

PATIENT INFORMATION

This leaflet summarizes the major risks and benefits of treatment with Premarin. Read this PATIENT INFORMATION before using the product and each time you get medicine because there may be new information. Talk with your healthcare provider if you have any questions about this medicine.

What is the most important information I should know about Premarin?

ESTROGENS INCREASE THE RISK OF CANCER OF THE UTERUS.

If you take any estrogen-containing medicine, it is important to visit your doctor regularly and report any unusual vaginal bleeding right away. Vaginal bleeding after menopause may be a warning sign of uterine cancer. Your healthcare provider should check any unusual vaginal bleeding to find out the cause. Women who do not have a uterus have almost no risk of endometrial cancer.

What is Premarin?

Premarin is a mixture of estrogens obtained from natural sources.

What is Premarin used for?

The use of Premarin, alone or in combination with a progestin, may increase your risk of getting breast cancer, blood clots, heart attacks, and strokes. Premarin should be used only as long as needed. Periodically, you and your healthcare provider should discuss whether you still need treatment.

Premarin should not be used to prevent heart disease.

Premarin is used:

- **To reduce moderate to severe menopausal symptoms.**

Estrogens are hormones produced by a woman's ovaries. Between ages 45 and 55, the ovaries normally stop making estrogens. This drop in body estrogen levels causes the "change of life" or menopause (the end of monthly menstrual periods). Sometimes both ovaries are removed during an operation before natural menopause takes place. The sudden drop in estrogen levels causes "surgical menopause."

When the estrogen levels begin dropping, some women develop very uncomfortable symptoms, such as feelings of warmth in the face, neck, and chest, or sudden intense episodes of heat and sweating ("hot flashes" or "hot flushes"). In some women the symptoms are mild and in others they can be severe. Taking Premarin can help reduce these symptoms.

Every 3 to 6 months you and your healthcare provider should discuss whether you still need Premarin to control your hot flashes.

- **To treat itching, burning, dryness in or around the vagina due to menopause.**

Every 3 to 6 months you and your healthcare provider should discuss whether you still need Premarin to control your vaginal symptoms.

- **To treat certain conditions in which a young woman's ovaries do not produce enough estrogen naturally.**
- **To treat certain cancers in special situations, in men and women.**
- **To help reduce your chance of getting osteoporosis (thin weak bones).**

Osteoporosis is a thinning of the bones that makes them weaker and allows them to break more easily.

If you use Premarin, alone or in combination with a progestin, only to prevent osteoporosis, discuss with your healthcare provider whether a different treatment might be more appropriate for you.

Women who have menopause at an early age, are thin, smoke and/or have a family history of osteoporosis are more likely to develop osteoporosis.

Premarin may be used as part of a program which includes weight-bearing exercise, like walking or running, and taking calcium and vitamin D supplements to reduce your chances of getting osteoporosis. Before you change your exercise habits or calcium or vitamin D intake, it is important to discuss these lifestyle changes with your healthcare provider to find out if they are safe for you. Before you make any change in your use of Premarin, talk with your healthcare provider.

During menopause, some women develop nervous symptoms or depression. Estrogens do not relieve these symptoms. You may have heard that taking estrogens for years after menopause will keep your skin soft and supple and keep you feeling young. There is no evidence for this.

Who should not take Premarin?

Do not take Premarin

- **If you think you may be pregnant.**
Taking Premarin while you are pregnant may harm your unborn child. Do not take Premarin to prevent miscarriage.
- **If you have unusual vaginal bleeding.**
Unusual vaginal bleeding can be a warning sign of a serious condition including cancer of the uterus, especially if it happens after menopause. If you develop vaginal bleeding while taking Premarin, you may need further evaluation. Your healthcare provider needs to find out the cause of the bleeding so that you can receive proper treatment. If you develop vaginal bleeding while taking Premarin, talk with your healthcare provider about proper treatment.

- **If you have or had certain cancers.**
Estrogens may increase the risks of certain types of cancers, including cancer of the breast or uterus. If you have or have had cancer, talk with your healthcare provider about whether you should take Premarin.
- **If you have or had blood clots, a heart attack, or a stroke.**
Talk with your healthcare provider if you have or had these conditions, or if you have abnormal blood-clotting conditions.
- **If you have recently had a baby.**
Preamarin can be passed to the nursing baby in the breastmilk. The effect of this on the baby is not known. Do not take Premarin to stop your breast from filling with milk after a baby is born.
- **If you are allergic to Premarin tablets or any of their ingredients.**

How should I take Premarin?

- Take one Premarin tablet each day at about the same time.
- If you miss a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take only your next regularly scheduled dose. Do not take two doses at the same time.

Preamarin comes in several strengths. Check with your healthcare provider periodically to make sure you are using the appropriate dose.

Preamarin use may increase your risk of getting breast cancer, blood clots, heart attacks, and strokes. Premarin should be used only as long as needed. Periodically, you and your healthcare provider should discuss whether you still need treatment.

What are the possible risks and side effects of Premarin?

1. Heart disease, stroke and blood clots

The use of Premarin, alone or in combination with progestins, may increase your chance of having a heart attack, a stroke, blood clots, a pulmonary embolus (a blood clot formed in the legs or pelvis that breaks off and travels to the lungs), retinal thrombosis (a clot in a blood vessel of the eye), or other blood clotting problems. Any of these conditions may cause death or serious long-term disability. These conditions have been seen in healthy, postmenopausal women, as well as in women with a history of heart disease.

