

ESTROGel® 0.06% (estradiol gel)

Talking With Your Doctor About Treatment

Once your symptoms have been assessed, you should discuss your treatment options with your healthcare provider. Together, you can create a treatment plan specifically for you. As a starting point, you can use this printable list of questions. Space is provided for you to add your own questions or notes.

- What do you recommend to treat my symptoms of menopause?

- What are the goals of this treatment?

- What type of side effects could occur with this treatment?

- Could it affect any of my other medical conditions? How?

- Could this treatment interact with any of the other medicines or over-the-counter products that I use?

Important Risk Information

EstroGel® 0.06% (estradiol gel) is approved by the FDA for use after menopause to reduce moderate to severe hot flashes and to treat moderate to severe menopausal changes in and around the vagina. 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.

WHAT IS THE MOST IMPORTANT RISK 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.

Do not start using EstroGel if you have unusual vaginal bleeding, have been diagnosed with a bleeding disorder, currently have or have had certain cancers, had a stroke or heart attack, currently have or have had blood clots, currently have or have had liver problems, or are allergic to EstroGel or any of its ingredients.

Before using EstroGel, tell your healthcare provider about all of your medical conditions, including if you have any unusual vaginal bleeding, have any other medical conditions that may become worse while you are using EstroGel, are going to have surgery or will be on bed rest, are pregnant or think you may be pregnant, are breastfeeding, and about all the medicines you take.

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.

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, and changes in laboratory test results such as bleeding time and high blood sugar.

Call your healthcare provider right away if you get any of the following symptoms: 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; swelling of face, lips, and tongue with or without red itchy bumps.

Common side effects of EstroGel include headache, breast tenderness or pain, stomach or abdominal cramps, bloating, nausea and vomiting, hair loss, fluid retention, and vaginal yeast infection.

If you would like more information, talk with your healthcare provider. You may report side effects to ASCEND Therapeutics® US, LLC at 1-877-204-1013.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.