

Patient Information

Estraderm[®]

(estradiol transdermal system)

Rx only

Read this PATIENT INFORMATION before you start using Estraderm[®] (estradiol transdermal system) and read all the information that you get each time you refill Estraderm. There may be new information. This information does not take the place of talking to your health care provider about your medical condition or your treatment.

What is the most important information I should know about Estraderm (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 health care 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 health care provider should talk regularly about whether you still need treatment with Estraderm.

What is Estraderm[®]?

Estraderm is a patch that contains the estrogen hormone, estradiol. When applied to the skin as directed below, Estraderm releases estrogen through the skin into the bloodstream.

What is Estraderm used for?

Estraderm 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 and 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 health care provider should talk regularly about whether you still need treatment with Estraderm.

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

You and your health care provider should talk regularly about whether you still need treatment with Estraderm to control these problems. If you use Estraderm only to treat your dryness, itching, and burning in or around your vagina, talk with your health care provider about whether a topical vaginal product would be better for you.

- **Treat certain conditions in which a young woman's ovaries do not produce enough estrogens naturally.**

- **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 Estraderm only to prevent osteoporosis from menopause, talk with your health care provider about whether a different treatment or medicine without estrogens might be better for you. You and your health care provider should talk regularly about whether you should continue with Estraderm.

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 health care provider before starting them.

Who should not use Estraderm?

Do not start using Estraderm 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 have had cancer, talk with your health care provider about whether you should take Estraderm.

- **Had a stroke or heart attack in the recent past (for example in the past year).**
- **Currently have or have had blood clots.**
- **Currently have or have had liver problems.**
- **Are allergic to Estraderm or any of its ingredients.**

See the end of this leaflet for a list of ingredients in Estraderm.

- **Think you may be, or know that you are, pregnant.**

Tell your health care provider:

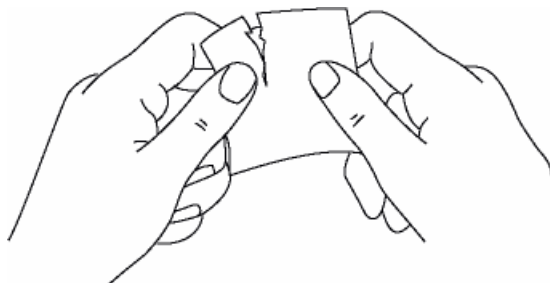
- **If you are breast-feeding.** The hormone in Estraderm can pass into your milk.
- **About all of your medical problems:** Your health care provider may need to check you more carefully if you have certain conditions such as asthma (wheezing), epilepsy (seizures), migraine, endometriosis, lupus, or problems with your heart, liver, thyroid, kidneys, or have high calcium levels in your blood.
- **About all the medicines you take,** including prescription and nonprescription medicines, vitamins, and herbal supplements. Some medicines may affect how Estraderm works. Estraderm may also affect how 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 Estraderm?

1. Start at the lowest dose and talk to your health care 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 Estraderm has not been determined. You and your health care provider should talk regularly (for example, every 3 to 6 months) about the dose you are taking and whether you still need treatment with Estraderm.

How and Where to Apply Estraderm

Each Estraderm system is individually sealed in a protective pouch. Tear open this pouch at the indentation (do not use scissors) and remove the system. Bubbles in the system are normal.



A stiff protective liner covers the adhesive side of the system — the side that will be placed against your skin. This liner must be removed before applying the system. Slide the protective liner sideways between your thumb and index finger. Then hold the system at one edge. Remove the protective liner and discard it. Try to avoid touching the adhesive.



Apply the adhesive side of the system to a clean, dry area of the skin on the trunk of the body (including the buttocks and abdomen).



The site selected should be one that is not exposed to sunlight. Some women may find that it is more comfortable to wear Estraderm on the buttocks. *Do not apply Estraderm to your breasts.* The sites of application must be rotated, with an interval of at least 1 week allowed between applications to a particular site. The area selected should not be oily, damaged, or irritated. Avoid the waistline, since tight clothing may rub the system off. Apply the system immediately after opening the pouch and removing the protective liner. Press the system firmly in place with the palm of your hand for about 10 seconds, making sure there is good contact, especially around the edges.

The Estraderm system should be worn continuously until it is time to replace it with a new system. You may wish to experiment with different locations when applying a new

system, to find ones that are most comfortable for you and where clothing will not rub on the system.

When to Apply Estraderm

The Estraderm system should be replaced twice weekly. Your Estraderm package contains a calendar checklist on the back to help you remember a schedule. Mark the 2-day schedule you plan to follow. Always change the system on the 2 days of the week you have marked.

When changing the system, remove the used Estraderm system and discard it. Any adhesive that might remain on your skin can be easily rubbed off. Then place the new Estraderm system on a different skin site. (The same skin site should not be used again for at least 1 week after removal of the system.)

Please note: Contact with water when you are bathing, swimming, or showering will not affect the system. In the unlikely event that a system should fall off, put this same system back on and continue to follow your original treatment schedule. If necessary, you may apply a new system but continue to follow your original schedule.

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 health care 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

Other side effects of Estraderm may be possible. If you have questions, talk to your health care provider or pharmacist.

What Can I Do To Lower My Chances Of A Serious Side Effect With Estraderm?

- Talk with your health care provider regularly about whether you should continue taking Estraderm.

- If you have a uterus, talk to your health care provider about whether the addition of a progestin is right for you.
- See your health care provider right away if you get vaginal bleeding while taking Estraderm.
- Have a breast exam and mammogram (breast X-ray) every year unless your health care 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 for getting heart disease. Ask your health care provider for ways to lower your chances for getting heart disease.

General Information About Safe And Effective Use Of Estraderm

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

This leaflet provides a summary of the most important information about Estraderm. If you would like more information, talk with your health care provider or pharmacist. You can ask for information about Estraderm that is written for health professionals. You can get more information by calling the toll-free number (888-NOW-NOVA (888-669-6682).

What Are The Ingredients In Estraderm?

The Estraderm system comprises four layers. Proceeding from the visible surface toward the surface attached to the skin, these layers are (1) a transparent polyester/ethylene vinyl acetate copolymer film, (2) a drug reservoir of estradiol USP and alcohol USP gelled with hydroxypropyl cellulose NF, (3) an ethylene-vinyl acetate copolymer membrane, and (4) an adhesive formulation of light mineral oil NF and polyisobutylene. A protective liner (5) of siliconized polyester film is attached to the adhesive surface and must be removed before the system can be used.

The active component of the system is estradiol. The remaining components of the system are pharmacologically inactive. Alcohol is also released from the system during use.

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