



PATIENT & CAREGIVER EDUCATION

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

Abigale; Abigale Lo; Activella; Amabelz [DSC]; CombiPatch; Mimvey

Brand Names: Canada

Activelle; Activelle LD; Estalis

Warning

- Do not use this drug to prevent heart disease or dementia. A study of women taking an estrogen with a progestin showed a raised chance of heart attack, stroke, blood clot, breast cancer, and dementia. The chance of stroke, blood clot, and dementia was also raised when the estrogen was taken alone. Not all products and doses were studied. It is not known if the same effects may happen with this drug.
- The risk of endometrial cancer may be raised with the use of estrogen alone in people who have a uterus. Use of a progestogen along with estrogen may lower the risk. Call your doctor right away if you have unusual vaginal bleeding. If you have a uterus, talk with your doctor about taking a progestogen.
- Use this drug for the shortest time needed at the lowest useful dose. Your doctor will talk with you on a regular basis to see if you need to keep taking this drug.

What is this drug used for?

- It is used to prevent soft, brittle bones (osteoporosis) after menopause.

- It is used to treat signs caused by menopause.
- It is used when the ovaries have been taken out, are not working the right way, or have stopped working.
- 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 had any of these health problems: Bleeding disorder, blood clots, a higher risk of having a blood clot, breast cancer, liver problems or liver tumor, heart attack, stroke, or a tumor where estrogen makes it grow.
- If you have had your uterus removed.
- If you have unexplained vaginal bleeding.
- 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?

All products:

- 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.
- High blood pressure has happened with drugs like this one. Have your blood pressure checked as you have been told by your doctor.
- Have your blood work and bone density 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.

- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- Limit your drinking of alcohol.
- Do not smoke. Smoking raises the chance of heart disease. Talk with your doctor.
- If you drink grapefruit juice or eat grapefruit often, talk with your doctor.
- 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.
- The risk of certain side effects like heart attack, stroke, breast cancer, ovarian cancer, and others may not be the same for everyone. Factors like how long an estrogen is taken, if it is taken with or without a progestin, and other factors may affect the risk for certain side effects. Talk with your doctor about the benefits and risks of using this drug.
- High triglyceride levels have happened with this drug. Tell your doctor if you have ever had high triglyceride levels.
- If you are 65 or older, use this drug with care. You could

have more side effects.

- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

Soft, brittle bones (osteoporosis):

- This drug works best when used with calcium/vitamin D and weight-bearing workouts like walking or PT (physical therapy).
- Follow the diet and exercise plan that your doctor told you about.

Skin patch:

- Protect patch from the sun.

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, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- 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 pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Signs of a pancreas problem (pancreatitis) like very bad stomach pain, very bad back pain, or very bad upset stomach or throwing up.
- Signs of low calcium levels like muscle cramps or spasms, numbness and tingling, or seizures.
- 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.
- A lump in the breast, breast pain or soreness, or nipple discharge.
- Vaginal itching or discharge.
- Vaginal bleeding that is not normal.

- Depression or other mood changes.
- Memory problems or loss.
- This drug may cause you to swell or keep fluid in your body. Tell your doctor if you have swelling, weight gain, or trouble breathing.
- 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.
- High calcium levels have happened with drugs like this one in some people with cancer. Call your doctor right away if you have signs of high calcium levels like weakness, confusion, feeling tired, headache, upset stomach or throwing up, constipation, or bone pain.

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:

All products:

- Headache.
- Back pain.

- Hair loss.
- Diarrhea, upset stomach, or throwing up.
- Trouble sleeping.
- Cramps.
- Bloating.
- Tender breasts.
- Enlarged breasts.
- Vaginal bleeding or spotting.
- Signs of a common cold.
- Weight gain.
- 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.

Skin patch:

- Irritation where this drug was used.

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.

Tablets:

- Take this drug at the same time of day.
- Take with or without food. Take with food if it causes an upset stomach.

Skin patch:

- Do not put on a cold patch. Before opening a pouch, let the pouch come to room temperature. Do not heat. Put the patch on right after taking out of a pouch.
- Put patch on clean, dry, healthy skin on the lower belly. Move the site with each new patch.
- Put patch on a site without hair.
- Do not place on breast. Place below waistline.
- Put the same patch on the same place if it falls off and has been off for less than 24 hours. If it will not stick, put a new patch on a different site. Then change next patch at your normal time.

- After you take off a skin patch, be sure to fold the sticky sides of the patch to each other. Throw away used patches where children and pets cannot get to them.

What do I do if I miss a dose?

Tablets:

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

Skin patch:

- Put on a missed patch as soon as you think about it after taking off the old one.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not put on 2 doses at the same time or extra doses.

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

Tablets:

- Store at room temperature in a dry place. Do not store in a bathroom.
- Protect from light.

Patch:

- Store in a refrigerator. Do not freeze.

All products:

- 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 generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the

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Last Reviewed Date

2024-03-19

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

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

Estradiol and Norethindrone - Last updated on December 12, 2022
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