

PATIENT INFORMATION

(Updated February 2007)

Femring® (estradiol acetate vaginal ring)

Read this PATIENT INFORMATION before you start using Femring® and read what you get each time you refill your Femring prescription. 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 FEMRING (AN ESTROGEN PRODUCT)?

- 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, strokes or dementia.

Using estrogens with or without progestins may increase your chances of getting heart attacks, 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. You and your healthcare provider should talk regularly about whether you still need treatment with Femring.

What is Femring?

Femring (estradiol acetate vaginal ring) is an off-white, soft, flexible vaginal ring with a center that contains an estrogen. Femring should be removed after 90 days of continuous use. If continuation of therapy is indicated, a new flexible ring should be replaced

What is Femring used for?

Femring 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 Femring.

- **treat moderate to severe dryness, itching and burning in and around the vagina**
You and your healthcare provider should talk regularly about whether you still need treatment with Femring to control these problems. If you use Femring only to treat your dryness, itching and burning in and around your vagina, talk with your healthcare provider about whether a topical vaginal product would be better for you.

Who should not use Femring?

Do not start using Femring 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 use Femring.
- **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 Femring or any of its ingredients.** See the end of this leaflet for a list of ingredients in Femring.
- **think you may be pregnant**

Tell your healthcare provider:

- **if you are breastfeeding.** The hormone in Femring 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 Femring works. Femring 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.

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

- 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

What are the possible side effects of vaginal rings?

A few cases of toxic shock syndrome (TSS) have been reported in women using vaginal rings.

These are not all the possible side effects of Femring. For more information, ask your healthcare provider or pharmacist.

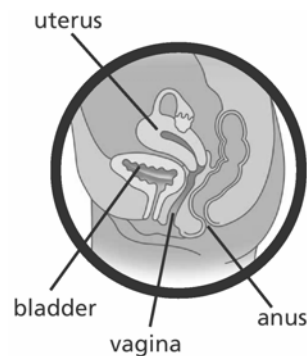
What can I do to lower my chances of a serious side effect with Femring?

- Talk with your healthcare provider regularly about whether you should continue using Femring.
- See your healthcare provider right away if you get vaginal bleeding while using Femring.
- If you have fever, nausea, vomiting, diarrhea, muscle pain, dizziness, faintness, or a sunburn-rash on face and body, remove Femring and contact your healthcare provider.

- 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 examinations 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.

How do I use Femring?

1. Start at the lowest dose and talk to your healthcare provider about how well that dose is working for you.
2. Estrogens should be used at the lowest dose possible for your treatment only as long as needed. The lowest effective dose of Femring has not been determined. You and your healthcare provider should talk regularly (for example, every 3 to 6 months) about the dose you are using and whether you still need treatment with Femring.



- Femring is inserted into your vagina by you or your healthcare provider.
- Femring should stay in your vagina for 3 months.
- After 3 months Femring should be removed and a new Femring should be inserted.

To insert Femring into your vagina:

1. Wash and dry your hands.
2. Remove Femring from its pouch.
3. Choose the position that is most comfortable for you. For example, lying down or standing with one leg up. (**Diagrams 1a and 1b**, respectively).



DIAGRAM 1a



DIAGRAM 1b

4. Use your thumb and index finger (pointer finger) to press the sides of the ring together. You may find it easier to insert Femring if you twist it into a figure-of-eight shape. **(Diagram 2)**



DIAGRAM 2

5. Use your other hand and hold open the folds of skin around your vagina. **(Diagram 3)**



DIAGRAM 3

6. Place the tip of the ring in the vaginal opening and then use your index finger to push the folded ring gently into your vagina. Push it up towards your lower back as far as you can. **(Diagram 4)**



DIAGRAM 4

If the ring feels uncomfortable, you probably did not push it into your vagina far enough. Use your index finger to push the ring as far as you can into your vagina (**Diagram 5**). There is no danger of Femring being pushed too far up in the vagina or getting lost.



DIAGRAM 5

Femring should now be in your upper vagina (**Diagram 6**). The exact position of Femring in the vagina is not important for it to work.



DIAGRAM 6

7. Wash your hands when you are done.

After 3 months, Femring may no longer release enough medicine to control your menopausal symptoms. To continue to have symptom relief your current Femring should be removed and replaced with a new one if you and your healthcare provider have decided that you still need treatment with Femring.

To remove Femring:

1. Wash and dry your hands.
2. Choose the position that is most comfortable for you (see **Diagrams 1a** and **1b**).
3. Put a finger into your vagina and hook it through the ring. (**Diagram 7**)



DIAGRAM 7

4. Gently pull downwards and forwards to remove Femring.
5. Wrap the used ring in tissue or toilet paper and put it in a trash can.
6. Wash your hands.

Insert another ring now if your healthcare provider has told you to.

If your Femring comes out of your vagina before 3 months, clean it with warm water and put it back in your vagina.

- Femring can come out if it is not put in far enough.
- Femring can come out when you are pushing hard during a bowel movement.
- Femring can come out if your vaginal muscles are weak.

If Femring comes out often, tell your healthcare provider. Femring may not be right for you.

Call your healthcare provider if you have any problems putting Femring in your vagina or taking it out.

You may leave Femring in place if you need to use medicine for a vaginal infection.

You may leave Femring in place during sex (intercourse). If you take Femring out during intercourse or it comes out, clean it with warm water and put it back in your vagina.

If you lose your Femring, a new Femring should be put in place for 3 months.

General information about safe and effective use of Femring.

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

Keep Femring out of the reach of children.

This leaflet provides a summary of the most important information about Femring. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about Femring 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 Femring?

Femring contains estradiol acetate, an estrogen. It also contains cured silicone elastomer composed of dimethyl polysiloxane silanol, silica (diatomaceous earth), normal propyl orthosilicate, stannous octoate; and barium sulfate. There are no coloring agents in Femring.

Rx only

Manufactured by: Warner Chilcott UK, Ltd., Larne, Northern Ireland, UK
Marketed by: Warner Chilcott (US) Inc., Rockaway, NJ 07866



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