

PATIENT INFORMATION

(Updated January 2007)

EstroGel[®]
(estradiol gel)

R_x only

Read this PATIENT INFORMATION before you start using EstroGel, and read the patient information each time you refill your EstroGel prescription. 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 EstroGel (AN ESTROGEN HORMONE)?

- Estrogens increase the chances of getting cancer of the uterus.

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 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.

- Do not use estrogens with or without progestins to prevent dementia.

Using estrogens with or without progestins may increase your risk of dementia.

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

What is EstroGel?

EstroGel is a clear, colorless gel medicine that contains an estrogen hormone (estradiol) which is absorbed through the skin into the bloodstream. The estrogen hormone in EstroGel is a synthetic estrogen made from a plant source.

How is EstroGel used?

EstroGel is used after menopause for the following:

- **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 have 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 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 EstroGel.

- **To treat moderate to severe dryness, itching, and burning in and around your 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 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.

Who should not use EstroGel?

Do not start using EstroGel if you have any of the following:

- **Have unusual vaginal bleeding**
- **Currently have or have had certain cancers**
Estrogens may increase the chances 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 in the past year**
- **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 end of this leaflet for a list of ingredients in EstroGel.
- **Think you may be pregnant**

Talk to your healthcare provider about the following:

- **If you are breastfeeding**
The hormone in EstroGel can pass into your breast 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, or problems with your heart, liver, thyroid, kidneys, or 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 EstroGel works. EstroGel may also affect how your other medicines work.

- **If you are going to have surgery or will be on bedrest**
You may need to stop taking estrogens.

How is EstroGel supplied?

EstroGel is available in a metered-dose pump that delivers 1.25 grams (g) of a gel containing 0.75 milligrams (mg) of estradiol each time the pump is depressed.

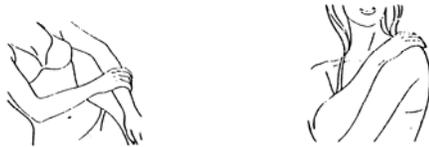
How should I use the EstroGel pump?

It is important that you read and follow these directions on how to use the EstroGel pump properly.

1. **Before using the pump for the first time, it must be primed.** Remove the large pump cover, and fully depress the pump twice. Discard the unused gel by thoroughly rinsing down the sink or placing it in the household trash in a manner that avoids accidental exposure or ingestion by household members or pets. **After priming, the pump is ready to use,** and 1 complete pump depression will dispense the same amount of EstroGel each time.
2. **Apply EstroGel at the same time each day.** You should apply your daily dose of gel to clean, dry, unbroken skin. If you take a bath or shower or use a sauna, apply your EstroGel dose after your bath, shower, or sauna. If you go swimming, try to leave as much time as possible between applying your EstroGel dose and going swimming.
3. **Be sure your skin is completely dry before applying EstroGel.**
4. To apply the dose, collect the gel into the palm of your hand by pressing the pump firmly and fully with 1 fluid motion without hesitation, as illustrated.



5. Apply the gel to 1 arm using your hand. Spread the gel as thinly as possible over the entire area on the inside and outside of your arm from wrist to shoulder, as illustrated.



6. Always place the small protective cap back on the tip of the pump and the large pump cover over the top of the pump after each use.
7. **Wash your hands with soap and water after applying the gel to reduce the chance that the medicine will spread from your hands to other people.**
8. It is not necessary to massage or rub in EstroGel. Simply allow the gel to dry for up to 5 minutes before dressing.
9. **Alcohol-based gels are flammable. Avoid fire, flame or smoking until the gel has dried.**
10. Once dry, EstroGel is odorless.
11. **Never apply EstroGel directly to the breast.** Do not allow others to apply the gel for you.
12. The EstroGel 93-gram pump contains enough product to allow for initial priming of the pump twice and delivery of 64 daily doses. After you have initially primed the pump twice and dispensed 64 doses, you will need to discard the pump.

What should I do if someone else is exposed to EstroGel?

If someone else is exposed to EstroGel by direct contact with the gel, that person should wash the area of contact with soap and water as soon as possible. The longer the gel is in contact with the skin before

washing, the greater the chance that the other person will absorb some of the estrogen hormone. This is especially important for men and children.

What should I do if I get EstroGel in my eyes?

If you get EstroGel in your eyes, rinse your eyes right away with warm, clean water to flush out any gel. Seek medical attention if needed.

What should I do if I miss a dose?

If you miss a dose, do not double the dose on the next day to catch up. If your next dose is less than 12 hours away, it is best just to wait and apply your normal dose the next day. If it is more than 12 hours until the next dose, apply the dose you missed, and resume your normal dosing the next day.

What should I avoid while using EstroGel?

It is important that you do not spread the medicine to others, especially men and children. Be sure to wash your hands after applying EstroGel. Do not allow others to make contact with the area of skin where you applied the gel for at least 1 hour after application. **Alcohol-based gels are flammable. Avoid fire, flame or smoking until the gel has dried.**

What are the possible adverse events of estrogens?

Less common but serious adverse events include

- Breast cancer
- Uterine cancer
- Stroke
- Heart attack
- Blood clots
- **Dementia**
- Gallbladder disease
- Ovarian cancer

These are some of the warning signs of serious adverse events:

- Breast lumps
- Unusual vaginal bleeding
- Dizziness and faintness
- Changes in speech
- Severe headaches
- Chest pain
- Shortness of breath
- Leg pain
- Changes in vision
- Vomiting

Call your healthcare provider right away if you have any of these warning signs or any other unusual symptoms that concern you.

Common adverse events include

- Headache
- Breast pain
- Irregular vaginal bleeding or spotting
- Stomach/abdominal cramps, bloating
- Nausea and vomiting
- Hair loss

Other adverse events 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 of the possible adverse events of EstroGel. For more information, ask your healthcare provider or pharmacist.

What can I do to lower my chances of having an adverse event 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 progestin is right for you. See your healthcare provider right away if you have **unusual** vaginal bleeding while using EstroGel. Have a breast exam and mammogram (breast x-ray) every year unless your healthcare provider tells you otherwise. 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 of getting heart disease. Ask your healthcare provider for ways to lower your chances of getting heart disease.

Have an annual gynecologic exam.

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. **Keep EstroGel out of the reach of children.**

This leaflet provides a summary of the most important information about EstroGel. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about EstroGel that is written for health professionals. You can get more information by calling the toll-free number, **1-877-204-1013**.

What are the ingredients in EstroGel?

EstroGel contains estradiol, purified water, alcohol, triethanolamine, and carbomer 934P.

EstroGel should be stored with the cap on securely. Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Do not freeze. The gel should not be used after the date printed on the end of the metered-dose pump after the term “Exp.” (expiration date).

Manufactured for:

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