

PATIENT INFORMATION

(Updated April 2009)

Femtrace[®] (estradiol acetate tablets)

Read this PATIENT INFORMATION before you start taking Femtrace and read what you get each time you refill Femtrace. 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 FEMTRACE (AN ESTROGEN HORMONE)?

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

Report 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 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 or strokes.

Using estrogens with or without progestins may increase your chances of getting heart attacks, strokes, breast cancer and blood clots. Using estrogens with progestins may increase your risk of dementia. You and your healthcare provider should talk regularly about whether you still need treatment with Femtrace.

What is Femtrace?

Femtrace is a medicine that contains an estrogen hormone.

What is Femtrace used for?

Femtrace is 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 healthcare provider should talk regularly about whether you still need treatment with Femtrace.

Who should not use Femtrace?

Do not start taking Femtrace if you:

- **have unusual vaginal bleeding**
- **currently have or have had certain cancers**
Estrogens may increase the chances of getting certain types of cancers, including cancer of the breast or uterus. If you have or had cancer, talk with your healthcare provider about whether you should take Femtrace.
- **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 Femtrace or any of its ingredients**
See the end of this leaflet for a list of ingredients in Femtrace.
- **think you may be pregnant**

Tell your healthcare provider:

- **if you are breastfeeding**
The hormone in Femtrace 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, problems with your heart, liver, thyroid, 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 Femtrace works. Femtrace 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 Femtrace?

1. Take one Femtrace tablet daily.
2. Start at the lowest dose and talk to your healthcare provider about how well that dose is working for you.
3. Estrogens should be used at the lowest dose possible for your treatment 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 Femtrace.

What are the possible side effects of estrogens?

Less common but serious side effects include:

- Breast cancer
- Cancer of the uterus
- Stroke
- Heart attack
- Blood clots
- Dementia

- Gallbladder disease
- Ovarian cancer

These are some of the warning signs of serious side effects:

- 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 healthcare 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 Femtrace. For more information, ask your healthcare provider or pharmacist.

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

- Talk with your healthcare provider regularly about whether you should continue taking Femtrace.
- If you have a uterus, talk to your healthcare provider about whether the addition of a progestin is right for you.
- See your healthcare provider right away if you get vaginal bleeding while taking Femtrace.
- 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 of getting heart disease. Ask your healthcare provider for ways to lower your chances for getting heart disease.

General information about safe and effective use of Femtrace.

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

Keep Femtrace out of the reach of children.

This leaflet provides a summary of the most important information about Femtrace. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about Femtrace that is written for health professionals. You can also get more information by calling the toll free number 800-521-8813.

What are the ingredients in Femtrace?

Femtrace contains estradiol acetate, an estrogen. It also contains the following inactive ingredients: ferric oxide, povidone, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, silicon dioxide, magnesium stearate and acetic acid; ferric oxide, a coloring agent, is not an ingredient in the 0.9 mg tablets.

Rx Only

Manufactured by:
Pharmaceuticals International, Inc., Hunt Valley, MD 21031
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Marketed by:
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To report SUSPECTED ADVERSE REACTIONS, contact Warner Chilcott at 1-800-521-8813 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.



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