

Patient Information

Climara (Klī-mâr-uh)

(estradiol transdermal system)

Read this Patient Information before you start using Climara and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your menopausal symptoms or your treatment.

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

- Using estrogen-alone may increase your chance of getting cancer of the uterus (womb).
- Report any unusual vaginal bleeding right away while you are using Climara. 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 estrogen-alone to prevent heart disease, heart attacks, strokes, or dementia (decline in brain function).
- Using estrogen-alone may increase your chances of getting strokes or blood clots.
- Using estrogen-alone may increase your chance of getting dementia, based on a study of women age 65 years of age and older.
- Do not use estrogens with progestogens to prevent heart disease, heart attacks, strokes or dementia.
- Using estrogens with progestogens may increase your chances of getting heart attacks, strokes, breast cancer, or blood clots.
- Using estrogens with progestogens may increase your chance of getting dementia, based on a study of women age 65 years of age and older.
- Only one estrogen-alone product and dose have been shown to increase your chances of getting strokes, blood clots, and dementia. Only one estrogen with progestogen product and dose have been shown to increase your chances of getting heart attacks, strokes, breast cancer, blood clots, and dementia.

Because other products and doses have not been studied in the same way, it is not known how the use of Climara will affect your chances of these conditions. You and your healthcare provider should talk regularly about whether you still need treatment with Climara.

What is Climara?

Climara is a prescription medicine patch (transdermal system) that contains estradiol (an estrogen hormone).

What is Climara used for?

The 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 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 estrogen levels begin dropping, some women develop very uncomfortable symptoms, such as feelings of warmth in the face, neck, and chest, or sudden intense feelings of heat and sweating ("hot flashes" or "hot flushes"). In some women, the symptoms are mild, and they will not need to use estrogens. In other women, symptoms can be more severe.

- **Treat moderate to severe menopausal changes in and 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 menopausal changes 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 women before menopause if their 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 Climara only to prevent osteoporosis due to 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 still need treatment with Climara.

Who should not use Climara?

Do not start using Climara if you:

- **have unusual vaginal bleeding**

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.

- **have been diagnosed with a bleeding disorder**

- **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 (womb). If you have or have had cancer, talk with your healthcare provider about whether you should use Climara.

- **had a stroke or heart attack**

- **currently have or have had blood clots**

- **currently have or have had liver problems**

- **are allergic to Climara or any of the ingredients in it.** See the list of ingredients in Climara at the end of this leaflet.

Before you use Climara, tell your healthcare provider about all of your medical conditions, including if you:

- **have any unusual vaginal bleeding**

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.

- **have any other medical conditions that may become worse while you are using Climara**

Your healthcare provider may need to check you more carefully if you have certain conditions, such as asthma (wheezing), epilepsy (seizures), diabetes, migraine, endometriosis, lupus, angioedema (swelling of face and tongue), or problems with your heart, liver, thyroid, kidneys, or have high calcium levels in your blood.

- **are going to have surgery or will be on bed rest.**

Your healthcare provider will let you know if you need to stop using Climara.

- **are pregnant or think you may be pregnant.**

Climara is not for pregnant women.

- **are breastfeeding**

The hormone in Climara can pass into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may affect how Climara works. Climara may also affect how your other medicines work. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get new medicine.

How should I use Climara?

For detailed instructions, see the step-by-step instructions for using Climara at the end of this Patient Information.

- Use Climara exactly as your healthcare provider tells you to use it.
- Climara is for skin use only.
- Change your Climara patch 1 time each week or every 7 days.
- Apply your Climara patch to a clean, dry area on your lower abdomen or buttocks. This area must be clean, dry, and free of powder, oil or lotion for your patch to stick to your skin.
- Apply your Climara patch to a different area of your abdomen or your buttocks each time. Do not use the same application site 2 times in the same week.
- Do not apply Climara to your breasts.
- If you forget to apply a new Climara patch, apply a new patch as soon as possible.
- You and your healthcare provider should talk regularly (every 3 to 6 months) about the dose you are using and whether you still need treatment with Climara.

How to Change Climara

- When changing Climara, peel off the used patch slowly from the skin.
- After removal of Climara if any adhesive residue remains on your skin, allow the area to dry for 15 minutes. Then, gently rub the area with an oil-based cream or lotion to remove the adhesive from your skin.
- Apply the new patch to a different area of your abdomen or buttocks. This area must be clean, dry, and free of powder, oil or lotion. Do not use the same site again for at least 1 week after removal of an old patch.

What are the possible side effects of Climara?

