

Estrogen Patient Information

PLEASE NOTE: THIS MEDICATION HAS NOT BEEN EXTENSIVELY STUDIED IN THE MEDICAL LITERATURE. WARNINGS AND CAUTIONS ARE NOT WELL DOCUMENTED. IF YOU HAVE ANY QUESTIONS YOU SHOULD DISCUSS THE USE OF THIS MEDICATION WITH YOUR PHYSICIAN.

Warning: Estrogens have been reported to increase the chance of womb (endometrial) cancer in women who have been through menopause, especially in women with a uterus who receive estrogen-only hormone therapy. Estrogens may also increase the risk of cancer of the ovary or breast. Estrogen-containing products should not be used to prevent heart disease. Estrogen given with another hormone (progestin) for replacement therapy can infrequently cause heart disease (e.g., heart attacks), stroke, serious blood clots in the legs or lungs (pulmonary embolism/deep vein thrombosis), dementia, and cancer of the breast. These risks appear to depend on the length of time this medicine is used and the amount of estrogen per dose. Therefore, this medicine should be used for the shortest possible length of time at the lowest effective dose so that you obtain the benefits and minimize the chance of serious side effects from long-term treatment. Consult your doctor or pharmacist for details. If using this medicine for an extended period, you should be evaluated at least once a year. This medicine is not effective in preventing or treating a tendency toward miscarriage, nor the threat of miscarriage. This medicine should not be used during pregnancy because its use may result in birth defects or cancer later in the child's life.

This medicine is a female estrogen hormone. It works by replacing natural estrogens in a woman who can no longer produce enough estrogen.

Do NOT use this medicine if:

- you are allergic to any ingredient in this medicine
- you are pregnant or suspect you may be pregnant, have recently given birth or are breast-feeding, or have vaginal bleeding of abnormal or unknown cause
- you have known or suspected breast cancer (unless directed by your doctor) or you have cancers that are estrogen-dependent
- you have blood clots, vein inflammation, liver disease, or the blood disease porphyria
- you have had a recent stroke or heart attack

Contact your doctor or health care provider right away if any of these apply to you.

Before using this medicine:

Some medical conditions may interact with this medicine. Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:

- if you are pregnant, planning to become pregnant, or are breast-feeding
- if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement
- if you have allergies to medicines, foods, or other substances
- if you have a family history of breast cancer, or you have breast lumps or disease or an abnormal mammogram
- if you have yellowing of the whites of the eyes or skin during pregnancy or with past estrogen use, or high blood pressure during pregnancy (toxemia)
- if you have a vaginal infection or womb problems (e.g., uterine fibroids/endometriosis, abnormal vaginal bleeding, other uterine problems)
- if you have abnormal calcium levels in the blood, asthma, cancer, cholesterol or lipid problems, depression, diabetes, epilepsy, excessive weight gain, gallbladder disease, heart disease or other heart problems, high blood pressure, kidney or liver disease, low thyroid hormone levels, lupus, migraine headaches, pancreas disease, seizures, or yellowing of the skin or eyes
- if you smoke or will be having surgery

Some MEDICINES MAY INTERACT with this medicine. Tell your health care provider if you are taking any other medicines, especially any of the following:

- Blood thinners (e.g., warfarin), corticosteroids (e.g., prednisone), tacrine, or succinylcholine because their actions and side effects may be increased by this medicine
- Blood thinners (e.g., warfarin) because their effectiveness may be decreased by this medicine
- Hydantoin (e.g., phenytoin), barbiturates (e.g., phenobarbital), or rifampin because the effectiveness of this medicine may be decreased

This may not be a complete list of all interactions that may occur. Ask your health care provider if this medicine may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine.

How to use this medicine:

Use this medicine as directed by your doctor. Check the label on the medicine for exact dosing instructions. Talk to your pharmacist or physician if you have questions about this information.

- For oral doses take this medicine by mouth with or without food. If stomach upset occurs, take with food to reduce stomach irritation. See accompanying directions for topical administration information.
- Grapefruit and grapefruit juice may increase the risk of this medicine's side effects. Talk to your doctor before including grapefruit or grapefruit juice in your diet while you are taking this medicine.
- If you miss a dose of this medicine, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

Ask your health care provider any questions you may have about how to use this medicine.

