

## INFORMATION FOR THE PATIENT

### **What is *femhrt* 1/5?**

Your healthcare provider has prescribed *femhrt* 1/5, a combination of two hormones, a progestin (1 mg norethindrone acetate) and an estrogen (5 mcg ethinyl estradiol) intended for use once a day. This insert describes the major benefits and risks of your treatment, as well as how and when treatment may be taken. If you have any questions, please contact your physician, nurse or pharmacist.

### ***femhrt* 1/5 is approved for use in the following ways:**

- **To reduce moderate to severe menopausal symptoms.** Estrogens are hormones produced by the ovaries of menstruating women. When a woman is between the ages of 45 and 55, the ovaries normally stop making estrogens. This drop in body estrogen levels causes the “change of life” or menopause, the end of monthly menstrual periods.

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. These symptoms may last only a few months or longer. Taking *femhrt* 1/5 can help reduce these symptoms. If you are not taking hormones for other reasons, such as the prevention of osteoporosis, you should take *femhrt* 1/5 only as long as you need it for relief from your menopausal symptoms.

- **To prevent thinning bones (osteoporosis).** Osteoporosis is a thinning of the bones that makes them weaker and allows them to break more easily. The bones of the spine, wrists, and hips may be affected by osteoporosis. *femhrt* 1/5 may be used as part of a program including weight-bearing exercise, such as walking or running, and calcium supplements.

Women likely to develop osteoporosis often have the following characteristics: white or Asian race, slim, cigarette smokers, and a family history of osteoporosis in a mother, sister or aunt. Women who have menopause at an earlier age, either naturally or because their ovaries were removed during an operation, are more likely to develop osteoporosis than women whose menopause happens later in life.

### **Who should not take *femhrt* 1/5?**

*femhrt* 1/5 should not be taken in the following situations:

- **During pregnancy.** If you think you may be pregnant, do not take *femhrt* 1/5. Taking estrogens while you are pregnant may cause your unborn child to have birth defects. Do not take *femhrt* 1/5 to prevent miscarriage.
- **If you have unusual vaginal bleeding that has not been checked by your healthcare provider.** Unusual vaginal bleeding can be a warning sign of a serious condition, including cancer of the uterus, especially if bleeding happens after

menopause. Your doctor must find out the cause of the bleeding to recommend the right treatment.

- **If you have had certain cancers.** Estrogens increase the risk of certain types of cancers, including cancer of the breast and uterus. If you have had cancer, talk with your doctor about whether you should take *femhrt 1/5*.
- **If you have any circulation problems.** Generally, estrogens should not be taken if you have ever had a blood-clotting condition or other circulatory problem. In special situations, some doctors may decide that estrogen therapy is so necessary that the risks of taking *femhrt 1/5* are acceptable. (see “What are the possible risks and side effects of *femhrt 1/5*?”)
- **After childbirth or when breast-feeding a baby.** *femhrt 1/5* should not be taken to try to stop the breasts from filling with milk after a baby is born. Taking *femhrt 1/5* may increase your risk of developing blood clots (see “What are the possible risks and side effects of *femhrt 1/5*?”)
- **If you have had a hysterectomy (uterus removed).** *femhrt 1/5* contains a progestin to decrease the risk of developing endometrial hyperplasia (an overgrowth of the lining of the uterus that may lead to cancer). If you do not have a uterus, you do not need a progestin, and you should not take *femhrt 1/5*.

### **How should I take *femhrt 1/5*?**

Take your *femhrt 1/5* 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 take only your next regularly scheduled dose. Do not take two doses at the same time.

The length of treatment with estrogens varies from woman to woman. You and your healthcare provider should reevaluate every 3 to 6 months whether or not you still need *femhrt 1/5* to control your hot flashes.

