Ospemifene (os-pe-mif-een)
Osphena

**Classification**
Therapeutic: Hormones
Pharmacologic: Estrogen agonists/antagonists

**Pregnancy Category** X

**Indications**
Moderate to severe dyspareunia due to menopausal vulvar/vaginal atrophy.

**Action**
Site-specific (estrogen-like) effects on the endometrium of the uterus; effects are tissue-specific. Therapeutic Effects: Decreased dyspareunia.

**Pharmacokinetics**
Absorption: Well absorbed following oral administration; food enhances absorption 2-3 fold.
Distribution: Unknown.
Protein Binding: 99%.
Metabolism and Excretion: Mostly metabolized by the liver (CYP3A4 and CYP2C9 enzyme systems); 75% excreted in feces, 7% in urine as metabolites; minimal amounts excreted unchanged in urine.
Half-life: 26 hr.

**TIME/ACTION PROFILE (improvement in symptoms)**
- **ROUTE**
  - **ONSET**
    - PO: unknown
  - **PEAK**
    - unknown
  - **DURATION**
    - unknown

**Contraindications/Precautions**
Contraindicated in: Undiagnosed/abnormal genital bleeding; History/suspicion of estrogen-dependent cancer; History of current/active DVT/PE/MIs/cardiovascular/arterial thromboembolic pathology; Concurrent endogenous estrogen agonist/antagonist use; Concurrent rifampin use; Concurrent fluconazole use.

**Adverse Reactions/Side Effects**
CV: STROKE, DEEP VEIN THROMBOSIS/PE.
GU: ENDOMETRIAL CANCER, genital/vaginal discharge.
Derm: hot flush, hyperhydrosis.
MS: muscle spasms.

**Interactions**
Drug-Drug: Blood levels, effects and risk of adverse reactions ↑ by Fluconazole, avoid concurrent use. Blood levels and effects may be ↓ by ketoconazole or other drugs that inhibit the CYP3A4 or CYP2C9 enzyme systems. Blood levels and beneficial effects ↓ by rifampin, avoid concurrent use. Avoid concurrent use of other estrogens or estrogen agonist/antagonists due to estrogen effects. May displace or be displaced by other drugs that are highly protein bound.

**Route/Dosage**
PO (Adults): 60 mg once daily with food.

**NURSING IMPLICATIONS**

**Assessment**
- Assess amount of pain during intercourse prior to and periodically during therapy.
- Determine methods previously used to treat dyspareunia.
- Assess BP before and periodically during therapy.

**Potential Nursing Diagnoses**
- Sexual dysfunction, related to medication regimen (Patient/Family Teaching)

**Implementation**
- PO: Administer once daily with/without food.

**Patient/Family Teaching**
- Encourage patient to take medication as directed. Advise patient to read Patient Information Sheet before starting therapy and with each Rx refill in case of changes.
- Advise patient to report signs and symptoms of unusual vaginal bleeding, changes in vision or speech, sudden new severe headaches, severe muscle cramps, or severe fluid retention.

**Side Effects**
- *Common* side effects include:
  - Hot flushes
  - Headaches
  - Swelling
- *Rare* side effects include:
  - Disturbance of vision

**Use Cautiously in:** Patients with risk factors for cardiovascular disease, arterial vascular disease or venous thromboembolism (including hypertension, obesity, family history, tobacco use, diabetes mellitus, history of DVT or pulmonary embolism, known or suspected breast cancer, severe hepatic impairment).

**Adverse Reactions/Side Effects**

**Interactions**
Drug-Drug: Blood levels, effects and risk of adverse reactions ↑ by Fluconazole, avoid concurrent use. Blood levels and effects may be ↓ by Ketoconazole or other drugs that inhibit the CYP3A4 or CYP2C9 enzyme systems. Blood levels and beneficial effects ↓ by Rifaximin, avoid concurrent use. Avoid concurrent use of other estrogens or estrogen agonist/antagonists due to estrogen effects. May displace or be displaced by other drugs that are highly protein bound.

**Route/Dosage**
PO (Adults): 60 mg once daily with food.

**NURSING IMPLICATIONS**

**Assessment**
- Assess amount of pain during intercourse prior to and periodically during therapy.
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Notify patient that ospemifene may cause hot flashes, vaginal discharge, muscle spasm, and increased sweating.

- Inform patient that patients who still have a uterus should discuss addition of progestin with health care professional.
- Instruct patient to notify health care professional of all Rx or OTC medications, vitamins, or herbal products being taken and consult health care professional before taking any new medications.
- Advise patient to notify health care professional of medication regimen before treatment or surgery.
- Women should be monitored for breast and uterine cancer (pelvic exam, breast exam, mammogram) at least yearly.
- Caution patient that cigarette smoking, high BP, high cholesterol, diabetes, and being overweight during estrogen therapy may increase risk of heart disease.
- Ospemifene should not be taken during pregnancy. Instruct patient to notify health care professional immediately if pregnancy is planned or suspected or if breast feeding.
- Advise patient to discuss dose and need for ospemifene every 3–6 months.

**Evaluation/Desired Outcomes**

- Decrease in pain during intercourse.