



PATIENT & CAREGIVER EDUCATION

Ospemifene

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: US

Osphena

Brand Names: Canada

Osphena

Warning

- This drug works like estrogen in the uterus. The risk of endometrial cancer (cancer of the lining of the uterus) may be raised with estrogens or with this drug. Progestins may lower this risk. Call your doctor right away if you have unexplained or long-lasting vaginal bleeding.
- This drug may raise the chance of a stroke or blood clots. Take this drug for the shortest time needed. 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 vaginal pain during sex or vaginal dryness caused by menopause. If you have been given this drug for some other reason, talk with your doctor for more information.

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: Blood clots or a higher risk of having a blood clot, breast cancer or other kind of cancer where estrogen makes it grow, liver problems, heart attack, or stroke.
- If you have unexplained vaginal bleeding.
- If you are taking any of these drugs: Estrogens, fluconazole, or 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.
- 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.

- Use care if you have risks for heart disease (high blood pressure, high cholesterol, overweight, high blood sugar or diabetes, smoking or other nicotine use, male older than 40 years of age, other family members with early heart disease, female after menopause). Talk with your doctor.
- 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.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Feeling very tired or weak.
- Vaginal bleeding that is not normal.
- A lump in the breast, breast pain or soreness, or nipple discharge.
- 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:

- Hot flashes.
- Vaginal discharge.
- Muscle spasm.
- Sweating a lot.
- Headache.
- Night sweats.

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 with food.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it, with food.
- 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.

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.
- 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

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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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