

(<https://www.aphadruginfoline.com>)

[Home](#) > Ospemifene gains new indication for moderate to severe vaginal dryness

Generic Name:

Ospemifene

Trade Name:

Osphena

Company:

Duchesnay

Notes:

[Duchesnay](#) announced FDA approval of ospemifene, an oral, nonhormonal treatment for moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA) due to menopause. Ospemifene helps improve specific vaginal tissues by increasing superficial cells, decreasing parabasal cells, and reducing vaginal pH.

Prior to this approval, ospemifene was indicated only for treatment of moderate to severe dyspareunia, also a symptom of VVA due to menopause.

Approval was based on a Phase III, randomized, double-blind, placebo-controlled multicenter study evaluating the efficacy and safety of ospemifene in patients with moderate to severe vaginal dryness.

Dosage is one 6-mg tablet taken orally once daily with food.

Common adverse effects include hot flushes or flashes, vaginal discharge, muscle spasms, headache, excessive sweating, heavy vaginal bleeding, and night sweats.

Serious but less common adverse effects can include stroke, blood clots, and endometrial cancer.

Medication Monitor Categories:

[Supplemental Approvals](#)

Source URL: <https://www.aphadruginfoline.com/supplemental-approvals/ospemifene-gains-new-indication-moderate-severe-vaginal-dryness>