

(BERLEX 6005100)

Continuous Delivery for  
Once-Weekly ApplicationClimara®  
(estradiol transdermal system)

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Climara®  
(estradiol transdermal system)Continuous Delivery for  
Once-Weekly Application**Rx only****PATIENT INFORMATION**

The Climara® patch that your healthcare provider has prescribed for you releases small amounts of an estrogen hormone through the skin.

This leaflet describes the risks and benefits of treatment with Climara®. Climara® is not for everyone. Talk to your healthcare provider if you have any questions or concerns about this medicine.

**WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT CLIMARA®?****ESTROGENS INCREASE THE RISK OF CANCER OF THE UTERUS**

If you use any drug that contains estrogen, it is important to visit your doctor or healthcare provider regularly and report any unusual vaginal bleeding right away. Vaginal bleeding after menopause may be a warning sign of uterine cancer. Your doctor or healthcare provider should evaluate any unusual vaginal bleeding to find out the cause. Women who do not have a uterus have no risk of endometrial cancer.

**What is Climara®?**

Climara® (pronounced Cly-MARE-a) is a patch that contains an estrogen hormone called 17β-estradiol. When applied to the skin as directed below, the Climara® patch releases estrogen through the skin into the bloodstream.

**CLIMARA® IS APPROVED FOR USE IN THE FOLLOWING WAYS:**

- **To reduce moderate or severe menopausal symptoms.**  
Estrogens are hormones made by a woman's ovaries. 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). If 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 intense episodes of heat and sweating ("hot flashes" or "hot flushes"). In some women the symptoms are mild and in others they can be severe. Using estrogen drugs can help the body adjust to lower estrogen levels and reduce these symptoms. Most women have only mild menopausal symptoms or none at all and do not need to use estrogen drugs for these symptoms. Others may need to take estrogens for a few months while their bodies adjust to lower estrogen levels. The majority of women do not need estrogen replacement for longer than six months for these symptoms.
- **To treat itching, burning and dryness in and around the vagina associated with menopause.**
- **To treat certain conditions in which a young woman's ovaries do not produce enough estrogen naturally.**
- **To help reduce your chances of getting osteoporosis (thin weak bones).**  
Osteoporosis is a thinning of the bones that makes them weaker and allows them to break more easily. Climara® may be used as part of a program of weight-bearing exercise like walking and running and calcium supplements to reduce your chances of getting osteoporosis. Before you change your calcium intake or exercise habits, it is important to discuss these lifestyle changes with your doctor to find out if they are safe for you. Women who are more likely to develop osteoporosis often have one or more of the following characteristics: white or Asian race, slim body frame, 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 USE CLIMARA®**

Climara® should not be used in the following situations:

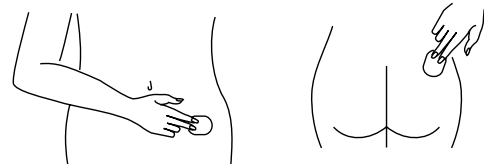
- **During pregnancy.**  
If you think you may be pregnant, do not use Climara®. Using Climara® while you are pregnant may harm your unborn child. Do not use Climara® to prevent miscarriage.
- **If you have unusual vaginal bleeding that has not been checked by your healthcare provider.**  
Unusual vaginal bleeding can be a warning sign of serious conditions including cancer of the uterus, especially if it happens after menopause. Your healthcare provider must find out the cause of the bleeding so that he or she can recommend the proper treatment.
- **If you have had cancer.**  
Estrogens increase the risk of certain types of cancer, including cancer of the breast or uterus. If you have had cancer, talk to your healthcare provider about the use of Climara®.
- **If you have any circulation problems.**  
Talk with your doctor about your condition. Do not take Climara® if you have blood clots or have had them in the past.
- **After childbirth or when breastfeeding a baby.**  
Do not use Climara® to stop the breasts from filling with milk after a baby is born.
- **If you are allergic to Climara® or any of the ingredients in it.**

**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 a week.

When changing the patch, peel off the used Climara® patch and throw it away. Any sticky material that might stay on your skin can be easily rubbed off. Then place a new Climara® patch on a different skin site. (Do not use the same skin site for at least 1 week.)

Tub bathing or swimming could loosen the patch. In the event that a patch should fall off, a new patch should be put on for the rest of the 7-day period.

**WHAT ARE THE POSSIBLE RISKS AND SIDE EFFECTS OF CLIMARA®?**

Common side effects include:

- Nausea and vomiting.
- Breast tenderness or enlargement.
- Enlargement of benign tumors ("fibroids") of the uterus.
- Retention of excess fluid. This may make some conditions worsen, such as asthma, epilepsy, migraine, heart disease, or kidney disease.
- A spotty darkening of the skin, particularly on the face.

Less common but serious effects include:

- Cancer of the uterus.
- Cancer of the breast.
- Gallbladder disease.
- Abnormal blood clotting.

If any of the following warning signals (or any other unusual symptoms) happen while you are using Climara®, call your healthcare provider right away:

- Abnormal bleeding from the vagina (possible uterine cancer).
- Pains in the calves or chest, sudden shortness of breath, or coughing blood (possible clot in the legs, heart, or lungs).
- Severe headache or vomiting, dizziness, faintness, changes in vision or speech, weakness or numbness of an arm or leg (possible clot in the brain or eye).
- Breast lumps (possible breast cancer). Check your breasts every month. Ask your doctor or health professional to show you how to examine your breasts.
- Yellowing of the skin or whites of the eyes (possible liver problem).
- Pain, swelling, or tenderness in the abdomen (stomach area; possible gallbladder problem).

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

If you use Climara®, you can reduce your risks by doing these things:

- **See your healthcare provider regularly.**  
While you are using Climara®, it is important to visit your healthcare provider at least once a year for a check-up. If you develop vaginal bleeding while taking Climara®, you may 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 to have more frequent breast examinations.

Do not store above 86°F (30°C). Do not store unopened. Apply immediately upon removal from the protective pouch.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Climara® for a condition 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.

This leaflet summarizes the most important information about Climara®. If you would like more information, talk with your healthcare provider. You can ask for information about Climara® that is written for health professionals.

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(3M #673300)

May 2003