2. Cancer of the uterus

The risk of cancer of the uterus increases when Premarin is used alone, the longer it is used, and when larger doses are taken. Also, Premarin increases the risk of getting a condition (endometrial hyperplasia) that may lead to cancer of the lining of the uterus. Taking progestins, another hormonal drug, with Premarin lowers the risk of getting this condition. Therefore, if your uterus has not been removed, your healthcare provider may prescribe a progestin for you to take together with Premarin.

3. Cancer of the breast

Long-term use of Premarin, alone or in combination with progestins, may increase your chance of having breast cancer. Regular breast exams by a healthcare professional and monthly self-exams are recommended for all women. Mammography should be scheduled depending on your age and risk factors.

4. Ovarian cancer

Some studies suggest that there is a greater risk of ovarian cancer in women who have used estrogen (such as Premarin) alone for a long period of time, especially 10 years or more. Other studies have not shown this risk. The risk with combined estrogen/progestin treatment is unclear.

5. Vaginal bleeding

If you develop vaginal bleeding while taking Premarin and progestins, discuss your bleeding pattern with your healthcare provider. This is because vaginal bleeding after menopause may be a warning sign of a serious condition, including cancer of the uterus.

6. Gallbladder disease

Women who use Premarin after menopause are more likely to develop gallbladder disease needing surgery than women who do not use estrogens.

7. Blood pressure

Some women who are taking Premarin may have increases in blood pressure.

8. Liver problems

If you had yellowing of your skin or eyes associated with pregnancy, or with taking estrogens (eg, oral contraceptives), this condition may occur again with Premarin treatment.

9. Hypothyroidism

Women who are taking Premarin, and who use thyroid replacement therapy may require increased doses of their thyroid medication.

10. Endometriosis

Taking Premarin may worsen endometriosis. Talk with your healthcare provider if you have had endometriosis.

11. Effects on blood sugar

Taking Premarin may affect blood sugar levels, which might make a diabetic condition worse.

12. Other conditions

Fluid retention due to Premarin treatment may make some conditions worse, such as heart disease or kidney disease. Premarin treatment may also worsen asthma, epilepsy, migraine, porphyria and endometriosis.

In addition to the risks listed above, the following side effects have been reported with estrogen use:

- Nausea and vomiting, cramps, or bloating in the abdomen.
- Hair loss or abnormal hairiness.
- Breast tenderness or enlargement, pain and discharge.
- Enlargement of benign tumors (“fibroids”) of the uterus.
- Change in amount of cervical secretion.
- Vaginal yeast infections.
- Retention of fluid (edema).
- A spotty darkening of the skin, particularly on the face, reddening of the skin, skin rashes.
- Headache, migraines, dizziness, or changes in vision (including intolerance to contact lenses).
- Involuntary muscle spasms.
- Increase or decrease in weight.
- Changes in sex drive.

What can I do to lower my chances of getting a serious side effect with Premarin?

If you take Premarin, you can reduce your risks by doing these things:

- **See your healthcare provider regularly.**

Check with your healthcare provider to make sure you do not stay on treatment longer than needed. While you are taking Premarin, it is important to visit your healthcare provider at least once a year for a check-up. If you develop vaginal bleeding while taking Premarin, you may need further evaluation. Every 3 to 6 months you and your healthcare provider should discuss whether or not you still need Premarin to control your hot flushes and vaginal symptoms.

You should talk with your healthcare provider about stopping Premarin 4 to 6 weeks before surgery or during prolonged bedrest.

If members of your family have had breast cancer or if you have ever had breast lumps or an abnormal mammogram (breast X-ray), you may need to have more frequent breast examinations. Examine your breasts for changes every month.

- **Be alert to signs of trouble.**

If any of the following warning signals (or any other unusual symptoms) happen while you are using Premarin, call your healthcare provider immediately:

- Abnormal bleeding from the vagina (possible uterine cancer).
- Pains in the calves or chest, sudden shortness of breath, or coughing blood (possible clots in the legs, heart, or lungs).
- Severe headache or vomiting, dizziness, faintness, or changes in vision or speech, weakness or numbness of an arm or leg (possible clot in the brain or eye).
- Breast lumps (possible breast cancer). Check your breasts every month. Ask your healthcare provider to show you how to examine your breasts.
- Yellowing of the skin or whites of the eyes (possible liver problem).
- Pain, swelling, or tenderness in the abdomen (stomach area, possible gallbladder problem).

Other information

1. Your healthcare provider prescribed this drug for you and you alone. Do not give this drug to anyone else.
2. Keep this and all drugs out of reach of children. In case of overdose, call your doctor, or healthcare provider, hospital or poison control center right away.

HOW SUPPLIED

Premarin[®] (conjugated estrogens tablets, USP) - tablets for oral administration.

Each oval purple tablet contains 2.5 mg.


Each oval yellow tablet contains 1.25 mg.

Each oval white tablet contains 0.9 mg.

Each oval maroon tablet contains 0.625 mg.

Each oval green tablet contains 0.3 mg.

The appearance of these tablets is a trademark of Wyeth-Ayerst Laboratories.

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