to prevent bone loss (osteoporosis) in people at high risk, to treat certain cancers in men and women (e.g., certain types of metastatic breast cancer), and to treat other conditions as determined by your doctor. If you are only being treated for vaginal menopause symptoms, products applied locally such as vaginal creams, tablets, or rings should be considered before products taken by mouth or absorbed through the skin. There are several medications (e.g., raloxifene or bisphosphonates) that are safe and effective to prevent or treat bone loss. These medicines should be considered for use before estrogen therapy. If you have other medical conditions as well, and are prescribed estrogens for more than one condition, consult your doctor about your treatment plan and its options.

HOW TO USE

Take this medication by mouth as directed by your doctor. It may be taken with food or immediately after a meal to prevent stomach upset. The dosage is based on your medical condition and response to therapy. Follow the dosing schedule carefully. Read the Patient Information Leaflet available from your pharmacist. Consult your doctor or pharmacist if you have any questions.

SIDE EFFECTS

Dizziness, lightheadedness, headache, stomach upset, bloating, nausea, weight changes, increased/decreased interest in sex, and breast tenderness may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood changes (e.g., severe depression, memory loss), calf pain/swelling, sudden severe headache, chest pain, trouble breathing, one-sided weakness, slurred speech, vision changes (e.g., change in contact lens fit, loss of vision), breast lumps, swelling of hands or feet, changes in vaginal bleeding (e.g., spotting, breakthrough bleeding, or prolonged bleeding), unusual vaginal discharge/itching/odor, yellowing of the eyes or skin. An allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

In a large study, women who took estrogen with progestins had a higher risk of heart attacks, strokes, blood clots in the lungs or legs, breast cancer, and dementia (loss of ability to think, learn, and understand). Women who take estrogen alone may also have a higher risk of developing these conditions. Tell your doctor if you smoke or use tobacco, if you have had a heart attack or a stroke in the past year, and if you or anyone in your family has or has ever had blood clots or breast cancer. Also tell your doctor if you have or have ever had high blood pressure, high blood levels of cholesterol or fats, diabetes, heart disease, lupus (a condition in which the body attacks its own tissues causing damage and swelling), breast lumps, or an abnormal mammogram (x-ray of the breast used to find breast cancer).

The following symptoms can be signs of the serious health conditions listed above. Call your doctor immediately if you experience any of the following symptoms while you are taking estrogen: sudden, severe headache; sudden, severe vomiting; speech problems; dizziness or faintness; sudden complete or partial loss of vision; double vision; weakness or numbness of an arm or a leg; crushing chest pain or chest heaviness; coughing up blood; sudden shortness of breath; difficulty thinking clearly, remembering, or learning new things; breast lumps or other breast changes; discharge from nipples; or pain, tenderness, or redness in one leg.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include: severe nausea/vomiting or excessive vaginal bleeding.

MISSED DOSE

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature between 59 and 86 degrees F (15 and 30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

WARNING:

Estrogen increases the risk that you will develop endometrial cancer (cancer of the lining of the uterus [womb]). The longer you take estrogen, the greater the risk that you will develop endometrial cancer. If you have not had a hysterectomy (surgery to remove the uterus), you should be given another medication called a progestin to take with estrogen. This may decrease your risk of developing endometrial cancer, but may increase your risk of developing certain other health problems, including breast cancer. Before you begin taking estrogen, tell your doctor if you have or have ever had cancer and if you have unusual vaginal bleeding. Call your doctor immediately if you have abnormal or unusual vaginal bleeding during your treatment with estrogen. Your doctor will watch you closely to help ensure you do not develop endometrial cancer during or after your treatment.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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