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2. Osphena

Osphena

Generic name: ospemifene [os-PEM-i-feen] **Drug class:** Selective estrogen receptor modulators

Medically reviewed by Philip Thornton, DipPharm. Last updated on Feb 24, 2025.

Uses Warnings Before taking Dosage Side effects Interactions FAQ

What is Osphena?

Osphena is a non-estrogen medicine that reverses certain changes in vaginal tissue that are caused by menopause.

Osphena is a prescription medicine used in menopausal women to relieve moderate to severe vaginal dryness.

Osphena is also used to treat moderate to severe pain during sexual intercourse.

Warnings

You should not use Osphena if you have: undiagnosed vaginal bleeding, if you will have major surgery, or if you have ever had a heart attack, a stroke, a blood clot, or cancer of the breast, uterus/cervix, or vagina.

Do not use Osphena if you are pregnant.

Osphena may increase your risk of developing a condition that may lead to uterine cancer. Report any unusual vaginal bleeding right away.

Using this medicine can increase your risk of blood clots, stroke, heart attack, or breast cancer.

Before taking this medicine

You should not use Osphena if you are allergic to ospemifene, if you are pregnant, or if you have:

- a history of heart attack, stroke, or blood clot;
- unusual vaginal bleeding that a doctor has not checked; or
- any type of breast, uterine, or hormone-dependent cancer.

Some drugs should not be used together with Osphena. Your doctor may change your treatment plan if you also use:

- · bazedoxifene;
- · clomiphene;

- fluconazole:
- · rifampin;
- tamoxifen;
- · toremifene:
- · birth control pills; or
- hormone replacement therapy.

To make sure Osphena is safe for you, tell your doctor if you have ever had:

- liver disease;
- breast cancer (in you or a family member); or
- risk factors for heart problems or blood clots (such as diabetes, smoking, being overweight, having high blood pressure, high cholesterol, or lupus).

Ospemifene may increase your risk of blood clots, stroke, heart attack, or breast cancer. Talk with your doctor about your individual risks.

Do not use ospemifene if you are pregnant or plan to become pregnant. It could harm the unborn baby or cause birth defects. Use effective birth control to prevent pregnancy while you are using this medicine.

You may need to have a negative pregnancy test before starting this treatment.

You should not breastfeed while using this medicine.

Osphena is not approved for use by anyone younger than 18 years old.

Osphena pregnancy and breastfeeding warnings (more detail)

How should I take Osphena?

Osphena tablets are usually taken once daily. Follow all directions on your prescription label and read all medication guides or instruction sheets.

Take this medicine with food.

Osphena may increase your risk of developing a condition that can lead to uterine cancer. To help lower this risk, your doctor may also want you to take a progestin. **Report any unusual vaginal bleeding right away.**

Your doctor should check your progress on a regular basis to determine whether you should continue this treatment. Self-examine your breasts for lumps on a monthly basis, and have regular pelvic exams and mammograms while taking Osphena.

If you need major surgery or will be on long-term bed rest, you may need to stop using this medicine for a short time. Any doctor or surgeon who treats you should know that you are using Osphena.

Store at room temperature away from moisture and heat.

Dosing information

Usual Adult Dose for Dyspareunia:

60 mg orally once a day with food

Comments:

-This drug should be used for the shortest duration consistent with treatment goals and risks; postmenopausal women should be re-evaluated periodically as clinically appropriate to determine if treatment is still necessary.

Uses: For the treatment of moderate to severe dyspareunia (painful intercourse) and moderate to severe vaginal dryness, both symptoms of vulvar and vaginal atrophy, due to menopause.

Detailed Osphena dosage information

What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. Do not take two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What to avoid

Follow your doctor's instructions about any restrictions on food, beverages, or activity.

Osphena side effects

Get emergency medical help if you have any of these **signs of an allergic reaction to Osphena:** hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have:

- signs of a stroke sudden numbness or weakness (especially on one side of the body), severe headache, slurred speech, balance problems;
- signs of a blood clot in the lung chest pain, sudden cough, wheezing, rapid breathing, coughing up blood;
- signs of a blood clot deep in the body swelling, warmth, or redness in an arm or leg; or
- · any unusual vaginal bleeding.

Common Osphena side effects may include:

- · vaginal discharge or heavy bleeding;
- hot flashes;
- headache;

- · increased sweating, night sweats; or
- muscle spasm.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

① Osphena side effects (more detail)

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What other drugs will affect Osphena?

Sometimes it is not safe to use certain medications at the same time. Some drugs can affect your blood levels of other drugs you take, which may increase side effects or make the medications less effective.

Tell your doctor about all your other medicines, especially:

- birth control pills; or
- hormone replacement therapy.
- Osphena drug interactions (more detail)

Does Osphena interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Osphena	
+	
Enter a drug name	Add

Popular FAQ

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References

1. Osphena Product Label

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- Drug images
- Side effects

- Dosage information
- During pregnancy
- · Generic availability
- · FDA approval history
- Drug class: selective estrogen receptor modulators
- En español

Professional resources

- Osphena prescribing information
- Ospemifene (AHFS Monograph)

Related treatment guides

- Vaginal Dryness
- Atrophic Vaginitis
- Dyspareunia
- Postmenopausal Symptoms
- Perimenopausal Symptoms

Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Osphena only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

৵ Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

10+ years FDA approved 2013

WADA Class



User Reviews & Ratings

5.3 / 10

45 Reviews

Images

Osphena 60 mg (60)

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