

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **OSPHENA**[®]

Ospemifene Tablets

Read this carefully before you start taking **Osphena** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Osphena**.

Serious Warnings and Precautions

- **Endometrial Cancer (cancer of the lining of the uterus):** Osphena is a drug that activates or blocks the estrogen receptors. Osphena activates the estrogen receptors in the lining of the uterus (womb). The risk of getting endometrial cancer is increased in a woman with a uterus who uses estrogen therapy alone without progesterone. Your healthcare professional will conduct an examination to rule out cancer if you are experiencing persistent or recurring unexplained vaginal bleeding.
- **Circulatory system problems:** Taking Osphena can increase your risk of developing:
 - a thromboembolic stroke (artery is blocked by blood clot)
 - a hemorrhagic stroke (bleeding in your brain from a torn blood vessel)
 - deep vein thrombosis (blood clot in the deep veins of the leg or arm)

What is Osphena used for?

Osphena is used in postmenopausal (after menopause) women to treat some symptoms of Genitourinary Syndrome of Menopause (GSM). GSM is a condition caused by lowering levels of the female hormone oestrogen in your body. Osphena is used to treat moderate to severe symptoms such as:

- pain during sex due to changes in and around the vagina;
- dryness due to changes in and around the vagina.

How does Osphena work?

Low levels of the female hormone estrogen can cause the vaginal walls to become thinner. Osphena is not estrogen but is believed to work in a similar way as estrogen in the vagina. It does this by increasing the thickness of the vaginal walls. It also restores the vaginal pH.

What are the ingredients in Osphena?

Medicinal ingredients: ospemifene.

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

Osphena comes in the following dosage forms:

60 mg tablets

Do not use Ospheⁿa if:

- You have unexplained vaginal bleeding
- You currently have or have had certain cancers which are sensitive to estrogens. If you have or have had cancer, talk with your healthcare professional about whether you should take Ospheⁿa.
- You currently have or have had a blood clots in a vein (thrombosis). Examples include blood clots in your legs (deep vein thrombosis) or lungs (pulmonary embolism).
- You currently have or has a blood clot in an artery. Examples include a stroke or heart attack
- Have severe liver problems
- You are allergic or have a history of serious allergic reactions to ospemifene or any other ingredients in Ospheⁿa. Symptoms include swelling, hives, rash, red itchy welts. If you are not sure about this, talk to your doctor before taking Ospheⁿa.
- You are pregnant or may become pregnant. **Ospheⁿa** is not for pregnant women. Ospheⁿa may cause harm to your unborn baby. 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 professional.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Ospheⁿa. Talk about any health conditions or problems you may have, including if you:

- Have or have had a cancer of the lining of the uterus (womb)
- Have or have had breast cancer
- Are at risk of developing a blood circulation problem (i.e. high blood pressure, diabetes, smoker, high cholesterol, obese)
- Have or have had blood clots
- Had a heart attack or other heart conditions. Taking Ospheⁿa can increase your risk of experiencing a heart attack.
- Have severe liver problems
- Are going to have surgery or will be on bed rest
- Have any unusual vaginal bleeding
- Think you are or may become pregnant. Ospheⁿa may cause harm to your unborn baby.
- Are breast feeding. It is not known if Ospheⁿa can pass into your breast milk. You should not breastfeed while taking Ospheⁿa.

Other warnings you should know about:

Treatment with Ospheⁿa could increase your risk of certain side effects, including:

- Endometrial Cancer. Ospheⁿa is a medicine that works like estrogen in the lining of the uterus (womb), and may increase your chance of getting cancer of the lining of the uterus (endometrial cancer). Endometrial cancer has been reported in women on longterm treatment with estrogen. This risk can continue for at least 8 to 15 years after estrogen therapy is stopped. Your doctor will monitor your condition during your treatment. Speak to your doctor if you experience unusual vaginal bleeding.
- Strokes. Your doctor may stop your treatment with Ospheⁿa immediately if you experience a stroke.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Osphe^{na}:

- antifungals (drugs used to treat fungal infections, such as fluconazole and ketoconazole);
- antibiotics such as rifampin;
- proton-pump inhibitors (drugs used for heartburn or stomach ulcers such as omeprazole);
- estrogens;
- hormone replacement therapy (ERT / HRT) or estrogens agonist / antagonist (estrogen-like medications such as tamoxifen and bazedoxifene);
- medications used to reduce the formation of clots (warfarin);
- medications used to treat osteoporosis (raloxifene).

