PATIENT INFORMATION

ESTRING
(estradiol vaginal ring)

Read this PATIENT INFORMATION before you start using ESTRING and read the patient information each time you refill your ESTRING prescription. There may be new information. This information does not take the place of talking to your healthcare provider about your menopausal symptoms and their treatment.

What is the most important information I should know about ESTRING (an estrogen hormone)?

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

Report any unusual vaginal bleeding right away while you are using ESTRING. Vaginal bleeding after menopause may be a warning sign of cancer of the uterine (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 chance 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 ESTRING.

What is ESTRING?

ESTRING (estradiol vaginal ring) is an off-white, soft, flexible ring with a center that contains 2 mg of estradiol (an estrogen hormone). ESTRING releases estradiol into the vagina in a consistent, stable manner for 90 days. The soft, flexible ring is placed in the upper third of the vagina (by the physician or the patient). ESTRING should be removed after 90 days of continuous use. If continuation of therapy is indicated, the flexible ring should be replaced.

What is ESTRING used for?

ESTRING is used after menopause to:

- Treat moderate to severe itching, burning, and dryness in or around the vagina.

You and your healthcare provider should talk regularly about whether you still need treatment with ESTRING to control these problems.

Who should not use ESTRING?

Do not start using ESTRING 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 had cancer, talk with your healthcare provider about whether you should use ESTRING.

- **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 any of the ingredients in ESTRING**

  See the list of ingredients in ESTRING at the end of this leaflet.

- **Think you may be pregnant**

Tell your healthcare provider:

- **If you are breastfeeding**

  The hormone in ESTRING can pass into your breast 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, or 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 ESTRING works. ESTRING 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 use ESTRING?

ESTRING is a local estrogen therapy designed to relieve itching, burning and dryness in and around the vagina . ESTRING PROVIDES RELIEF OF LOCAL SYMPTOMS OF MENOPAUSE ONLY.

Estrogens should be used only as long as needed. You and your healthcare provider should talk regularly (for example, every 3 to 6 months) about whether you still need treatment with ESTRING.

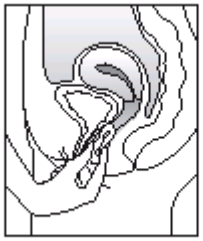
ESTRING INSERTION

ESTRING can be inserted and removed by you or your doctor or healthcare provider. To insert ESTRING yourself, choose the position that is most comfortable for you: standing with one leg up, squatting, or lying down.

1. After washing and drying your hands, remove ESTRING from its pouch using the tear-off notch on the side. (Since the ring becomes slippery when wet, be sure your hands are dry before handling it.)

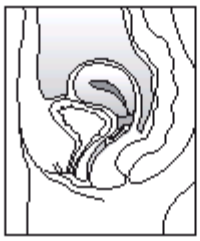
2. Hold ESTRING between your thumb and index finger and press the opposite sides of the ring together as shown.

3. Gently push the compressed ring into your vagina as far as you can.



ESTRING PLACEMENT

The exact position of ESTRING is not critical, as long as it is placed in the upper third of the vagina.



When ESTRING is in place, you should not feel anything. If you feel uncomfortable, ESTRING is probably not far enough inside. Use your finger to gently push ESTRING further into your vagina.

There is no danger of ESTRING being pushed too far up in the vagina or getting lost. ESTRING can only be inserted as far as the end of the vagina, where the cervix (the narrow, lower end of the uterus) will block ESTRING from going any further (see diagram of Female Anatomy).

ESTRING USE

Once inserted, ESTRING should remain in place in the vagina for 90 days.

Most women and their partners experience no discomfort with ESTRING in place during intercourse, so it is NOT necessary that the ring be removed. If ESTRING should cause you or your partner any discomfort, you may remove it prior to intercourse (see ESTRING Removal, below). Be sure to reinsert ESTRING as soon as possible afterwards.

ESTRING may slide down into the lower part of the vagina as a result of the abdominal pressure or straining that sometimes accompanies constipation. If this should happen, gently guide ESTRING back into place with your finger.

There have been rare reports of ESTRING falling out in some women following intense straining or coughing. If this should occur, simply wash ESTRING with lukewarm (NOT hot) water and reinsert it.

ESTRING DRUG DELIVERY

Once in the vagina, ESTRING begins to release estradiol immediately. ESTRING will continue to release a low, continuous dose of estradiol for the full 90 days it remains in place.