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:

- heart attack
- stroke
- blood clots
- breast cancer
- cancer of the lining of the uterus (womb)
- cancer of the ovary
- dementia
- high or low blood calcium
- gallbladder disease
- visual abnormalities
- high blood pressure
- high levels of fat (triglyceride) in your blood
- liver problems
- changes in your thyroid hormone levels
- fluid retention
- cancer changes of endometriosis
- enlargement of benign tumors of the uterus ("fibroids")
- worsening of swelling of face and tongue (angioedema) in women with a history of angioedema

Call your healthcare provider right away if you get any of the following warning signs or any other unusual symptoms that concern you:

- new breast lumps
- unusual vaginal bleeding
- changes in vision or speech
- sudden new severe headaches
- severe pains in your chest or legs with or without shortness of breath, weakness and fatigue

Common side effects of Climara include:

- headache
- breast tenderness or pain
- irregular vaginal bleeding or spotting
- stomach or abdominal cramps, bloating
- nausea and vomiting
- hair loss
- fluid retention
- vaginal yeast infection
- redness and/or irritation at the patch placement site

These are not all the possible side effects of Climara. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effects that bother you or do not go away.

You may report side effects to FDA at 1-800-FDA-1088. You may report side effects to Bayer Healthcare Pharmaceuticals at 1-888-842-2937.

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 with your healthcare provider about whether the addition of a progestogen is right for you. In general, the addition of a progestogen is generally recommended for a woman with a uterus to reduce the chance of getting cancer of the uterus (womb).

- See your healthcare provider right away if you get vaginal bleeding while using Climara.
- Have a pelvic exam, 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 of getting heart disease.

How should I store and throw away used Climara?

- Store Climara at room temperature 68°F to 77°F (20°C to 25°C).
- Do not store Climara patches outside of their pouches. Apply immediately upon removal from the protective pouch.
- Used patches still contain estrogen. To throw away the patch, fold the sticky side of the patch together, place it in a sturdy child-proof container, and place this container in the trash. Used patches should not be flushed in the toilet.

Keep Climara and all medicines out of the reach of children.

General information about the safe and effective use of Climara.

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use 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.

You can ask your healthcare provider or pharmacist for information about Climara that is written for health professionals. For more information, go to www.climara.com or call Bayer HealthCare Pharmaceuticals Inc at 1-888-842-2937.

What are the ingredients in Climara?

Active ingredient: estradiol

Inactive ingredient: acrylate copolymer adhesive, fatty acid esters, and polyethylene backing.

INSTRUCTIONS FOR USE

Climara (Klī-mâr-uh)

(estradiol transdermal system)

Read this Patient Information before you start using Climara and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your menopausal symptoms or your treatment.

You will need the following supplies: See Figure A

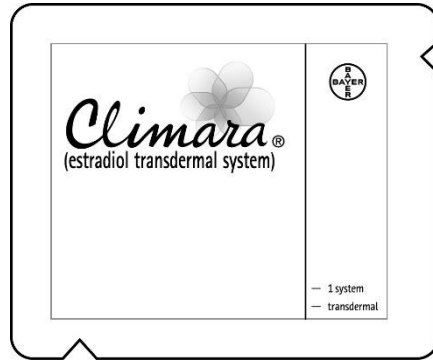


Figure A

Step 1: Pick the days you will change your Climara.

You will need to change your patch 1 time each week or every 7 days.

Step 2. Remove the Climara patch from the pouch.

- Remove patch from its protective pouch by tearing at the notch (do not use scissors). **See Figure B**
- Do not remove your patch from the protective pouch until you are ready to apply it.

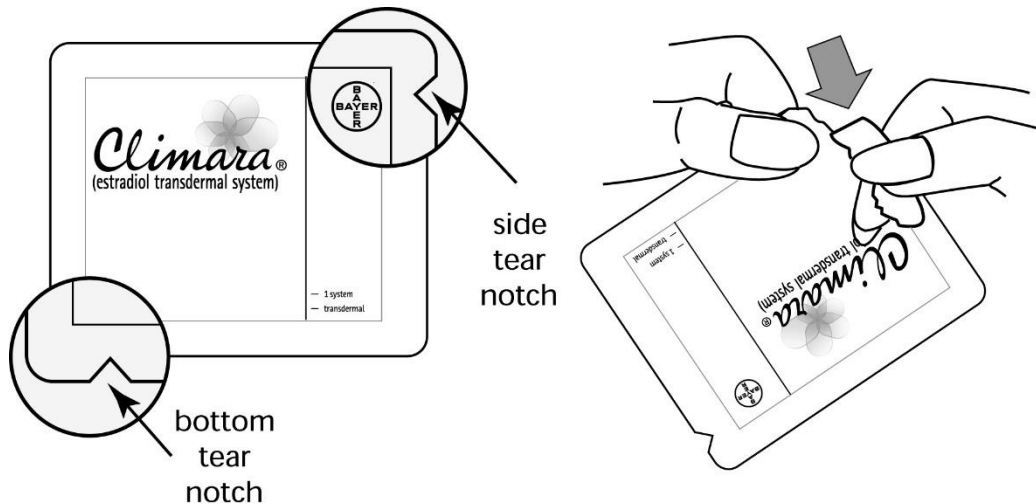


Figure B

Step 3. Remove the adhesive liner. See Figure C

- You will see that Climara is an oval shaped clear patch that is attached to a thick, hard-plastic adhesive liner and covered by a clear, plastic film. **See Figure C**
- To apply your patch you must first remove the protective, clear plastic film that is attached to the clear thicker plastic backing. **See Figure D**

