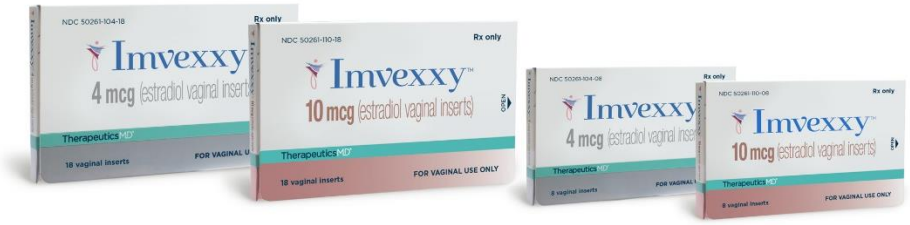
Imvexxy (estradiol)



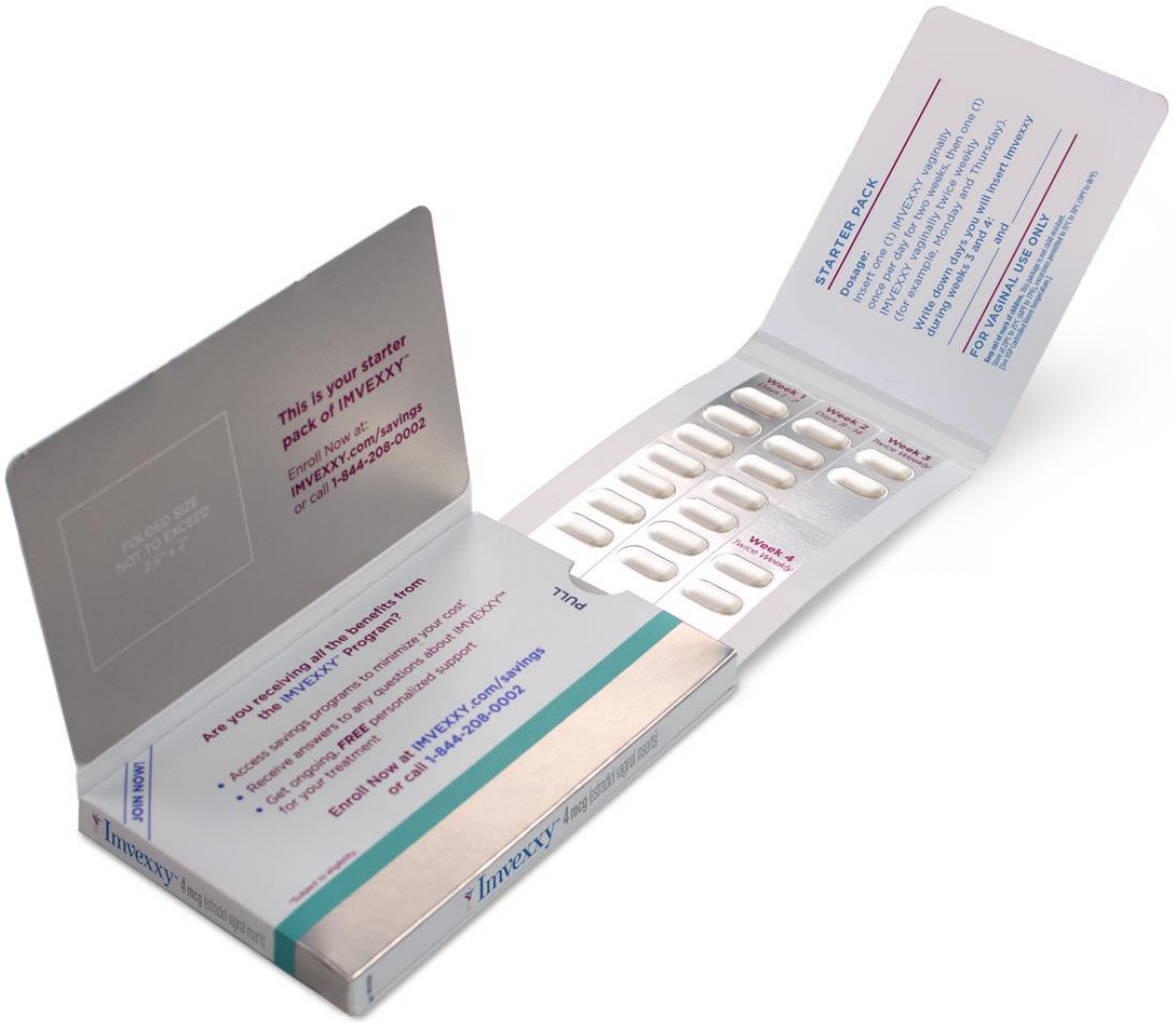
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Imvexxy
- **Generic name:** Estradiol
- **Pharmacological class:** Estrogen
- **Strength and Formulation:** 4mcg, 10mcg; vaginal inserts
- **Manufacturer:** TherapeuticsMD, Inc.
- **How supplied:** Vaginal inserts—8, 18
- **Legal Classification:** Rx