It will take about 2 to 3 weeks to restore the tissue of the vagina and urinary tract to a healthier condition and to feel the full effect of ESTRING in relieving vaginal and urinary symptoms. If your symptoms persist for more than a few weeks after beginning ESTRING therapy, contact your doctor or healthcare provider.

One of the most frequently reported effects associated with the use of ESTRING is an increase in vaginal secretions. These secretions are like those that occur normally prior to menopause and indicate that ESTRING is working. However, if the secretions are associated with a bad odor or vaginal itching or discomfort, be sure to contact your doctor or healthcare provider.

ESTRING REMOVAL

After 90 days there will no longer be enough estradiol in the ring to maintain its full effect in relieving your vaginal or urinary symptoms. ESTRING should be removed at that time and replaced with a new ESTRING, if your doctor determines that you need to continue your therapy.

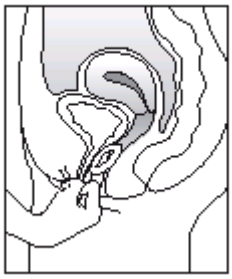
To remove ESTRING:

1. Wash and dry your hands thoroughly.

2. Assume a comfortable position, either standing with one leg up, squatting, or lying down.

3. Loop your finger through the ring and gently pull it out.

4. Discard the used ring in a waste receptacle. (Do not flush ESTRING.)



If you have any additional questions about removing ESTRING, contact your doctor or healthcare provider.

What are the possible side effects of ESTRING?

A few cases of toxic shock syndrome (TSS) have been reported in women using vaginal rings. Toxic shock syndrome is a rare but serious illness caused by a bacterial infection. If you have fever, nausea, vomiting, diarrhea, muscle pain, dizziness, faintness, or a sunburn-like rash on face and body, remove ESTRING and contact your healthcare provider. A few cases of the vaginal ring becoming attached to the vaginal wall, making ring removal difficult, have been reported.

The most frequently reported side effect with ESTRING use is increased vaginal secretions. Many of these vaginal secretions are like those that occur normally prior to menopause and indicate that ESTRING is working. Vaginal secretions that are associated with a bad odor, vaginal itching, or other signs of vaginal infection are NOT normal and may indicate a risk or a cause for concern. Other side effects may include vaginal discomfort, abdominal pain, or genital itching.

What are the possible side effects of estrogens ?

Side effects are grouped by how serious they are and how often they happen when you are treated.

Serious but less common side effects include**:**

- Breast cancer
- Cancer of the uterus
- Stroke
- Heart attack
- Blood clots
- Dementia
- Gallbladder disease
- Ovarian cancer
- High blood pressure
- Liver problems
- High blood sugar
- Enlargement of benign tumors of the uterus ("fibroids")

  Some of the warning signs of these serious side effects include:

  - 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
  - Yellowing of the skin, eyes or nail beds

  Call your healthcare provider right away if you get any of these warning signs, or any other unusual symptom that concerns you.

Less serious but common side effects include:

- Headache
- Breast pain
- Irregular vaginal bleeding or spotting
- Stomach/abdominal cramps, bloating
- Nausea and vomiting
- Hair loss
- Fluid retention
- Vaginal yeast infection

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

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

- Follow carefully the instructions for use.

- Talk with your healthcare provider regularly about whether you should continue using ESTRING.

- See your healthcare provider right away if you get vaginal bleeding while using ESTRING.
- If you have fever, nausea, vomiting, diarrhea, muscle pain, dizziness, faintness, or a sunburn-like rash on face and body, remove ESTRING and contact your healthcare provider.
- Contact your healthcare provider if you have difficulty removing the vaginal ring.
- 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 for 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 ESTRING

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

Keep ESTRING out of the reach of children.

This leaflet provides a summary of the most important information about ESTRING. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about ESTRING that is written for health professionals. You can get more information by calling the toll free number 1-888-691-6813.

What are the ingredients in ESTRING?

ESTRING (estradiol vaginal ring) is a slightly opaque ring with a whitish core containing a drug reservoir of 2 mg estradiol (an estrogen hormone). Estradiol, silicone polymers and barium sulfate are combined to form the ring.

Storage: Store at controlled room temperature 15° to 30° C (59° to 86° F).

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