WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ESTROGENS?

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

Encourage any unusual vaginal bleeding right away while you are taking estrogens. Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb). Your health care provider should check any unusual vaginal bleeding to find out the cause.

How is (Compound Name)?

Compound Name is a compound that contains estrogen hormones (estrogens). Estrogens are naturally occurring female hormones. These estrogens are derived from wild yams.

What are estrogens used for?

During menopause, women may have lower levels of some hormones and experience hot flashes and vaginal dryness. To help with these symptoms, some physicians prescribe hormones like estrogen or estrogen with a progestin or progesterone. FDA has approved drugs for use in hormone therapy for menopause symptoms, and advises women who choose to use hormones to use them at the lowest dose that helps, for the shortest time needed.

Estrogens are used after menopause to:

• **Reduce moderate to severe hot flashes**

Estrogens are hormones made by a woman’s ovaries. The ovaries normally stop making estrogens when a woman is between 45 to 55 years old. 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 strong feelings of heat and sweating (“hot flashes” or “hot flushes”). In some women, the symptoms are mild, and they will not need estrogens. In other women, symptoms can be more severe. You and your health care provider should talk regularly about whether you still need treatment with estrogens.

• **Treat moderate to severe dryness, itching, and burning in and around the vagina**

You and your health care provider should talk regularly about whether you still need treatment with estrogens to control these problems. If you use estrogens only to treat your dryness, itching, and burning in and around your vagina, talk with your health care provider about whether a topical vaginal product would be better for you.

Who should not take estrogens?

Do not start taking estrogens 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 health care provider about whether you should take estrogens.
• **Had a stroke or heart attack in the past year**
• **Currently have or have had blood clots**
• **Currently have or have had liver problems**
• **Are allergic to estrogens or any of the inactive ingredients in your compound (you may ask the pharmacist for a list of inactive ingredients)**
• **Think you may be pregnant.**

Tell your health care provider:

• **If you are breastfeeding.** Estrogens can pass into your breast milk.

• **About all of your medical problems:** Your health care provider may need to check you more carefully if you have certain conditions, such as asthma (wheezing); epilepsy (seizures); migraine; endometriosis; lupus; problems with your heart, liver, thyroid, or kidneys; or have high calcium levels in your blood.

• **About all the medicines you take.** This includes prescription and nonprescription medicines, vitamins, and herbal supplements. Some medicines may affect how estrogens work. Estrogens may also affect how your other medicines work.

• **If you are going to have surgery or will be on bed rest.** You may need to stop taking estrogens.

How should I take estrogens?

1. Start at the lowest dose and talk to your health care provider about how well that dose is working for you.
What do I do in case of an overdose/emergency?
The Florida Poison Information Center Network (FPICN) is dedicated to providing emergency services 24 hours a day to the citizens of Florida by offering poison prevention and management information through the use of a nationwide, toll-free hotline (1-800-222-1222) accessible by voice and TTY.

What should I do if I forget a dose?
If you miss a dose do not double the dose on the next day to catch up. If your next dose is less than 12 hours away, skip the missed dose and go back to your regular dosing schedule. If it is more than 12 hours until the next dose, take the dose you missed and resume your normal dosing the next day.

What storage conditions are needed for this medication?
Store at room temperature between 68-77 degrees F (20-25 degrees C) away from light and moisture; excursions permitted to 59-86 degrees F (15-30 degrees C). [see USP Controlled Room Temperature]. Do not store in bathroom, the car or expose to heat.

What are the possible side effects of estrogens?
- Breast cancer
- Cancer of the uterus
- Stroke
- Heart attack
- Blood clots
- Dementia
- Gallbladder disease
- Ovarian cancer

Some of the warning signs of 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

Call your health care provider right away if you get any of these warning signs, or any other unusual symptom that concerns you.

Common side effects include:
- Headache
- Breast pain
- Irregular vaginal bleeding or spotting
- Stomach/abdominal cramps, bloating
- Nausea and vomiting
- Hair loss

Other side effects include:
- High blood pressure
- Liver problems
- High blood sugar
- Fluid retention
- Enlargement of benign tumors of the uterus ("fibroids")
- Vaginal yeast infection

These are not all the possible side effects of estrogens. For more information, ask your health care provider or pharmacist.

What can I do to lower my chances of a serious side effect with estrogens?
Talk with your health care provider regularly about whether you should continue taking estrogens. If you have a uterus, talk to your health care provider about whether the addition of a progestin or progesterone is right for you. In general, the addition of a progestin or progesterone is recommended for women with a uterus to reduce the chance of getting cancer of the uterus. See your health care provider right away if you get vaginal bleeding while taking estrogens. Have a breast exam and mammogram (breast X-ray) every year unless your health care provider tells you otherwise. 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 a higher chance of getting heart disease. Ask your health care provider for ways to lower your chance of getting heart disease.

Have an annual gynecologic exam

General information about safe and effective use of estrogens
Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not take estrogens for conditions for which it was not prescribed. Do not give estrogens to other people, even if they have the same symptoms you have. It may harm them.

Keep estrogens out of the reach of children and pets
This leaflet provides a summary of the most important information about estrogens. If you would like more information, talk with your health care provider or pharmacist. You can get more information by speaking to one of our pharmacists directly in person or over the telephone (800-224-7711).