Read this Patient Information leaflet before you start taking any estrogen(s) and progesterone and read what you get each time you refill your prescription. There may be new information. This information does not take the place of talking to your health care provider about your medical condition or your treatment.

**What is **(Compound Name)**?**

(Compound Name) is a medicine that contains two kinds of hormones, estrogen hormones (estrogens) and progesterone. These hormones are derived from wild yams.

**What are estrogens and progesterone 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 progesterone. FDA has approved drugs for use in hormone therapy for menopausal symptoms, and advises women who choose to use hormones to use them at the lowest dose that helps, for the shortest time needed.

Estrogens and progesterone 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 and progesterone to control these problems. If you use estrogens and progesterone 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.

- **Protection of the Endometrium (Lining of the Uterus)**

Progesterone is used in combination with estrogens in postmenopausal women with a uterus. Taking estrogens alone increases the chance of developing a condition called endometrial hyperplasia, that may lead to cancer of the lining of the uterus. In general, the addition of progesterone is recommended for women with a uterus to reduce the chance of getting cancer of the uterus.

**Who should not take estrogens and progesterone?**

Do not start taking estrogens and progesterone 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, progesterone 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 and progesterone 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 and progesterone work. Estrogens and progesterone 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 and progesterone.

How should I take estrogens and progesterone?

1. Start at the lowest dose and talk to your health care provider about how well that dose is working for you.
2. Estrogens and progesterone should be used at the lowest dose possible for your treatment only as long as needed. You and your health care provider should talk regularly (e.g., every 3 to 6 months) about the dose you are taking and whether you still need treatment with estrogens and progesterone.
3. Estrogens and progesterone can be compounded in many different dosage forms, including oral capsules, troches, topical creams/gels applied to the skin or vaginal area.
   a. Oral preparations may be taken with or without food.
   b. Troche preparations should be dissolved under the tongue or in the cheek. It should dissolve in 10-15 minutes. Do not eat or drink anything for 10-15 minutes after and brush your teeth before going to bed.
   c. Topical preparations should be applied to the area or inserted as indicated on the prescription label or as directed by your health care provider. Make sure to wash hands before and after each use. Measure dose indicated on prescription label using the syringe or measuring device provided.
4. Progesterone may cause drowsiness therefore is usually taken in the evening or at bedtime. Some women become very drowsy and/or dizzy after taking progesterone. In a small percentage of these women, these effects may be increased including blurred vision, difficulty speaking, difficulty walking and feeling abnormal. If you experience these symptoms, discuss them with your health care provider immediately. Use caution when driving a motor vehicle or operating machinery.
5. Take estrogens and progesterone at the same time each day.

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 and progesterone? Some of the warning signs of serious side effects include:

- Breast cancer
- Cancer of the uterus
- Stroke
- Heart attack
- Blood clots
- Dementia
- Gallbladder disease
- Ovarian cancer
- 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
- Mental Depression

These are not all the possible side effects of estrogens and progesterone. 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 and progesterone?

Talk with your health care provider regularly about whether you should continue taking estrogens and progesterone. See your health care provider right away if you get vaginal bleeding while taking estrogens and progesterone. 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 and progesterone

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

Keep estrogens and progesterone out of the reach of children and pets

This leaflet provides a summary of the most important information about estrogens and progesterone. 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).

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