

# High rates of satisfaction for applicator free local estrogen softgel ovule

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A new investigational delivery method for localized vaginal estrogen therapy that utilizes an applicator free softgel to alleviate moderate-to-severe vaginal pain during intercourse (dyspareunia), a symptom of vulvar and vaginal atrophy (VVA), received high rates of patient satisfaction among post-menopausal women, according to post-trial survey results published in the journal *Menopause*.

"These survey results show that something as simple as a change to a more elegant delivery system that is easier to use and not messy might empower more post-menopausal women to seek prescription [treatment](#) for VVA, and perhaps help them stay with the application guidelines for longer," said study first author Sheryl Kingsberg, PhD, Division Chief, OB/GYN Behavioral Medicine, UH Cleveland Medical Center; Professor of Obstetrics and Gynecology and Psychiatry, Case Western Reserve University School of Medicine; and first author of the survey analysis. "We still have to find better ways to educate the millions of women suffering with VVA about the symptoms, however, so that more of them know it is common, decide to discuss treatment with their healthcare professional, and seek symptom relief with appropriate treatment."

The new results were part of a multi-center randomized, placebo-controlled phase 3 clinical trial for TX004HR, an investigational bio-identical 17 $\beta$ -estradiol applicator free vaginal softgel capsule. Previous publications have shown TX004HR to be safe and effective at alleviating symptoms of VVA. The survey, which included 731 respondents with a

96 percent response rate, sought to quantify participants' satisfaction with the application method and overall treatment delivery system. The majority of women taking either TX004HR or placebo (85.4 - 92.1 percent) found the product easy to use.

VVA is a chronic condition associated with genitourinary syndrome of menopause (GSM). VVA affects 50 to 70 percent of post-menopausal women, and is characterized by pain with sexual activity, dryness, and discomfort. Current on-the-market treatments for VVA include both over-the-counter creams and moisturizers as well as several safe and effective prescription treatments in cream, tablet, ring or oral form.

Previous survey research completed by Dr. Kingsberg and others has shown that while 32 million women may be experiencing symptomatic VVA and suffering from related impacts on sexual function, interpersonal relationships, self-esteem and overall quality of life, only 7 percent are currently using a prescription therapy to alleviate symptoms. Though they may suffer from physical and emotional pain as a result of VVA, [women](#) may not feel comfortable discussing these symptoms with a healthcare professional, may not recognize the symptoms as treatable, may not fully understand the treatment options available, or if they did receive treatment, found the current prescription treatment options inconvenient, messy, or uncomfortable to use.

Provided by University Hospitals Cleveland Medical Center

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