Important safety information about this medicine:

- This medicine may cause dizziness. This effect may be worse if you take it with alcohol or certain medicines. Use this medicine with caution. Do not drive or perform other possibly unsafe tasks until you know how you react to it.
- Limit alcoholic beverages while you are taking this medicine.
- This medicine may cause dark skin patches on your face (melasma). Exposure to the sun may make these patches darker and you may need to avoid prolonged sun exposure and sunlamps. Consult your doctor regarding the use of sunscreens and protective clothing.
- This medicine may increase the risk of blood clots (especially in women older than 35 years of age). The risk may be greater if you smoke.
- Contact your health care provider if vaginal bleeding of unknown cause occurs. This could be a sign of a serious condition requiring immediate medical attention.
- Contact your health care provider if vaginal discomfort occurs or if you suspect you have developed an infection while taking this medicine.
- Follow your doctor's instructions for examining your breasts and report any lumps immediately.
- Additional monitoring of your dose or condition may be necessary if you are presently taking an azole antifungal (e.g., itraconazole), carbamazepine, a macrolide antibiotic (e.g., erythromycin), ritonavir, cimetidine, or St. John's wort.
- If you wear contact lenses and you develop problems with them, contact your doctor.
- If you will be having surgery or will be confined to a chair or bed for a long period of time (e.g., a long plane flight), notify your doctor beforehand. Special precautions may need to be taken in these circumstances while you are taking this medicine.
- Nonprescription therapy to help prevent bone loss includes a weight-bearing exercise plan, as well as adequate daily calcium and vitamin D intake. Consult your doctor or pharmacist for more details.
- This medicine may interfere with certain lab tests. Be sure your doctor and lab personnel know you are taking this medicine.
- Diabetes patients - This medicine may affect your blood sugar. Check blood sugar levels closely. Ask your doctor before you change the dose of your diabetes medicine.
- Lab tests, including physical exams and blood pressure, may be performed while you use this medicine. You should have breast and pelvic exams, and a Pap test at least once a year. You should also have periodic mammograms as determined by your doctor. Be sure to keep all doctor and lab appointments.
- This medicine should not be used in CHILDREN; safety and effectiveness in children have not been confirmed.
- PREGNANCY and BREAST-FEEDING: Do not use this medicine if you are pregnant. Avoid becoming pregnant while you are taking it. If you think you may be pregnant, contact your doctor right away. This medicine may be found in breast milk. If you are or will be breast-feeding while you use this medicine, check with your doctor. Discuss any possible risks to your baby.

Possible side effects of this medicine:

All medicines may cause side effects, but many people have no, or minor, side effects.

Check with your doctor if any of these most COMMON side effects persist or become bothersome:

Abnormal hair growth; breast tenderness; changes in sex drive; cramps; depression; dizziness; flushing; hair loss; headache; intolerance to contact lenses; lightheadedness; nausea; reduced tolerance to carbohydrates; stomach bloating and upset; swelling; vaginal infection; weight changes.

Seek medical attention right away if any of these SEVERE side effects occur:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); abnormal vaginal bleeding; breast lumps; changes in vaginal bleeding (e.g., spotting, breakthrough bleeding, prolonged bleeding); changes in vision or speech (e.g., change in contact lens fit, loss of vision); coughing of blood; mental/mood changes

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(e.g., severe depression, memory loss); pain in calves or chest; pain, swelling, or tenderness in the stomach; severe headache or vomiting; sudden shortness of breath; swelling of hands or feet; unusual vaginal discharge, itching, or odor; weakness or numbness of an arm or leg; yellowing of the skin or eyes.

This is not a complete list of all side effects that may occur. If you have questions or need medical advice about side effects, contact your doctor or health care provider. You may report side effects to the FDA at 1-800-FDA-1088 (1-800-332-1088) or at <http://www.fda.gov/offcampus.lib.washington.edu/medwatch>.

If OVERDOSE is suspected:

Contact 1-800-222-1222 (the American Association of Poison Control Centers), your local poison control center (<http://www.aapcc.org/findyour.htm>), or emergency room immediately (911). Symptoms may include excessive vaginal bleeding; severe nausea; vomiting.

Proper storage of this medicine:

Store this medicine at room temperature, 59 to 86 degrees F (15 to 30 degrees C), in a tight, light-resistant container. Store away from heat, moisture, and light. Do not store in the bathroom. Keep this medicine out of the reach of children and away from pets.

General information:

- If you have any questions about this medicine, please talk with your doctor, pharmacist, or other health care provider.
- This medicine is to be used only by the patient for whom it is prescribed. Do not share it with other people.
- If your symptoms do not improve or if they become worse, check with your doctor.

This information is a summary only. It does not contain all information about this medicine. If you have questions about the medicine you are taking or would like more information, check with your doctor, pharmacist, or other health care provider.

My signature confirms that I have read and understand this document on Estrogen. I understand that if I have any questions, concerns or would like more information I will ask Dr. Mariotti to provide me with more information.

Date

Signature of Patient

Signature of Patient Representative or Guardian