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Generic Name:

Estradiol vaginal inserts

Trade Name:

Imvexxy

Company:

TherapeuticsMD

Notes:

FDA approved [estradiol vaginal inserts](#) for treatment of moderate to severe vaginal pain associated with sexual activity, a symptom of vulvar and vaginal atrophy (VVA) due to menopause. It is the only product in its therapeutic class to offer a 4-mcg and 10-mcg dose, the 4 mcg representing the lowest approved dose of vaginal estradiol available.

VVA is a component of genitourinary syndrome of menopause, which may include but is not limited to genital symptoms of dryness, burning, and irritation; sexual symptoms such as decreased lubrication, discomfort, and pain; and urinary symptoms such as urgency, dysuria, and recurrent urinary tract infections. VVA is a chronic, progressive condition that leads to distressing symptoms and can worsen if not treated.

The product's mechanism of action is re-estrogenization of the tissue in and around the vagina. The formulation ensures that it dissolves completely without mess, so patients can use it any time of day by placing the softgel capsule in the lower part of the vagina to treat the vulva and vagina.

The inserts are administered daily for 2 weeks, followed by only twice-a-week dosing.

The most common adverse reaction (incidence ?3%) and greater than placebo was headache. No clinically significant differences in adverse events were observed between treatment and placebo groups.

Medication Monitor Categories:

[Supplemental Approvals](#)

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