

**Patient Information**

**OSPHENA® (os fee' nah)  
(ospemifene)  
tablets**

Read this Patient Information before you start taking OSPHENA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

**What is the most important information I should know about OSPHENA ?**

- **OSPHENA is a medicine that works like estrogen in the lining of the uterus (womb), but can work differently in other parts of the body. Taking estrogen-alone or OSPHENA may increase your chance of getting cancer of the lining of the uterus (womb). Vaginal bleeding after menopause may be a warning sign of cancer of the lining of the uterus (womb). Your healthcare provider should check any unusual vaginal bleeding to find out the cause. Tell your healthcare provider right away if you have any unusual vaginal bleeding while you are taking OSPHENA.**
- **OSPHENA may increase your chance of getting strokes and blood clots.**
- **You and your healthcare provider should talk regularly about whether you still need treatment with OSPHENA.**

**What is OSPHENA?**

OSPHENA is an oral prescription medicine that contains ospemifene.

**What is OSPHENA used for?**

OSPHENA is used after menopause for women with or without a uterus to:

- Treat moderate to severe pain during sexual intercourse due to changes in and around your vagina.

**Who should not take OSPHENA?**

Do not start taking OSPHENA if you:

- **have unusual vaginal bleeding**  
Vaginal bleeding after menopause may be a warning sign of cancer of the lining of the uterus (womb). Your healthcare provider should check any unusual vaginal bleeding to find out the cause.
- **currently have or have had certain cancers**  
Estrogen may increase the chances of getting certain types of cancers, such as cancer of the lining of the uterus. If you have or have had cancer, talk with your healthcare provider about whether you should take OSPHENA.
- **currently have or have had blood clots**

- **had a stroke or heart attack**
- **are allergic to OSPHENA or any of its ingredients:**  
See the list of ingredients in OSPHENA at the end of this leaflet.
- **think you may be pregnant**  
OSPHENA is not for pregnant women. If you think you may be pregnant, you should have a pregnancy test and know the results. Do not take OSPHENA if the test is positive and talk to your healthcare provider.

**What should I tell my healthcare provider before taking OSPHENA?**

**Before you take OSPHENA, tell your healthcare provider if you:**

- **have any unusual vaginal bleeding**  
Vaginal bleeding after menopause may be a warning sign of cancer of the lining of the uterus (womb). Your healthcare provider should check any unusual vaginal bleeding to find out the cause.
- **have any other medical conditions**  
Such as severe liver problems.
- **are going to have surgery or will be on bed rest**  
Your healthcare provider will let you know if you need to stop taking OSPHENA.
- **are breast feeding**  
It is not known if OSPHENA can pass into your breast milk.

**Tell your healthcare provider about all medicines you take,** including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how OSPHENA works. OSPHENA may also affect how other medicines work. Keep a list of your medicines and show it to your healthcare provider and pharmacist each time you get a new medicine.

**How should I take OSPHENA?**

- Take OSPHENA exactly how your healthcare provider tells you to take it.
- Take OSPHENA by mouth 1 time each day with food.
- You and your healthcare provider should talk regularly (every 3 to 6 months) about the dose you are taking and whether or not you still need treatment with OSPHENA.

**What are the possible side effects of OSPHENA?**

See **"What is the most important information I should know about OSPHENA?"**

**Serious, but less common side effects include:**

- stroke
- blood clots
- cancer of the lining of the uterus (womb)

**Call your healthcare provider right away if you get any of the following warning signs or any other unusual symptoms that concern you:**

- unusual vaginal bleeding
- changes in vision or speech
- sudden new severe headaches
- severe pains in your chest or legs with or without shortness of breath, weakness and fatigue

**Less serious, but common side effects include:**

- hot flushes or flashes
- vaginal discharge
- muscle spasms
- increased sweating

These are not all the possible side effects of OSPHERA. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider about any side effects that bother you or does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**What can I do to lower my chances of a serious side effect with OSPHERA?**

- Talk with your healthcare provider regularly about whether you should continue taking OSPHERA.
- If you have a uterus, talk with your healthcare provider about whether the addition of a progestin is right for you.
- See your healthcare provider right away if you develop vaginal bleeding while taking OSPHERA.
- Have a pelvic exam, breast exam and mammogram (breast x-ray) every year unless your healthcare provider tells you something else.
- If members of your family have had breast cancer or if you have ever had breast lumps or an abnormal mammogram (breast x-ray), you may need to have breast exams more often.
- If you have high blood pressure, high cholesterol (fat in the blood), diabetes, are overweight, or use tobacco, you may have a higher chance of getting heart disease.
- Tell your healthcare provider if you are going to have surgery or will be on bed rest.

Ask your healthcare provider for ways to lower your chances of getting heart disease.

**How should I store OSPHERA?**

- Store OSPHERA at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep OSPHERA and all medicines out of the reach of children.**

**General information about the safe and effective use of OSPHERA.**

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not take OSPHERA for conditions for which it was not prescribed. Do not give OSPHERA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about OSPHERA. If you would like more information, talk with your healthcare provider or pharmacist. You can ask your healthcare provider or pharmacist for more information about OSPHERA that is written for health professionals.

For more information, go to [www.osphena.com](http://www.osphena.com) or call Shionogi Inc. at 1-855-OSPHERA (1-855-677-4362).

**What are the ingredients in OSPHERA?**

Active Ingredient: ospemifene

Inactive ingredients: colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, mannitol, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, and triacetin.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured for:  
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Manufactured by:  
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