

## Effects of Ospemifene on Genitourinary Health: Prospective Vulvar-Vestibular Photography and Direct Assessments in Post-Menopausal Women

ROSEMONT, PA. June 5, 2019 – Duchesnay Inc., a pharmaceutical company specializing in women’s health, is pleased to announce the publication of a [study](#) showing improvements in vulvovaginal health with ospemifene as assessed by prospective vulvar-vestibular photography and other direct visual assessments. This data was obtained during a large phase 3, randomized, double-blind, placebo-controlled multicenter trial which showed that ospemifene was effective and well tolerated for the treatment of moderate-to-severe vaginal dryness in postmenopausal women with vulvo-vaginal atrophy (VVA). Duchesnay USA markets Osphe<sup>®</sup>na (ospemifene) in the U.S.

This 12-week double blind, multi-institutional, prospective clinical pivotal phase three trial utilized, for the first time, vulvar and vestibular photography to evaluate the effects of ospemifene on the vulva and vagina in postmenopausal women (aged 40 to 80 years) with moderate to severe vaginal dryness as their most bothersome symptom (MBS).

The [study](#) concluded that following treatment with ospemifene, improvements in vulvovaginal health were observed using vulvar-vestibular photography and other direct visual assessments. The results support not only the efficacy of ospemifene in the treatment of moderate to severe vaginal dryness due to menopause, but also the use of photographic and direct visual evaluations in future clinical trials.

*“For the first time, we can demonstrate that oral ospemifene improves genital tissue health using vulvar and vestibular photography. Photographs showed improvements of vulvar vaginal tissues including increases in moisture of vestibular tissue. We are very encouraged by these observations and hope that further studies of menopausal drug treatments will use the same outcome assessment of visual results of vulvar and vestibular photography,”* added Dr. Irwin Goldstein, one of the study’s authors who received the International Pelvic Pain Society’s 2018 Top Poster Award.

Read the complete article [here](#).

For more information about Osphe<sup>®</sup>na, including Important Safety Information, including **Boxed Warning regarding Endometrial Cancer and Cardiovascular Disorders**, and Full Prescribing Information, please visit [osphe<sup>®</sup>na.com](http://osphe<sup>®</sup>na.com).

**Full disclosure:** Two authors of this study are employed by Duchesnay Inc. and were employed by the company at the time of the study.

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### IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING AND INDICATION

#### Indication: What is Osphe<sup>®</sup>na?

Osphe<sup>®</sup>na is a prescription oral pill that treats:

- moderate to severe painful intercourse
- moderate to severe vaginal dryness, symptoms of changes in and around your vagina, due to menopause.

**WARNING: ENDOMETRIAL CANCER AND CARDIOVASCULAR DISORDERS**

Osphena® works like estrogen in the lining of the uterus (endometrium), but can work differently in other parts of the body. Taking estrogen alone or Osphena® may increase your chance for getting cancer of the lining of the uterus. Vaginal bleeding after menopause may be a warning sign of cancer of the lining of the uterus. Your healthcare provider should check any unusual vaginal bleeding to find out the cause, so tell him or her right away if this happens while you are using Osphena®.

Osphena® may increase your chances of having a stroke or blood clots.

You and your healthcare provider should talk regularly about whether you still need treatment with Osphena®.

Call your healthcare provider right away if you have unusual vaginal bleeding, changes in vision or speech, sudden new severe headaches, and pains in your chest or legs with or without shortness of breath, weakness and fatigue.

**Who should not take OSPHENA?**

Osphena® should not be used if you have unusual vaginal bleeding, have or have had certain types of cancers (including cancer of the breast or uterus), have or have had blood clots, had a stroke or heart attack, have severe liver problems, are allergic to Osphena® or any of its ingredients, or think you may be pregnant. Tell your healthcare provider if you are going to have surgery or will be on bed rest.

**POSSIBLE SIDE EFFECTS**

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

- stroke
- blood clots
- cancer of the lining of the uterus

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

- hot flashes or flashes
- headache
- heavy vaginal bleeding (vaginal hemorrhage)
- vaginal discharge
- excessive sweating
- night sweats
- muscle spasms
- (hyperhidrosis)

**Tell your healthcare provider about all of the medicines and supplements you take, as some medicines may affect how Osphena® works. Osphena® may also affect how other medicines work.**

**Duchesnay USA encourages you to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

**About Duchesnay**

Duchesnay is a specialty pharmaceutical company with a long-standing commitment to women's health. The company focuses on filling the void in terms of scientific research and education and on developing pharmacological solutions that are safe and effective for use during pregnancy and breastfeeding. Duchesnay also commercializes a broad portfolio of products to offer safe and effective therapeutic options that meet the health and quality of life needs of women and their family members at various stages of their lives. For more information, visit [DuchesnayUSA.com](http://DuchesnayUSA.com).

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