PATIENT & CAREGIVER EDUCATION

Tibolone

This information from UpToDate® Lexidrug™ 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: Canada

Tibella

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 treat symptoms of low estrogen levels caused by menopause.

- It may be given to you for other reasons. Talk with the doctor.
- Do not use this drug as birth control to prevent pregnancy.

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 ever had any of these health problems: Blood clots, breast cancer, chest pain, heart attack, transient ischemic attack (TIA), stroke, or heart disease.
- If you have any of these health problems: Blood clotting problems like protein C, protein S, or antithrombin deficiency; liver problems or raised liver enzymes; thickening of the endometrium; tumor where estrogen or other hormones make it grow; unexplained vaginal bleeding; change in eyesight from blood vessel problems in the eye; or porphyria.
- If you have been told that your body has problems with certain sugars (lactose, glucose, galactose). Some products have lactose.
- 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.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- 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.

- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- If you have high blood sugar (diabetes), you will need to watch your blood sugar closely. Tell your doctor if you get signs of high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- High blood pressure has happened with this drug. Have your blood pressure checked as you have been told by your doctor.
- If you have lupus, this drug can make your lupus active or get worse. Tell your doctor right away if you get any new or worse signs.
- 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.
- Call your doctor right away if you have 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.

- If you are 60 or older, use this drug with care. You could have more side effects.
- If you are pregnant or you get pregnant while taking this drug, 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 gallbladder problems like pain in the upper right belly area, right shoulder area, or between the shoulder blades; change in stools; dark urine or yellow skin or eyes; or fever with chills.
- 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 high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Vaginal bleeding that does not stop or go back to normal.
- A lump in the breast, breast pain or soreness, or nipple discharge.
- Vaginal itching or discharge.
- Pelvic pain.
- Pain when passing urine.
- Trouble passing urine.
- Eyesight changes or loss, bulging eyes, or change in how contact lenses feel.
- A heartbeat that does not feel normal.
- A burning, numbness, or tingling feeling that is not normal.
- New or worse migraines.
- Depression or other mood changes.
- Memory problems or loss.
- Swelling.

- 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:

- Vaginal bleeding or spotting.
- Upset stomach or throwing up.
- Stomach pain or cramps.
- Feeling dizzy, tired, or weak.
- Headache.
- Appetite changes.
- Weight gain or loss.
- Change in sex interest.
- Muscle or joint pain.
- Feeling nervous and excitable.
- Pimples (acne).
- Hair growth.

- Hair loss.

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.
- Swallow whole with some water or other drink.
- Do not chew or crush.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it has been 12 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.
- Store in the original container to protect from light.
- 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.
- 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.

- 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.
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- 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

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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.

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