

**PATIENT INFORMATION**  
**OSPHERA® (os fee' nah)**  
**(ospemifene)**  
**tablets, for oral use**

Read this Patient Information before you start taking OSPHERA 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 OSPHERA?**

- OSPHERA is a medicine that works like estrogen in the lining of the uterus (womb) but can work differently in other parts of the body.
- **OSPHERA 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 OSPHERA.
- **OSPHERA may increase your chance of getting strokes and blood clots.**

**What is OSPHERA?**

- OSPHERA is a prescription medicine that contains ospemifene.
- **OSPHERA 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.
  - Moderate to severe vaginal dryness due to changes in and around your vagina.

**Who should not take OSPHERA?**

**Do not start taking OSPHERA 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.** If you have or have had cancer, talk with your healthcare provider about whether you should take OSPHERA.
- **currently have or have had blood clots.**
- **had a stroke or heart attack.**
- **are allergic to ospemifene or any of the ingredients in OSPHERA.** Allergic reaction to OSPHERA can include swelling of the face or tongue (angioedema), hives (urticaria), rash, and itching (pruritus). See the end of this Patient Information leaflet for a complete list of ingredients in OSPHERA.
- **are pregnant or plan to become pregnant.** OSPHERA is not for pregnant women.

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

**Before you take OSPHERA, tell your healthcare provider about all of your medical conditions, including if you:**

- have any unusual vaginal bleeding.
- have or have had certain cancers. See **“Who should not take OSPHERA?”**
- have liver problems. You should not use OSPHERA if you have certain 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 OSPHERA.
- are breastfeeding or plan to breastfeed. It is not known if OSPHERA can pass into your breast milk. **Do not** breastfeed while taking OSPHERA.

**Tell your healthcare provider about all medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may affect how OSPHERA works. OSPHERA may also affect how other medicines work.

Know the medicines you take. 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 OSPHERA?**

- Take OSPHERA exactly how your healthcare provider tells you to take it.
- Take 1 OSPHERA tablet by mouth each day with food.
- You and your healthcare provider should talk regularly about the dose of OSPHERA you are taking and whether or not you still need treatment with OSPHERA.

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

**OSPHERA may cause serious side effects, including:**

- See **“What is the most important information I should know about OSPHERA?”**

**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
- pain in your chest or legs with or without shortness of breath, weakness and fatigue

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

- hot flushes (also known as hot flashes)
- vaginal discharge
- muscle spasms
- headache
- excessive sweating (hyperhidrosis)
- heavy vaginal bleeding (vaginal hemorrhage)
- night sweats

These are not all the possible side effects of OSPHENA. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider about any side effects that bother you or do 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 OSPHENA?**

- Talk with your healthcare provider regularly about whether you should continue taking OSPHENA.
- See your healthcare provider right away if you get vaginal bleeding while taking OSPHENA.
- 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, diabetes, are overweight, or use tobacco, you may have a higher chance of getting heart disease. Ask your healthcare provider for ways to lower your chances of getting heart disease.
- Tell your healthcare provider if you are going to have surgery or will be on bed rest.

**How should I store OSPHENA?**

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

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

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

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not take OSPHENA for a condition for which it was not prescribed. Do not give OSPHENA to other people, even if they have the same symptoms you have. It may harm them.

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

**What are the ingredients in OSPHENA?**

**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.

Distributed by: Shionogi Inc.

Florham Park, NJ 07932

Marketed by: Duchesnay USA, Inc.

Bryn Mawr, PA 19010

Made in UK

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

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

Revised: 01/2019

**OSP-PI-06**