### **What are the possible risks and side effects of *femhrt 1/5*?**

- **Cancer of the uterus.** *femhrt 1/5* has estrogen and progestin in it. If you take any drug that contains estrogen, including *femhrt*, you should see your doctor for regular check-ups and report any unusual vaginal bleeding right away. Vaginal bleeding after menopause may be a warning sign of a serious condition, including cancer of the uterus. Your doctor should identify the cause of any unusual vaginal bleeding. The risk of cancer of the uterus increases when estrogens are used without a progestin. The risk also increases the longer estrogens are taken and the larger the doses. You are more likely to get cancer of the uterus if you are overweight, diabetic, or have high blood pressure. *Femhrt 1/5*, which contains a progestin, reduces the estrogen-related risk of getting a condition of the uterine lining called endometrial hyperplasia. This condition may lead to cancer of the uterus (see “Other information”).
- **Cancer of the breast.** Most studies have not shown a higher risk of breast cancer in women who have used estrogens. However, some studies report that breast cancer developed more often (up to twice the usual rate) in women who used estrogens for longer time periods, especially more than 10 years, or who used high doses for a

shorter time period. The effects of added progestin on the risk of breast cancer are unknown. You should have regular breast examinations by a health professional and examine your own breasts monthly. Ask your health care provider to show you how to do a breast exam yourself. If you are over 50 years of age, you should have a mammogram every year.

- **Gallbladder disease.** Women who use estrogens after menopause are more likely to develop gallbladder disease that leads to surgery than women who do not use estrogens.
- **Abnormal blood clotting.** Taking estrogens may cause changes in your blood clotting system that allow the blood to clot more easily. If blood clots form in your bloodstream, they can cut off the blood supply to vital organs, causing serious problems. These problems may include a stroke (by cutting off blood to the brain), a heart attack (by cutting off blood to the heart), or a pulmonary embolus (by cutting off blood supply to the lungs). Any of these conditions may cause death or serious long-term disability.
- **Vaginal bleeding.** With *femhrt 1/5*, menstrual-like vaginal bleeding may occur. If bleeding occurs, it is frequently light spotting or bleeding, but it may be moderate or heavy. If you experience vaginal bleeding while taking *femhrt 1/5*, discuss your bleeding pattern with your healthcare provider.

**In addition to the risks and side effects just listed, patients taking estrogen or progestin have reported the following side effects:**

- nausea and vomiting
- breast tenderness or enlargement
- headache
- retention of extra fluid (edema), which may make some conditions worse, such as asthma, epilepsy, migraine, heart disease, or kidney disease
- runny nose
- abdominal pain
- enlargement of non-cancerous tumors (fibroids) of the uterus
- spotty darkening of the skin, particularly on the face; reddening of the skin; skin rashes

**How can I reduce the risks associated with taking *femhrt 1/5*?**

If you take *femhrt 1/5*, you can reduce your risks by carefully monitoring your treatment.

**See your healthcare provider regularly.** While you take *femhrt 1/5*, see your doctor at least once a year for a checkup. If you develop vaginal bleeding while taking *femhrt 1/5*, you might need further evaluation. 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 more frequent breast examinations.

**Reassess your need for treatment.** Every 3-6 months, you and your doctor should discuss whether or not you still need *femhrt 1/5* for control of your hot flashes.

**Be alert for signs of trouble.** If any of the following warning signs (or any other unusual symptoms) happen while you are taking *femhrt* 1/5, call your doctor right away:

- pains in the calves or chest, sudden shortness of breath or coughing blood (possible clots in the legs, heart, or lungs)
- severe headache or vomiting, dizziness, faintness, or changes in vision or speech, weakness or numbness of an arm or leg (possible clots in the brain or eye)
- breast lumps (possible breast cancer)
- yellowing of the skin or whites of the eyes (possible liver problem)
- pain, swelling, or tenderness in the abdomen (possible gallbladder problem)

### **Other Information**

- Discuss carefully with your doctor or health care provider all the possible risks and benefits of long-term estrogen and progestin treatment as they affect you personally.
- If you take calcium supplements as part of your treatment to help prevent osteoporosis, ask your doctor about the amounts recommended. A daily intake of 1500 mg of calcium is often recommended for postmenopausal women. Vitamin D (400 IU daily) may help your body use more of the calcium.
- Taking estrogens with progestins may have unhealthy effects on blood sugar, which might make a diabetic condition worse.
- Your doctor has prescribed this drug for you and you alone. Do not give your *femhrt* 1/5 to anyone else. Do not take *femhrt* 1/5 for conditions for which it was not prescribed.
- Keep all drugs out of the reach of children. In case of overdose, call you doctor, hospital or poison control center right away.

This leaflet provides the most important information about *femhrt* 1/5. If you want more information, ask your doctor or pharmacist for the professional labeling. The professional labeling is published in a book called “The Physicians’ Desk Reference” or PDR, available in bookstores and public libraries.