



PATIENT & CAREGIVER EDUCATION

Elagolix, Estradiol, and Norethindrone

This information from Lexicomp[®] explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

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Warning

- This drug may raise the chance of blood clots, a stroke, or a heart attack. Talk with the doctor.
- Do not take this drug if you have or have ever had a blood clot or have been told you are at risk of getting a blood clot.
- Smoking cigarettes while using this drug raises the chance of severe heart and blood-related side effects. This chance is raised with age (mainly older than 35 years of age). It is also raised with the number of cigarettes smoked. It is strongly advised not to smoke. Do not use this drug if you smoke and are older than 35 years of age.
- If you have high blood pressure, talk with your doctor. This drug must not be used in people who have high blood pressure that is

not controlled.

What is this drug used for?

- It is used to control heavy menstrual bleeding caused by uterine fibroids in people who have not been through menopause. If you have been given this drug for some other reason, talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have any of these health problems: Blood vessel problems in the brain or heart; heart attack or stroke; liver problems; a heart infection called endocarditis; a certain abnormal heartbeat (atrial fibrillation); diabetes with kidney, eye, nerve, or blood vessel problems; severe headache or migraine; or soft, brittle bones (osteoporosis).
- If you have ever had breast cancer or another cancer where hormones make it grow.
- If you have unexplained vaginal bleeding.
- If you are taking rifampin.
- If you are pregnant or may be pregnant. Do not take this drug if you are pregnant.

This is not a list of all drugs or health problems that interact with

this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists. This drug may need to be stopped before certain types of surgery as your doctor has told you. If this drug is stopped, your doctor will tell you when to start taking this drug again after your surgery or procedure.
- High blood pressure has happened with drugs like this one. Have your blood pressure checked as you have been told by your doctor.
- Be sure to have regular breast exams and gynecology check-ups. You will also need to do breast self-exams as you have been told.
- Talk with your doctor if you will need to be still for long periods of time like long trips, bedrest after surgery, or illness. Not moving for long periods may raise your chance of blood clots.
- Avoid grapefruit and grapefruit juice.

- If you have high blood sugar (diabetes), talk with your doctor. This drug may raise blood sugar.
- Check your blood sugar as you have been told by your doctor.
- This drug may cause high cholesterol and triglyceride levels. Talk with the doctor.
- If you are allergic to tartrazine (FD&C Yellow No. 5), talk with your doctor. Some products have tartrazine.
- This drug may cause loss of bone density. This may happen more the longer the drug is used. Bone effects may not go back to normal after this drug is stopped. Have your bone density checked as you have been told by your doctor.
- Take calcium and vitamin D as you were told by your doctor.
- Hair loss and hair thinning can happen with this drug. This can go on even after stopping this drug. It is not known if hair will go back to normal after this drug is stopped. If you have concerns, talk with your doctor.
- This drug may stop you from having a period (menstrual bleeding) or cause other changes in menstrual bleeding. This may make it hard to know if you are pregnant. Watch for other signs of pregnancy like tender breasts, weight gain, and upset stomach.
- Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy. Use some other kind of birth control, like a condom, while you are taking this drug and

for 28 days after stopping it.

- This drug may cause harm to the unborn baby or loss of the unborn baby if you take it while you are pregnant.
- Have a pregnancy test before starting this drug, or start taking it within 7 days of when your menstrual period starts. Talk with your doctor if you are not sure how to start this drug.
- If you get pregnant or think you may be pregnant, call your doctor right away.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing

up, or yellow skin or eyes.

- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Signs of gallbladder problems like pain in the upper right belly area, right shoulder area, or between the shoulder blades; yellow skin or eyes; fever with chills; bloating; or very upset stomach or throwing up.
- Signs of high blood sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Eyesight changes or loss, bulging eyes, or change in how contact lenses feel.
- Bone pain.
- A lump in the breast, breast pain or soreness, or nipple discharge.
- New or worse behavior or mood changes like depression or thoughts of suicide.
- Call your doctor right away if you have signs of a blood clot like chest pain or pressure; coughing up blood; shortness of breath; swelling, warmth, numbness, change of color, or pain in a leg or arm; or trouble speaking or swallowing.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Flushing.
- Headache.
- Feeling tired or weak.
- Period (menstrual) changes.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at <https://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take this drug at the same time of day.
- Take with or without food.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it has been 4 hours or more since the missed dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.

- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine.

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If you have any questions, contact a member of your healthcare team directly. If you're a patient at MSK and you need to reach a provider after 5:00 PM, during the weekend, or on a holiday, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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