- There is a silver foil-sticker attached to the inside of the pouch. Do not remove the silver foil sticker from the pouch. See Figure E

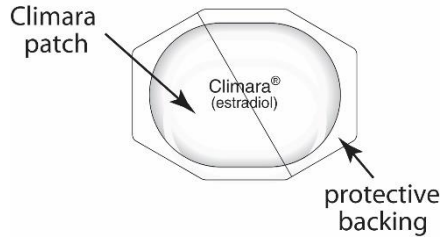


Figure C

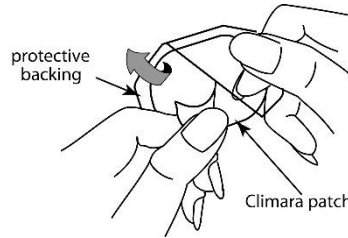


Figure D

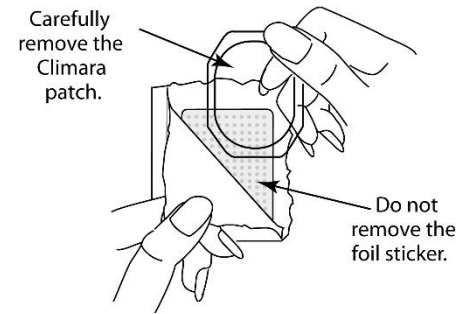


Figure E

Step 4. Placing the patch on your skin.

- Apply the sticky side of the patch to 1 of the areas of skin shown below. See **Figure F** and **Figure G**
- **Do not** touch the sticky side of the patch with your fingers.

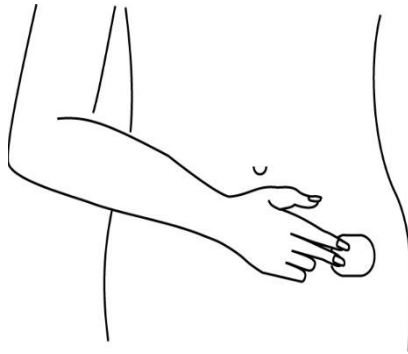


Figure F

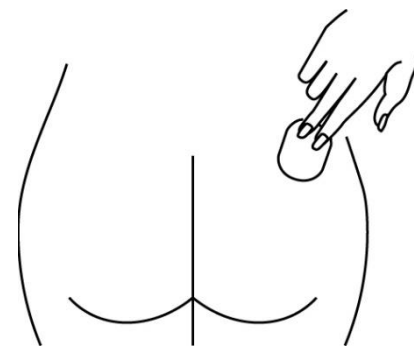


Figure G

Note:

- Avoid the waistline, since clothing and belts may cause the patch to be rubbed off.
- Do not apply Climara to your breasts.
- Only apply Climara to skin that is clean, dry, and free of any powder, oil, or lotion.
- Do not apply the patch to injured, burned, or irritated skin, or areas with skin conditions (such as birth marks, tattoos, or that is very hairy).

Step 5. Press the patch firmly onto your skin.

- Press the patch firmly in place with your fingers for at least 10 seconds
- Rub the edges of the patch to make sure that it will stick to your skin. (**See Figure H**)



Figure H

Note:

- Contact with water while you are swimming, using a sauna, bathing, or showering may cause the patch to fall off.
- If your patch falls off reapply it. If you cannot reapply the patch, apply a new patch to another area (See Figures F and G), and continue to follow your original application schedule.
- If you stop using your Climara patch or forget to apply a new patch as scheduled, you may have spotting, or bleeding, and your symptoms may come back.

Step 6: Throwing away your used patch.

- When it is time to change your patch, remove the old patch before you apply a new patch.
- To throw away the patch, fold the sticky side of the patch together, place it in a sturdy child-proof container, and place this container in the trash. Do not flush used patches in the toilet.

This Patient Information and Instructions for Use have been approved by the U.S Food and Drug Administration.

Revised: 9/2021

© 2013, Bayer HealthCare Pharmaceuticals Inc. All rights reserved.

Manufactured for:

Bayer HealthCare Pharmaceuticals Inc.
Whippany, NJ 07981

Manufactured by

Kindeva Drug Delivery L.P
Northridge, CA 91324