



PATIENT & CAREGIVER EDUCATION

Segesterone Acetate and Ethinyl Estradiol

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

Annovera

Warning

- Smoking cigarettes while using this drug raises the chance of very bad heart and blood-related side effects. This chance is raised with age (mainly in women 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.

What is this drug used for?

- It is used to prevent pregnancy.
- It may be given to you for other reasons. 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 a blood clot, have ever had a blood clot, or have been told you are at risk of getting a blood clot.

- If you have ever had a heart attack or stroke.
- If you have ever had breast cancer or another cancer where hormones make it grow.
- If you have any of these health problems: Blood clotting problem; diseased blood vessels in the brain or heart; heart valve problems or other heart disease; high blood pressure; high blood sugar (diabetes); kidney or liver problems; liver tumor; or very bad headache or migraine; headaches with change in eyesight, numbness, or weakness.
- If you have unexplained vaginal bleeding.
- If you are taking ombitasvir, paritaprevir, and ritonavir (with or without dasabuvir).
- If you turned yellow during pregnancy or with estrogen-based or hormone contraceptive use.
- If you are pregnant or may be pregnant. Do not take this drug if you are pregnant.
- If you are breast-feeding. Do not breast-feed while you take this drug.

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.

- 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.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- High blood pressure has happened with drugs like this one. Have your blood pressure checked as you have been told by your doctor.
- This drug may raise the chance of blood clots, a stroke, or a heart attack. Talk with the doctor.
- 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.
- 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.
- 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.
- If you drink grapefruit juice or eat grapefruit often, talk with your doctor.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- This drug may cause dark patches of skin on your face. Avoid sun, sunlamps, and tanning beds. Use sunscreen and wear clothing and eyewear that protects you from the sun.
- This drug does not stop the spread of diseases like HIV or hepatitis that are passed through having sex. Do not have any kind of sex without using a latex or polyurethane condom. If you have questions, talk with your doctor.

- If you use a lubricant, do not use an oil-based or silicone-based lubricant. If you have questions, talk with your doctor.
- Check to see if this drug is in place as you have been told by your doctor or read the package insert. If you cannot find the ring after putting it in or if you are not able to take it out, call your doctor right away.
- Do not use in children who have not had their first menstrual period.
- If you have any signs of pregnancy or if you have a positive pregnancy test, call your doctor right away.

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 a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.

- Low mood (depression).
- Eyesight changes or loss, bulging eyes, or change in how contact lenses feel.
- A lump in the breast, breast pain or soreness, or nipple discharge.
- Vaginal itching or discharge.
- Spotting or vaginal bleeding that is very bad or does not go away.
- Toxic shock syndrome (TSS) has happened in a few patients using vaginal rings. TSS is rare, but can be deadly. Tell your doctor right away if you have diarrhea, dizziness or light-headedness, passing out, fever, muscle pain, upset stomach, throwing up, or a sunburn-like rash.

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:

- Vaginal irritation.
- Headache.
- Upset stomach or throwing up.
- Stomach pain or diarrhea.
- Painful periods.
- Period (menstrual) changes. These include spotting or bleeding between cycles.

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.

- This drug may not work as well if not used the right way. Be sure you know how and when to start using this drug and if you will need to use an extra form of birth control like condoms. If you are not sure how or when to start using this drug, talk with your doctor.
- Put into the vagina and leave in place for 3 weeks.
- Take out ring at the start of the 4th week.
- After taking the ring out, clean it with mild soap and warm water. Dry with a clean towel and put in the storage case. When ready to put the ring back in 7 days later, clean it before putting it back in.
- Put the ring back in at the same time of day that it was taken out 7 days ago.
- Wash your hands before use.
- Be sure your hands are dry before you touch this drug.
- Press sides of ring at the same time between thumb and index finger and put folded ring into the vagina.
- Perfect placement is not needed for the ring to work. The ring will not hurt.
- To take out, hook your index finger around the rim or hold rim between index finger and middle finger and pull out.
- Do not throw the vaginal ring in the toilet.
- Do not use the vaginal ring for more than 13 dosing cycles. If you have questions, talk with your doctor.
- If you miss a planned menstrual period, call your doctor. You may need a pregnancy test.
- Certain drugs, herbal products, or health problems could cause this drug to not work as well. Be sure your doctor knows about all of your drugs and health problems.
- If the ring comes out during the 3 weeks of use, wash with mild soap and warm water, pat dry with a towel, and put it back in as soon as you can.

- If the ring is out for more than 2 hours total during the 3 weeks cycle, you must use an extra kind of birth control also (like condoms or spermicide) for 7 days after putting the ring back in.
- If the ring has been in for more than 3 weeks, take it out and leave out for 7 days. Continue the normal dosing cycle by putting back in 7 days later.

What do I do if I miss a dose?

- If the ring is out for more than 1 week, take a pregnancy test before starting the next dosing cycle.
- You must use an extra kind of birth control also (like condoms or spermicide) for 7 days after putting the ring back in
- If you are not sure what to do if you miss a dose, call your doctor.

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

- Store at room temperature. Do not refrigerate or freeze.
- Protect from heat and sunlight.
- 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.

- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, nurse, 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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