

femhrt[®]
(norethindrone acetate/ethinyl estradiol tablets)

INFORMATION FOR THE PATIENT
(Revised October 2009)

Please read this PATIENT INFORMATION before you start taking *femhrt*[®] and each time you refill *femhrt*. 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 *femhrt* (a combination of estrogen and progestin hormones)?

- Do not use estrogens and progestins to prevent heart disease, heart attacks, strokes or dementia.

Using estrogens and progestins may increase your chances of getting heart attack, strokes, breast cancer, and blood clots. Using estrogens, with or without progestins may increase your risk of dementia, based on a study of women age 65 years or older. It is unknown whether this study applies to women who began estrogen and progestin therapy before age 65. You and your healthcare provider should talk regularly about whether you still need treatment with *femhrt*.

What is *femhrt*?

femhrt is medicine that contains two kinds of hormones, an estrogen and a progestin.

What is *femhrt* used for?

femhrt 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 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; in others they can be severe. You and your healthcare provider should talk regularly about whether you still need treatment with *femhrt*.

- **help reduce your chances of getting osteoporosis (thin, weak bones)**

Osteoporosis from menopause is a thinning of the bones that makes them weaker and easier to break. If you use *femhrt* only to prevent osteoporosis from menopause, talk with your healthcare provider about whether a different treatment or medicine without estrogens might be better for you. You and your healthcare provider should talk regularly about whether you should continue with *femhrt*.

Weight-bearing exercise, like walking or running, and taking calcium and vitamin D supplements may also lower your chances of getting postmenopausal osteoporosis. It is important to talk about exercise and supplements with your healthcare provider before starting them.

Who should not take *femhrt*?

Do not take *femhrt* if you have had your uterus removed (hysterectomy).

femhrt contains a progestin to decrease the chances of getting cancer of the uterus. If you do not have a uterus, you do not need a progestin and you should not take *femhrt*.

Do not start taking *femhrt* if you:

- **currently have or have had certain cancers.** Estrogens may increase the chances of getting certain types of cancers, including cancer of the breast and uterus. If you have or had cancer, talk with your healthcare provider about whether you should take *femhrt*.
- **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 *femhrt* or any of its ingredients.** See the end of this leaflet for a list of ingredients in *femhrt*.
- **think you may be pregnant.** If you think you may be pregnant, do not take *femhrt*.

Tell your healthcare provider:

- **if you are breastfeeding.** The hormones in *femhrt* 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**, including prescription and nonprescription medicines, vitamins, and herbal supplements. Some medicines may affect how *femhrt* works. *femhrt* 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 progestins.

How should I take *femhrt*?

Take your *femhrt* pill once a day at about the same time each day. If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and go back to your normal schedule. Do not take two doses at the same time.

Start at the lowest dose and talk to your healthcare provider about how well that dose is working for you.

Estrogens should only be used as long as needed. You and your healthcare provider should reevaluate every 3 to 6 months whether or not you still need treatment with *femhrt*.

What are the possible risks and side effects of *femhrt*?

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 *femhrt*. For more information, ask your healthcare provider or pharmacist.

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

- Talk with your healthcare provider regularly (every 3-6 months) about whether you should continue taking *femhrt*.
- See your healthcare provider right away if you develop vaginal bleeding while taking *femhrt*.
- 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 (breast x-ray), 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 use tobacco, you may have higher chances for getting heart disease. Ask your healthcare provider for ways of lowering your chances for getting heart disease.

General information about safe and effective use of *femhrt*

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not take *femhrt* for conditions for which it was not prescribed.

Do not give *femhrt* to other people, even if they have the same symptoms you have. It may harm them.

Keep all drugs out of the reach of children. In case of overdose, call your doctor, hospital, or poison control center right away. This leaflet provides a summary of the most important information about *femhrt*. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about *femhrt* that is written for health professionals. You can get more information by calling the toll free number 800-521-8813.

What are the ingredients in *femhrt*?

Each white tablet contains norethindrone acetate and ethinyl estradiol. Each tablet also contains calcium stearate, lactose monohydrate, microcrystalline cellulose, and cornstarch.

Manufactured by:

Warner Chilcott Company, LLC
Fajardo, Puerto Rico 00738

Marketed by:

Warner Chilcott (US), LLC
Rockaway, NJ 07866
1-800-521-8813

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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