

PATIENT INFORMATION

ESTRADIOL TABLETS, USP

INTRODUCTION: Read this PATIENT INFORMATION before you start taking estradiol tablets and read what you get each time you refill estradiol tablets. 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 ESTRADIOL TABLETS (AN ESTROGEN HORMONE)?

- Estrogens increase the chances of getting cancer of the uterus.
Report any unusual vaginal bleeding right away while you are taking estrogens. 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. Using estrogens with progestins may increase your risk of dementia. You and your healthcare provider should talk regularly about whether you still need treatment with estradiol tablets.

WHAT IS ESTRADIOL?

Estradiol tablets are a medicine that contains estrogen hormones.

WHAT IS ESTRADIOL USED FOR?

Estradiol is used to:

- **reduce moderate to severe hot flashes**

Estrogens are hormones made by a woman's ovaries. Between ages 45 and 55, the ovaries normally stop making estrogens. This leads to a drop in body estrogen levels which 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 estradiol.

Weight-bearing exercise, like walking or running, and taking calcium with vitamin D supplements may also lower your chances for getting postmenopausal osteoporosis. It is important to talk about exercise and supplements with your healthcare provider before starting them.

- **treat dryness, itching, and burning in or around the vagina, difficulty or burning on urination associated with menopause**

You and your healthcare provider should talk regularly about whether you still need treatment with estradiol to control these problems. If you use estradiol 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.

- **treat certain conditions in which a young woman's ovaries do not produce enough estrogen naturally**
- **treat certain types of abnormal vaginal bleeding due to hormonal imbalance when your doctor has found no serious cause of the bleeding**
- **treat certain cancers in special situations, in men and women**
- **prevent thinning of bones**

Osteoporosis from menopause is a thinning of the bones that makes them weaker and easier to break. If you use estradiol only to prevent osteoporosis from 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 should continue with estradiol.

WHO SHOULD NOT USE ESTRADIOL?

Do not start taking estradiol if you:

- **have unusual vaginal bleeding which has not been evaluated by your doctor (see BOXED WARNINGS)**

Unusual vaginal bleeding can be a warning sign of cancer of the uterus, especially if it happens after menopause. Your doctor must find out the cause of the bleeding so that he or she can recommend the proper treatment. Taking estrogens without visiting your doctor can cause you serious harm if your vaginal bleeding is caused by cancer of the uterus.

- **currently have or have had certain cancers**

Estrogens may increase the risk of certain types of cancer, including cancer of the breast or uterus. If you have or had cancer, talk with your healthcare provider about whether you should take estradiol.

(For certain patients with breast or prostate cancer, estrogens may help.)

- **had a stroke or heart attack in the past year**

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

- **have or have had liver problems**

- **are allergic to estradiol tablets or any of its ingredients**

See the end of this leaflet for a list of ingredients in estradiol tablets.

- **think you may be pregnant**

Tell your healthcare provider:

- **if you are breast-feeding**

The hormone in estradiol tablets 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, 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 estradiol works. Estradiol 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 taking estrogens.

HOW SHOULD I TAKE ESTRADIOL TABLETS?

1. Start at the lowest dose and talk to your healthcare provider about how well that dose is working for you.

2. Estrogens should be used at the lowest dose possible for your treatment 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 estradiol.

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 the 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 (“fibroids”) of the uterus
- A spotty darkening of the skin, particularly on the face
- Vaginal yeast infection

These are not all the possible side effects of estradiol tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

WHAT CAN I DO TO LOWER MY CHANCES OF A SERIOUS SIDE EFFECT WITH ESTRADIOL?

If you use estrogens, you can reduce your risks by doing these things:

- **Talk with your healthcare provider:**
 1. While you are using estrogens, it is important to visit your doctor at least once a year for a check-up.
 2. If you have a uterus, talk to your healthcare provider about whether the addition of a progestin is right for you.
 3. See your healthcare provider right away if you have vaginal bleeding while taking estradiol.
 4. 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 (breast x-ray), you may need to have more frequent breast examinations.
 5. 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 for getting heart disease.
 6. Talk with your healthcare provider regularly about whether you should continue taking estradiol. You and your doctor should reevaluate whether or not you still need estrogens at least every 6 months.
- **Be alert for signs of trouble**

If any of these warning signals (or any other unusual symptoms) happen while you are using estrogens, call your doctor immediately:

- Abnormal bleeding from the vagina (possible uterine cancer)
- Pains in the calves or chest, sudden shortness of breath or coughing blood (possible clot in the legs, or lungs)
- Severe headache or vomiting, dizziness, faintness, changes in vision or speech, weakness or numbness of an arm or leg (possible clot in the brain or eye)

Breast lumps (possible breast cancer; ask your doctor or health professional to show you how to examine your breasts monthly)

Yellowing of the skin or eyes (possible liver problem)

Pain, swelling, or tenderness in the abdomen (possible gallbladder problem)

GENERAL INFORMATION ABOUT SAFE AND EFFECTIVE USE OF ESTRADIOL TABLETS

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

KEEP ESTRADIOL TABLETS OUT OF THE REACH OF CHILDREN.

This leaflet provides a summary of the most important information about estradiol tablets. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about estradiol that is written for health professionals. You can get more information by calling Mylan Pharmaceuticals Inc. toll free at 1-877-446-3679 (1-877-4-INFO-RX).

WHAT ARE THE INGREDIENTS IN ESTRADIOL TABLETS?

Estradiol tablets USP, 0.5 mg, contain 0.5 mg estradiol, USP and the following inactive ingredients: anhydrous lactose, colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose and sodium lauryl sulfate.

Estradiol tablets USP, 1 mg, contain 1 mg estradiol, USP and the following inactive ingredients: anhydrous lactose, colloidal silicon dioxide, crospovidone, FD&C Red No. 40 Aluminum Lake, magnesium stearate, microcrystalline cellulose and sodium lauryl sulfate.

Estradiol tablets USP, 2 mg, contain 2 mg estradiol, USP and the following inactive ingredients: anhydrous lactose, colloidal silicon dioxide, crospovidone, FD&C Blue No. 1 Aluminum Lake, magnesium stearate, microcrystalline cellulose and sodium lauryl sulfate.



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