How to take Osphe^{na}:

- Take exactly how your healthcare professional tells you to take it
- Talk to your healthcare professional often (every 3 to 6 months) about your dose. Your healthcare professional will decide if you still need treatment with Osphe^{na}.

Usual dose:

Take one 60 mg tablet once a day with food. Take the Osphe^{na} tablet by mouth.

Overdose:

If you think you, or a person you are caring for, have taken too much Osphe^{na}, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you missed a dose of this medication, take it as soon as you remember. But if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Go back to the regular dosing schedule. Do not take two doses at the same time.

What are possible side effects from using Osphe^{na}?

These are not all the possible side effects you may have when taking Osphe^{na}. If you experience any side effects not listed here, tell your healthcare professional.

The side effects of Osphe^{na} are:

- Acne, red itchy skin;
- Diarrhea;
- Excess hair on the face, chest, abdomen or legs;
- Feeling hot (hot flushes or flashes);
- Headache;
- Increased / excessive sweating;

- Joint or muscle pain;
- Muscle spasms, such as leg cramps;
- Nausea;
- Swelling of legs and hands;
- Stomach pain;
- Urge to move legs;
- Vaginal discharge;

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Breast mass (breast lump) pain, tenderness in breast		✓	
Hypersensitivity reaction: rash, itchiness along with difficulty breathing with or without swelling of the face, lips, tongue and throat.			✓
Depression: persistent sad mood.		✓	
Urinary tract infection (infection in urinary system including kidneys, ureters, bladder and urethra): Pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine		✓	
Shortness of breath			✓
Vaginal infection (fungal, yeast or bacterial infection of the vulva or vagina): vaginal discharge, vaginal redness, vaginal swelling, vaginal burning sensation and vaginal discomfort		✓	
Ovarian cyst: pelvic pain, abdominal bloating / swelling, frequent need to urinate, painful bowel movements, vaginal bleeding.		✓	
Vulvovaginal hemorrhage (vaginal bleeding): unexplained vaginal bleeding.		✓	
RARE			
Deep vein thrombosis: swelling of your foot, ankle, or leg, usually on			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
one side; cramping pain in your affected leg that usually begins in your calf; severe, unexplained pain in your foot and ankle; an area of skin that feels warmer than the skin on the surrounding areas; skin over the affected area turning pale or a reddish or bluish color.			
VERY RARE			
Myocardial infarction also known as heart attack: pressure, tightness, pain or a squeezing sensation in chest or arms that may spread to neck, jaw or back, nausea, heartburn or abdominal pain, shortness of breath, lightheadedness or sudden dizziness.			✓
Pulmonary embolism (blood clot in lungs): sudden shortness of breath or sudden chest pain that may be worse with breathing or coughing, coughing blood.			✓
Transient ischemic attack (TIA) / Cerebrovascular accident also known as stroke: severe and sudden headache, sudden numbness / weakness / paralysis, sudden trouble walking, talking or understanding, sudden trouble seeing / blurred vision in one or both eyes, loss of balance / lack of coordination.			✓
Visual impairment: sudden partial or complete loss of vision.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store Osphe^{na} at room temperature between 15°C to 30°C.

Keep out of reach and sight of children.

If you want more information about Osphe^{na}:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website (<https://www.duchesnay.com/en/>), or by calling 1-888-666-0611.

This leaflet was prepared by Duchesnay Inc.

Last Revised JUL 15, 2021