

Patient Information

EstroGel® 0.06% (ěs' trə jěł)

(estradiol gel)

Read this Patient Information before you start using EstroGel 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 EstroGel (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 EstroGel. 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 and blood clots.
- Using estrogen-alone may increase your chance of getting dementia, based on a study of women 65 years of age and older.
- Do not use estrogens with progestogens to prevent heart disease, heart attack, 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 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 EstroGel will affect your chances of these conditions. You and your healthcare provider should talk regularly about whether you still need treatment with EstroGel.

What is EstroGel?

EstroGel is a prescription medicine gel that contains estradiol (an estrogen hormone).

What is EstroGel used for?

EstroGel 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 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. You and your healthcare provider should talk regularly about whether you still need treatment with EstroGel.

- **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 EstroGel to control these problems. If you use EstroGel 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.

Who should not use EstroGel?

Do not start using EstroGel 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 cancer, including cancer of the breast or uterus. If you have or have had cancer, talk with your healthcare provider about whether you should use EstroGel.

- **had a stroke or heart attack**

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

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

- **are allergic to EstroGel or any of its ingredients**

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

Before you use EstroGel, 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 EstroGel**

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), problems with your heart, liver, thyroid, kidneys, or 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 EstroGel.

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

EstroGel is not for pregnant women.

- **are breastfeeding**

The hormone in EstroGel 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 EstroGel works. EstroGel 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 a new medicine.

How should I use EstroGel?

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

- Use EstroGel exactly as your healthcare provider tells you to use it.
- EstroGel is for skin use only.
- EstroGel contains alcohol, which is flammable. Avoid fire, flame or smoking until EstroGel has dried.
- 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 EstroGel.

What are the possible side effects of EstroGel?

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 (triglycerides) 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 EstroGel include:

- headache
- breast tenderness or pain
- stomach or abdominal cramps, bloating
- nausea and vomiting
- hair loss
- fluid retention
- vaginal yeast infection

These are not all of the possible side effects of EstroGel. 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 ASCEND Therapeutics® US, LLC at 1-877-204-1013 or to FDA at 1-800-FDA-1088.

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

- Talk with your healthcare provider regularly about whether you should continue using EstroGel.
- 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 recommended for women 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 EstroGel.
- 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 (breast x-ray), 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 of getting heart disease.

Ask your healthcare provider for ways to lower your chances of getting heart disease.

How should I store EstroGel?

- Store EstroGel at room temperature between 68°F to 77°F (20°C to 25°C).

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

General information about the safe and effective use of EstroGel

Medicines are sometimes prescribed for conditions that are not mentioned in Patient Information leaflets. Do not use EstroGel for conditions for which it was not prescribed. Do not give EstroGel 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 EstroGel that is written for health professionals.

For more information, go to www.estrogel.com, or call ASCEND Therapeutics® US, LLC at 1-877-204-1013.

What are the ingredients in EstroGel?

Active ingredient: estradiol

Inactive ingredients: purified water, alcohol, triethanolamine, and carbomer 934P.

Instructions for Use
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(estradiol gel)

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You will need the following supplies to use EstroGel: See Figure A.



Figure A

EstroGel is supplied in a metered-dose pump that delivers a measured amount of estradiol to your skin each time you press the pump.

EstroGel is available in a 50-gram canister

Step 1. Priming the EstroGel pump

- **Before using the EstroGel pump for the first time, the pump must be primed.** The EstroGel canister contains enough medicine to allow you to prime the pump before you use it for the first time.
- Remove the large cap from the canister. **See Figure B.**



Figure B

- Slowly push the pump all the way down 5 times. **Do not** use any EstroGel that came out while priming. Wash it down the sink to avoid accidental exposure to others.
- After priming, the EstroGel pump is ready to use. One complete press of the pump will give the same amount of EstroGel each time.

Step 2. Applying EstroGel to your skin

- **Do not allow other people to apply EstroGel to your skin for you.**
- **Apply EstroGel to clean, dry, unbroken skin.**
- Apply EstroGel after your bath or shower. If you go swimming, try to leave as much time as possible between using your EstroGel and going swimming.

- Remove the small cover on the tip of the pump if you have not done so already. **See Figure C.**



Figure C

- To use EstroGel, press the EstroGel pump firmly and fully 1 time into the palm of your hand. **See Figure D.**



Figure D

- Using your hand, apply EstroGel to the skin of your other arm. **See Figure E.** Spread the gel as thinly as possible over the entire area on the inside and outside of your arm from your wrist to your shoulder. **See Figure F.**



Figure E



Figure F

- **Do not** apply EstroGel directly to your breasts or in and around your vagina.
- **Do not** massage or rub in EstroGel. Allow the gel to dry for 5 minutes before you get dressed.

Step 3. After you use EstroGel

- Place the small cap back on the tip of the pump. Place the large cap over the top of the canister.
- **Wash your hands right away with soap and water after applying EstroGel.** This will lower the chance that the medicine will spread from your hands to other people.
- Do not allow others to make contact with the area of skin where you applied the gel for at least 1 hour after application.
- EstroGel is flammable until dry. Let EstroGel dry before smoking or going near an open flame.

Step 4. Throwing away used EstroGel canisters

- **The EstroGel 50-gram canister** contains enough medicine to allow for priming your canister with up to 5 full pump depressions and delivery of 30 daily doses. After you have first primed your canister and used 30 doses, you will need to throw away the canister. Do not use the canister for more than 30 doses even though the canister may not be completely empty. You may not get the correct dose.

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

Manufactured for:

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Utilizes EHG® Technology

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