



Climara®

(estradiol transdermal system)

Continuous Delivery For Once-Weekly Application

Rx only

PATIENT INFORMATION Updated June 2005

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(estradiol transdermal system)

Read this PATIENT INFORMATION before you start using Climara and read what you get each time you refill Climara. 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 Climara (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 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 attack, strokes, breast cancer, and blood clots. Using estrogens with progestins may increase your risk of dementia. You and your healthcare provider should talk regularly about whether you still need treatment with Climara.

What is Climara?

Climara is a medicine that contains estrogen hormones.

What is Climara used for?

Climara 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 Climara.
- **treat moderate to severe dryness, itching, and burning in or around the vagina.** You and your healthcare provider should talk regularly about whether you still need treatment with Climara to control these problems. If you use Climara 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.
- **treat certain conditions in which a young woman's ovaries do not produce enough estrogen 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 Climara 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 Climara.

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 use Climara?

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

Tell your healthcare provider:

- **if you are breastfeeding.** The hormone in Climara 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 Climara works. Climara 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 Climara?

Climara is a patch that you wear on your skin. The estrogen in the Climara patch passes through your skin. You must change your Climara patch every 7 days (once a week). See the end of this leaflet for complete instructions on how to use Climara.

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. You and your healthcare provider should talk regularly (for example, every 3 to 6 months) about the dose you are taking and whether you still need treatment with Climara.

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 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 Climara. For more information, ask your healthcare provider or pharmacist.

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

Talk with your healthcare provider regularly about whether you should continue using Climara:

- If you have a uterus, talk to your healthcare provider about whether the addition of a progestin is right for you.
- See your healthcare provider right away if you get vaginal bleeding while using Climara.
- 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 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 healthcare provider for ways to lower your chances for getting heart disease.

General information about safe and effective use of Climara.

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

Keep Climara out of the reach of children.

This leaflet provides a summary of the most important information about Climara. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about Climara that is written for health professionals. You can get more information by calling the toll free number (1-888-84BAYER).

What are the ingredients in Climara?

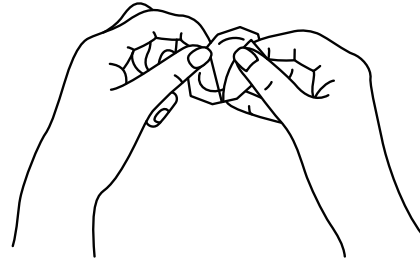
The active ingredient of Climara is estradiol. Climara also contains acrylate copolymer adhesive, fatty acid esters, and polyethylene backing.

Instructions for Use

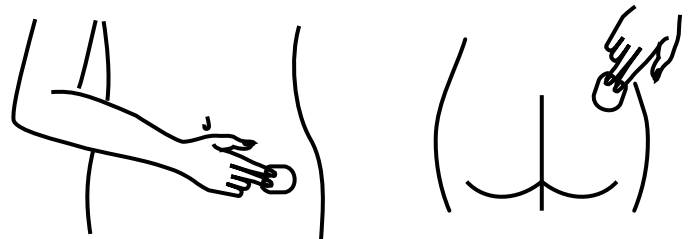
How and Where to Apply the Climara Patch

Each Climara patch is individually sealed in a protective pouch. To open the pouch, hold it vertically with the Climara name facing you. Tear off the top of the pouch using the top tear notch. Tear off the side of the pouch using the side tear notch. Pull the pouch open. The Climara patch is the see-through plastic film attached to the clear thicker plastic backing. There is a silver foil-sticker attached

to the inside of the pouch. **Do not remove it from the pouch.** The sticker contains a moisture protectant (desiccant). **Lift out the Climara patch.** Notice that the patch is attached to a thicker, hard-plastic backing and that the patch itself is oval and see-through.



Apply the sticky side of the Climara patch to a clean, dry area of the lower stomach below your belly button or the top of the buttocks (see diagram below). **Do not apply the Climara patch to your breasts.** The sites of application on the lower stomach and buttocks must be rotated, allowing at least 1 week between applications to the same site. The site selected should not be oily, damaged, or irritated. Avoid the waistline, since tight clothing may rub and remove the patch. Also, do not put the patch on areas where sitting would rub it off or loosen it. Apply the patch right after opening the pouch and removing the protective liner. Press the patch firmly in place with your fingers for about 10 seconds. Make sure that it sticks all over, especially around the edges.



The Climara patch should be worn continuously for one week. You may wish to try different sites when putting on a new patch, to find ones that are most comfortable for you and where clothing will not rub on the patch or loosen it.

When to Apply the Climara System?

The Climara patch should be changed once weekly. Remove the used patch. Carefully fold it in half so that it sticks to itself because used patches still contain active hormones and discard it. Any adhesive that might remain on your skin can be easily rubbed off. Then place the new Climara patch on a different skin site. (The same skin site should not be used again for at least 1 week after removal of the patch.)

Contact with water when you are bathing, swimming, or showering may affect the patch. If the patch falls off, the same patch may be reapplied to another area of the lower abdomen. Make sure that there is good contact, especially around the edges. If the patch will not stick completely to your skin, put a new patch on a different area of the lower abdomen. Do not apply two patches at the same time.

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

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