

 **Imvexxy**[®]
(estradiol vaginal inserts)
4 mcg • 10 mcg

EFFECTIVE DYSpareunia RELIEF INSIDE AND OUTSIDE

WITHOUT MESSY ADMINISTRATION¹⁻⁴



Proven efficacy inside and outside the vagina with onset of action as early as 2 weeks^{1,2,4,5*}



Applicator-free and mess-free administration¹⁻³



The only ultra-low-dose vaginal estradiol available in both 4-mcg and 10-mcg doses^{1,6}

*Secondary endpoint from a 12-week clinical trial.²

**COVERED BY MOST
INSURANCE PLANS⁷**

Eligible patients may pay as little as

\$35[†]
Per Rx

†Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs (including any state pharmaceutical assistance programs). Please see program terms, conditions and eligibility criteria at savings.imvexxy.com.

IMPORTANT SAFETY INFORMATION

**WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS,
BREAST CANCER and PROBABLE DEMENTIA**

See full prescribing information for complete boxed warning.

Estrogen-Along Therapy

- There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens
- Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia
- The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT)
- The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

Please note that this information is not comprehensive. Please click [here](#) for the Full Prescribing Information, including BOXED WARNING.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER and PROBABLE DEMENTIA

See full prescribing information for complete boxed warning.

Estrogen Plus Progestin Therapy

- **Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia**
- **The WHI estrogen plus progestin substudy reported increased risks of stroke, DVT, pulmonary embolism (PE) and myocardial infarction (MI)**
- **The WHI estrogen plus progestin substudy reported increased risks of invasive breast cancer**
- **The WHIMS estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older**

CONTRAINDICATIONS

- IMVEXXY (estradiol vaginal inserts) is contraindicated in women with any of the following conditions: undiagnosed abnormal genital bleeding; known, suspected, or history of breast cancer; known or suspected estrogen-dependent neoplasia; active DVT, PE, or history of these conditions; active arterial thromboembolic disease or a history of these conditions; known anaphylactic reaction or angioedema to IMVEXXY; known liver impairment or disease; known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders.

WARNINGS AND PRECAUTIONS

- IMVEXXY is intended only for vaginal administration. Systemic absorption may occur with the use of IMVEXXY.
- The use of estrogen-alone and estrogen plus progestin therapy has been reported to result in an increase in abnormal mammograms requiring further evaluation.
- The WHI estrogen plus progestin substudy reported a statistically non-significant increased risk of ovarian cancer. A meta-analysis of 17 prospective and 35 retrospective epidemiology studies found that women who used hormonal therapy for

menopausal symptoms had an increased risk for ovarian cancer. The exact duration of hormone therapy use associated with an increased risk of ovarian cancer, however, is unknown.

- Other warnings include: gallbladder disease; severe hypercalcemia, loss of vision, severe hypertriglyceridemia or cholestatic jaundice.
- Estrogen therapy may cause an exacerbation of asthma, diabetes mellitus, epilepsy, migraine, porphyria, systemic lupus erythematosus, and hepatic hemangiomas and should be used with caution in women with these conditions.
- Women on thyroid replacement therapy should have their thyroid function monitored.

ADVERSE REACTIONS

- The most common adverse reaction with IMVEXXY ($\geq 3\%$) was headache.

INDICATION

IMVEXXY (estradiol vaginal inserts) is an estrogen indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

Please note that this information is not comprehensive. Please click [here](#) for the Full Prescribing Information, including BOXED WARNING.

References: 1. Imvexxy [package insert]. Boca Raton, FL: TherapeuticsMD, Inc; 2019. 2. Constantine GD, Simon JA, Pickar JH, et al. The REJOICE trial: a phase 3 randomized, controlled trial evaluating the safety and efficacy of a novel vaginal estradiol soft-gel capsule for symptomatic vulvar and vaginal atrophy. *Menopause*. 2017;24(4):409-416 3. Simon JA, Pickar JH, Shadiack AM, et al. Physical characteristics and properties of estradiol softgel vaginal inserts. *Menopause*. 2019. doi: 10.1097/GME.0000000000001443. 4. Simon JA, Archer DF, Kagan R, et al. Visual improvements in vaginal mucosa correlate with symptoms of VVA: data from a double-blind, placebo-controlled trial. *Menopause*. 2017;24(9):1003-1010. 5. Constantine GD, Millheiser LS, Kaunitz AM, et al. Early onset of action with a 17 β -estradiol, softgel, vaginal insert for treating vulvar and vaginal atrophy and moderate to severe dyspareunia. *Menopause*. 2019;26(11). doi: 10.1097/GME.0000000000001394. 6. Data on file. Vaginal Estrogen Pls.. 7. Data on file. IMVEXXY MMIT Formulary Coverage Analysis November 2020.