

PATIENT INFORMATION

Premarin® (conjugated estrogens) Vaginal Cream

Read this PATIENT INFORMATION before you start using Premarin Vaginal Cream and read what you get each time you refill your Premarin Vaginal Cream prescription. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about Premarin Vaginal Cream (an estrogen mixture)?

- Estrogens increase the chance of getting cancer of the uterus.

Report any unusual vaginal bleeding right away while you are using Premarin Vaginal Cream. Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb). Your healthcare provider should check any unusual vaginal bleeding to find out the cause.

- Do not use estrogens with or without progestins to prevent heart disease, heart attacks, strokes, or dementia.

Using estrogens, with or without progestins, may increase your chance of getting heart attacks, strokes, breast cancer, and blood clots. Using estrogens, with or without progestins, may increase your chance of getting dementia, based on a study of women age 65 years or older. You and your healthcare provider should talk regularly about whether you still need treatment with Premarin Vaginal Cream.

What is Premarin Vaginal Cream?

Premarin Vaginal Cream is a medicine that contains a mixture of estrogen hormones.

What is Premarin Vaginal Cream used for?

Premarin Vaginal Cream is used after menopause to:

- **Treat moderate to severe dryness, itching, and burning, in and around the vagina.** You and your healthcare provider should talk regularly about whether you still need treatment with Premarin Vaginal Cream to control these problems.

Who should not use Premarin Vaginal Cream?

Do not start using Premarin Vaginal Cream if you:

- **Have unusual vaginal bleeding.**
- **Currently have or have had certain cancers.**

Estrogens may increase the chance of getting 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 use Premarin Vaginal Cream.

- **Had a stroke or heart attack in the past year.**

- **Currently have or had blood clots.**
- **Currently have or have had liver problems.**
- **Are allergic to Premarin Vaginal Cream or any of its ingredients.**

See the [list of ingredients](#) in Premarin Vaginal Cream at the end of this leaflet.

- **Think you may be pregnant.**

Tell your healthcare provider:

- **If you are breast feeding.** The hormones in Premarin Vaginal Cream can pass into your milk.
- **About all of your medical problems.** Your healthcare provider may need to check you more carefully if you have certain conditions, such as asthma (wheezing), epilepsy (seizures), migraine, endometriosis, lupus, or problems with your heart, liver, thyroid, kidneys, or have high calcium levels in your blood.
- **About all the medicines you take,** including prescription and nonprescription medicines, vitamins, and herbal supplements. Some medicines may affect how Premarin Vaginal Cream works. Premarin Vaginal Cream may also affect how your other medicines work.
- **If you are going to have surgery or will be on bedrest.** You may need to stop using Premarin Vaginal Cream.

How should I use Premarin Vaginal Cream?

The Gentle Measure™ Applicator has been specifically designed for comfortable, easy use.

1. Remove cap from tube.
2. Screw nozzle end of applicator onto tube.
3. *Gently* squeeze tube from the *bottom* to force sufficient cream into the barrel to provide the prescribed dose. Use the marked stopping points on the applicator as a guideline to measure the correct dose, as prescribed by your healthcare provider.
4. Unscrew applicator from tube.
5. Lie on back with knees drawn up. To deliver medication, gently insert applicator deeply into vagina and press plunger downward to its original position.

TO CLEANSE: Pull plunger to remove it from barrel. Wash with mild soap and warm water.

DO NOT BOIL OR USE HOT WATER.

Premarin Vaginal Cream should be used at the lowest possible dose for your treatment and only as long as needed. You and your healthcare provider should talk regularly (for example, every

3 to 6 months) about the dose you are taking and whether you still need treatment with Premarin Vaginal Cream.

What are the possible side effects of Premarin Vaginal Cream?

Premarin Vaginal Cream is only used in and around the vagina. However, the risks associated with oral Premarin treatment should be taken into account.

Side effects are grouped by how serious they are and how often they happen when you are treated.

Serious but less common side effects include:

- Breast cancer
- Cancer of the uterus
- Stroke
- Heart attack
- Blood clots
- Dementia
- Gallbladder disease
- Ovarian cancer
- High blood pressure
- Liver problems
- High blood sugar
- Enlargement of benign tumors of the uterus (“fibroids”)

Some of the warning signs of these serious side effects include:

- Breast lumps
- Unusual vaginal bleeding
- Dizziness and faintness
- Changes in speech
- Severe headaches
- Chest pain
- Shortness of breath

- Pains in your legs
- Changes in vision
- Vomiting
- Yellowing of the skin, eyes or nail beds

Call your healthcare provider right away if you get any of these warning signs, or any other unusual symptoms that concern you.

Less serious but common side effects of include:

- Headache
- Breast pain
- Irregular vaginal bleeding or spotting
- Stomach/abdominal cramps, bloating
- Nausea and vomiting
- Hair loss
- Fluid retention
- Reactions from inserting Premarin Vaginal Cream such as vaginal burning, irritation, and itching

These are not all the possible side effects of Premarin Vaginal Cream. For more information, ask your healthcare provider or pharmacist.

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

- Talk with your healthcare provider regularly about whether you should continue using Premarin Vaginal Cream.
- If you have a uterus, talk with your healthcare provider about whether the addition of a progestin (a different prescribed hormone medication) is right for you. The addition of a progestin is generally recommended for women with a uterus to reduce the chance of getting cancer of the uterus.
- See your healthcare provider right away if you get vaginal bleeding while using Premarin Vaginal Cream.
- Have a breast exam and mammogram (breast X-ray) every year unless your healthcare provider tells you something else. If members of your family have had breast cancer or if you have ever had breast lumps or an abnormal mammogram, you may need to have breast exams more often.

- If you have high blood pressure, high cholesterol (fat in the blood), diabetes, are overweight, or if you use tobacco, you may have higher chances for getting heart disease. Ask your health care provider for ways to lower your chances for getting heart disease.

General information about the safe and effective use of Premarin Vaginal Cream

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Premarin Vaginal Cream for conditions for which it was not prescribed. Do not give Premarin Vaginal Cream to other people, even if they have the same symptoms you have. It may harm them. **Keep Premarin Vaginal Cream out of the reach of children.**

This leaflet provides a summary of the most important information about Premarin Vaginal Cream. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about Premarin Vaginal Cream that is written for health professionals. You can get more information by calling the toll free number 1-800-934-5556.

What are the ingredients in Premarin Vaginal Cream?

Premarin Vaginal Cream contains a mixture of conjugated estrogens, which are a mixture of sodium estrone sulfate and sodium equilin sulfate and other components including sodium sulfate conjugates: 17 α -dihydroequilin, 17 α -estradiol, and 17 β -dihydroequilin. Premarin Vaginal Cream also contains cetyl esters wax, cetyl alcohol, white wax, glyceryl monostearate, propylene glycol monostearate, methyl stearate, benzyl alcohol, sodium lauryl sulfate, glycerin, and mineral oil.

Premarin[®] (conjugated estrogens) Vaginal Cream—Each gram contains 0.625 mg conjugated estrogens, USP.

Combination package: Each contains Net Wt. 1 ½ oz (42.5 g) tube with one plastic applicator calibrated in ½ g increments to a maximum of 2 g (NDC 0046-0872-93).

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F)
[See USP Controlled Room Temperature].

Wyeth[®]

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