Imvexxy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PULL
JOIN NOW
Imvexxy 4 mcg estradiol vaginal inserts
STARTER PACK
Dosage:
Insert one (1) IMVEXXY vaginally once per day for two weeks, then one (1) IMVEXXY vaginally twice weekly (for example, Monday and Thursday).
Write down days you will insert Imvexxy during weeks 3 and 4:
and
FOR VAGINAL USE ONLY
Week 1
Week 2
Week 3
Week 4
Imvexxy 4 mcg estradiol vaginal inserts

Indications

- Moderate-to-severe dyspareunia due to menopause

Dosage & Administration

- Use lowest effective dose for the shortest duration
- Initially one 4mcg insert intravaginally once daily for 2 weeks, then 1 insert twice weekly every 3–4 days
- Reevaluate periodically

Considerations for Special Populations

- **Pregnancy:** Not indicated
- **Nursing mothers:** Not indicated
- **Pediatric:** Not indicated
- **Elderly:** Insufficient number studied to determine difference in response
- **Hepatic impairment:** See Contraindications

Contraindications

- Undiagnosed abnormal genital bleeding
- Known, suspected, or history of breast cancer or estrogen-dependent neoplasia
- Active DVT, PE, or history of these conditions. Active arterial thromboembolic disease (eg, stroke, MI) or a history of these conditions

Contraindications

- Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders
- Hepatic impairment or disease
- Known anaphylactic reaction or angioedema

Warnings/Precautions

- Increased risk of **endometrial carcinoma** or **hyperplasia** in women with intact uterus (adding progestin is essential)
- **Not** for prevention of cardiovascular disease or dementia
- Increased risk of cardiovascular disorders (eg, stroke, DVT, VTE); discontinue if occurs or suspected
- Manage risk factors for cardiovascular disease and venous thromboembolism appropriately

Warnings/Precautions

- Discontinue at least 4–6 weeks before surgery type associated with increased risk of thromboembolism or during prolonged immobilization
- Increased risk of breast or ovarian cancer
- Risk of probable dementia in women ≥65yrs of age
- Gallbladder disease
- Bone disease associated with hypercalcemia

Warnings/Precautions

- Visual abnormalities
- History of hypertriglyceridemia
- Discontinue if cholestatic jaundice, pancreatitis, hypercalcemia, or retinal vascular lesions occur
- Monitor thyroid function
- Conditions aggravated by fluid retention
- Hypoparathyroidism
- Endometriosis
- Hereditary angioedema

Warnings/Precautions

- Asthma
- Diabetes
- Epilepsy
- Migraine
- Porphyria
- SLE
- Hepatic hemangiomas
- Do initial complete physical and repeat annually (include Pap smear, mammogram, BP)
- Reevaluate periodically

Interactions

- May be **antagonized** by CYP3A4 inducers (eg, St. John's wort, phenobarbital, carbamazepine, rifampin)
- May be **potentiated** by CYP3A4 inhibitors (eg, erythromycin, clarithromycin, ketoconazole, itraconazole, ritonavir, grapefruit juice)

Interactions

- Concomitant **thyroid replacement**; may need to increase thyroid dose
- May interfere with **lab tests** (eg, thyroid, PT, coagulation factors, glucose tolerance, HDL/LDL, triglycerides, hormone concentrations, other binding or plasma proteins)

Adverse Reactions

- Headache
- Thromboembolism
- Neoplasms

Mechanism of Action

- Circulating estrogens modulate the pituitary secretion of the gonadotropins, luteinizing hormone (LH) and follicle stimulating hormone (FSH), through a negative feedback mechanism

- Estrogens act to reduce the elevated levels of these hormones seen in postmenopausal women

Clinical Studies

- The safety and efficacy of Imvexxy on moderate to severe dyspareunia were examined in a 12-week, randomized, double-blind, placebo-controlled, parallel-group trial (N=574) of generally healthy postmenopausal women aged 40 to 75 years

Clinical Studies

- Women were assigned to placebo, Imvexxy 4mcg or Imvexxy 10mcg
- All were assessed for improvement in the mean change from baseline to week 12 for:
  - Most bothersome moderate to severe symptom of dyspareunia
  - Percentage of vaginal superficial and percentage of vaginal parabasal cells on vaginal smear
  - Vaginal pH

Clinical Studies

- Results showed Imvexxy 4mcg and 10mcg inserts were **statistically superior** vs placebo in reducing the severity of moderate to severe dyspareunia at week 12
  - Imvexxy 4mcg: -1.52 (*P* =.0149)
  - Imvexxy 10mcg: -1.69 *(P* <.0001)
  - Placebo: -1.28

Clinical Studies

- A **statistically significant increase** in the percentage of superficial cells and a corresponding **statistically significant decrease** in the percentage of parabasal cells on a vaginal smear were also seen for Imvexxy 4mcg and 10mcg (*P* <.0001)

Clinical Studies

- The mean reduction in vaginal pH between baseline and week 12 was also statistically significant for Imvexxy 4mcg and 10mcg (*P* <.0001)

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/imvexxy/drug/34845/