

NOW AVAILABLE



A new ultra-low-dose estradiol treatment for moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause¹
4-mcg and 10-mcg doses—the lowest effective doses of vaginal estradiol available¹⁻²

PRICING AND PACKAGING INFORMATION



IMVEXXY™ Starter Pack

National Drug Code: 50261-104-18 (4 mcg)

National Drug Code: 50261-110-18 (10 mcg)

Product: IMVEXXY™ (estradiol vaginal inserts)

Package size*: 18 softgel vaginal inserts (starter pack)

*An SKU for sales purposes is 1 box containing 18 softgel vaginal inserts. A pharmacist will dispense 1 box.

[†]Wholesale Acquisition Cost (WAC) means the Manufacturer's list price for the drug wholesalers, not including prompt pay, discounts, rebates or other reductions in price.

IMVEXXY™ Maintenance Pack

National Drug Code: 50261-104-08 (4 mcg)

National Drug Code: 50261-110-08 (10 mcg)

Product: IMVEXXY™ (estradiol vaginal inserts)

Package size*: 8 softgel vaginal inserts (maintenance pack)

[†]An SKU for sales purposes is 1 box containing 8 softgel vaginal inserts. A pharmacist will dispense 1 box, which is considered a 1-month cycle.

[§]Wholesale Acquisition Cost (WAC) means the Manufacturer's list price for the drug wholesalers, not including prompt pay, discounts, rebates or other reductions in price.

Wholesaler Item Codes: 4 mcg

Amerisource Bergen:

10188812 - Imvexxy 4 mcg. (18 ct.)

10188811 - Imvexxy 4 mcg. (8 ct.)

CardinalHealth:

5465943 - Imvexxy 4 mcg. (18 ct.)

5465950 - Imvexxy 4 mcg. (8 ct.)

HD Smith:

5724927 - Imvexxy 4 mcg. (18 ct.)

5724935 - Imvexxy 4 mcg. (8 ct.)

McKesson:

3923307 - Imvexxy 4 mcg. (18 ct.)

3923315 - Imvexxy 4 mcg. (8 ct.)

SMITH Drug:

856385 - Imvexxy 4 mcg. (18 ct.)

856377 - Imvexxy 4 mcg. (8 ct.)

Value Drug:

194677 - Imvexxy 4 mcg. (18 ct.)

194675 - Imvexxy 4 mcg. (8 ct.)

Wholesaler Item Codes: 10 mcg

Amerisource Bergen:

10188813 - Imvexxy 10 mcg. (18 ct.)

10188814 - Imvexxy 10 mcg. (8 ct.)

CardinalHealth:

5465927 - Imvexxy 10 mcg. (18 ct.)

5465935 - Imvexxy 10 mcg. (8 ct.)

HD Smith:

5724919 - Imvexxy 10 mcg. (18 ct.)

5724943 - Imvexxy 10 mcg. (8 ct.)

McKesson:

3923257 - Imvexxy 10 mcg. (18 ct.)

3923281 - Imvexxy 10 mcg. (8 ct.)

SMITH Drug:

855080 - Imvexxy 10 mcg. (18 ct.)

855098 - Imvexxy 10 mcg. (8 ct.)

Value Drug:

194671 - Imvexxy 10 mcg. (18 ct.)

194673 - Imvexxy 10 mcg. (8 ct.)

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.

IMPORTANT SAFETY INFORMATION

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

See full prescribing information for complete boxed warning.

Estrogen-Alone 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

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

Please see Important Safety Information continued on the following page.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

- IMVEXXY™ 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 (incidence ≥ 3 percent) and greater than placebo was headache.

Please note that this information is not comprehensive. Please see the Full Prescribing Information, including the BOXED WARNING in pocket.

References:

1. Imvexxy [package insert]. Boca Raton, FL: TherapeuticsMD, Inc; 2018.
2. Data on File, TherapeuticsMD, Inc.