Bijuva (estradiol, progesterone)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Bijuva
- **Generic name:** Estradiol, progesterone
- **Pharmacological class:** Estrogen + progestin
- **Strength and Formulation:** 1mg/100mg capsules
- **Manufacturer:** TherapeuticsMD, Inc.
- **How supplied:** Blister pack—30 capsules
- **Legal Classification:** Rx

Bijuva

Indication

- Moderate to severe **vasomotor symptoms due to menopause** in women with a uterus

Dosage & Administration

- Use lowest effective dose and for the shortest duration
- Take with food
- 1 cap daily in the evening

Considerations for Special Populations

- **Pregnancy:** not indicated for use in pregnancy
- **Nursing mothers:** not indicated for use in females of reproductive potential
- **Pediatric:** not indicated in children
- **Elderly:** not enough data to determine whether those >65 years old differ from younger women in their response
- **Renal impairment:** estrogens and progestins may cause some degree of fluid retention
- **Hepatic impairment:** see Contraindications

Contraindications

- Undiagnosed abnormal genital bleeding
- Breast or other estrogen-dependent neoplasms
- Active DVT, PE, or history of
- Active arterial thromboembolic disease, or history of
- Known hepatic impairment or disease
- Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders

Warnings/Precautions

- Not for prevention of cardiovascular disease or dementia
- Increased risk of cardiovascular events (eg, MI, stroke, VTE); discontinue if occurs or suspected
- Manage risk factors for cardiovascular disease and/or venous thromboembolism appropriately
- Discontinue at least 4–6 weeks before surgery type associated with increased risk of thromboembolism or during prolonged immobilization

Warnings/Precautions

- Increased risk of endometrial cancer in women with intact uterus (adding progestins has been shown to reduce endometrial hyperplasia risk)
- Breast or ovarian cancer
- Risk of probable dementia in women ≥65yrs of age
- Gallbladder disease
- Severe hypercalcemia in breast cancer or bone metastases
- Visual abnormalities

Warnings/Precautions

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

Warnings/Precautions

- Hereditary angioedema
- Asthma
- Diabetes
- Epilepsy
- Migraine
- Porphyria
- SLE
- Hepatic hemangiomas
- Perform yearly breast exams (including mammography)
- Reevaluate periodically

Interactions

- May be **potentiated by CYP3A4 inhibitors** (eg, erythromycin, clarithromycin, ketoconazole, itraconazole, ritonavir, grapefruit juice)
- May be **antagonized by CYP3A4 inducers** (eg, phenobarbital, carbamazepine, rifampin, St. John's wort)
- Concomitant **thyroid replacement**; may need to increase thyroid dose

Interactions

- May interfere with **lab tests** (eg, thyroid, PT, coagulation factors, glucose tolerance, HDL/LDL, triglycerides, hormone concentrations, other binding or plasma proteins)

Adverse Reactions

- **Most common** (incidence ≥3% of women and greater than placebo): breast tenderness, headache, vaginal bleeding, vaginal discharge and pelvic pain
- **Others**: thromboembolism, neoplasms

Mechanism of Action

- Bijuva is the first bio-identical hormone therapy combining estradiol and progesterone in a single capsule

- Compared with synthetic hormone products, the estradiol and progesterone found in Bijuva are structurally identical to the hormones naturally circulating in the body

Clinical Studies

- The effectiveness and safety of Bijuva on moderate to severe vasomotor symptoms due to menopause were examined in a 12-week randomized, double-blind, placebo-controlled substudy of a single 52-week safety study

- A total of 726 postmenopausal women were randomized to multiple dose combinations of estradiol and progesterone, and placebo

Clinical Studies

- The **co-primary efficacy endpoints** included:
  - mean weekly reduction in frequency of moderate to severe vasomotor symptoms with Bijuva vs placebo at Weeks 4 and 12; a clinically meaningful threshold for the reduction in frequency of vasomotor symptoms, defined as 14 vasomotor symptoms per week above placebo, was applied
  - mean weekly reduction in severity of moderate to severe vasomotor symptoms with Bijuva compared with placebo at Weeks 4 and 12

Clinical Studies

- Bijuva was associated with a statistically significant reduction in both the frequency and severity of moderate to severe vasomotor symptoms vs placebo
- **Frequency**:
  - Week 4: -40.6 vs -26.4; difference from placebo: -12.81; *P*<.001
  - Week 12: -55.1 vs -40.2; difference from placebo -16.58; *P*<.001
- **Severity**:
  - Week 4: -0.48 vs -0.34; difference from placebo: -0.13; *P*=.031
  - Week 12: -1.12 vs -0.56; difference from placebo: -0.57; *P*<.001

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/bijuva/