

PATIENT INFORMATION

Elestrin[®] **(estradiol gel)**

By prescription only

Read this Patient Information leaflet before you start using Elestrin[®] and read what you get each time you refill your Elestrin[®] prescription. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition and your treatment.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT Elestrin[®] (AN ESTROGEN HORMONE)?

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

Report any unusual vaginal bleeding right away while you are using Elestrin[®]. 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, 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, based on a study of women age 65 years or older.

You and your healthcare provider should talk regularly about whether you still need treatment with Elestrin[®].

What is Elestrin[®]?

Elestrin[®] is a medicine in a colorless gel that contains an estrogen hormone (estradiol) which is absorbed through the skin into the bloodstream.

What is Elestrin[®] used for?

Elestrin[®] 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 Elestrin[®].

Who should not use Elestrin[®]?

Do not start using Elestrin[®] 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 use Elestrin[®].
- **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 Elestrin[®] or any of its ingredients**
See below for a list of ingredients in Elestrin[®].
- **Think you may be pregnant**

Tell your healthcare provider:

- **If you are breastfeeding**
The hormone in Elestrin[®] 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, or 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 Elestrin[®] works. Elestrin[®] 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 using Elestrin[®].

What are the ingredients in Elestrin[®]?

Active ingredient: estradiol.

Inactive ingredients: purified water, ethanol, propylene glycol, diethylene glycol monoethyl ether, carbomer 940, triethanolamine, and edetate disodium.

How should I use Elestrin[®]?

1. Start at the lowest dose and talk to your healthcare provider about how well that dose is working for you.
2. Elestrin[®] should be used at the lowest dose possible for your treatment and 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 Elestrin[®].

Elestrin[®] comes in a metered-dose pump container. One actuation of Elestrin[®] is released each time the pump is depressed (pressed down).

Use Elestrin[®] exactly how your healthcare provider tells you.

The Elestrin[®] pump container holds enough of the medicine to let you prime the pump before you use it the first time. To prime, actuate the pump until gel is dispensed. Discard the first actuation that produces gel as this will not contain a full actuation. The pump is now primed and ready to use. Use the pump a total of 30 times (30 actuations) as prescribed by your healthcare provider. After you have initially primed the pump and have used a total of 30 actuations of Elestrin[®], you will need to throw the pump container away and use a new one. The correct amount of medicine in each actuation cannot be assured after 30 actuations have been used, even though the pump container is not completely empty.

Important things to remember when using Elestrin[®]

Wash your hands with soap and water after applying the gel to reduce the chance that the medicine will be spread from your hands to other people.

Allow the gel to dry for five minutes or more before dressing. Try to keep the area dry for as long as possible.

Do not allow others to come in contact with the area of skin where you applied the gel for at least two hours after you apply Elestrin[®].

Always place the cap over the top of the pump after each use.

Never apply Elestrin[®] to the breast. Never apply Elestrin[®] in or around the vagina.

Do not allow others to apply the gel for you.

Do not apply sunscreen to the area where the gel was applied for at least 25 minutes.

Do not apply sunscreen to the area where the gel was applied for 7 or more consecutive days.

Avoid fire, flame or smoking until the gel has dried. Elestrin[®] contains alcohol. Alcohol based gels are flammable.

It is important that you read and follow the detailed "Patient Instructions for Use" at the end of this leaflet on how to use the Elestrin[®] pump and apply the dose.

What should I do if someone else is exposed to Elestrin[®]?

If someone else is exposed to Elestrin[®] 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 is 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 Elestrin[®] in my eyes?

If you get Elestrin[®] in your eyes, rinse your eyes right away with warm clean water to flush out any Elestrin[®]. 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 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 Elestrin[®]. For more information, ask your healthcare provider or pharmacist.

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

Talk with your healthcare provider regularly about whether you should continue using Elestrin®. If you have a uterus, talk to your healthcare provider about whether the addition of a progestin is right for you. In general, the addition of a progestin is recommended for women with a uterus to reduce the chance of getting cancer of the uterus. See your healthcare provider right away if you get vaginal bleeding while using Elestrin®. 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 a higher chance for 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 safe and effective use of Elestrin®

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

KEEP OUT OF REACH OF CHILDREN; THE PUMP CONTAINER IS NOT CHILD-RESISTANT.

This leaflet provides a summary of the most important information about Elestrin®. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about Elestrin® that is written for health professionals. You can get more information by calling **1-800-890-3098** (toll free).

Patient Instructions for Use.

1. Remove the cap.

2. Prime the pump before using the pump for the first time.

- To prime, actuate the pump until gel is dispensed. Discard the first actuation that produces gel as this will not contain a full actuation. The pump is now primed and ready to use.
- Throw away the unused gel by placing it in the trash to avoid another person or pet from accidental contact with the gel, or eating or drinking it.
- **After priming, the pump is ready to use.**
One complete actuation will dispense the same amount of Elestrin® each time.
After each daily dose, **replace the cap** before you put it away.

3. Apply Elestrin®.

- **Dry skin completely before applying Elestrin®.**
You should apply your daily actuation(s) of gel to clean, dry, unbroken skin. If you take a bath or shower or use a sauna, apply Elestrin® after your bath, shower, or sauna. If you go swimming, try to leave as much time as possible, at least 2 hours, between applying your Elestrin® actuation(s) and going into the water.
- **Apply Elestrin® at the same time and the same locations each day.**

Figure 1

To apply the dose, hold the pump with the tip facing the application area of the arm. For each actuation needed, press the pump firmly and fully with a continuous motion without hesitation.



Figure 2

Gently spread the gel using only 2 fingers. Spread and gently rub in the gel over the entire area of your upper arm and shoulder area, as illustrated.



4. Wash your hands with soap and water.

Elestrin[®] should not be used after the date printed on the container (expiration date).

Elestrin[®] is a trademark of Azur Pharma International II Limited

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