

# Learn more about BIJUVA®

(estradiol and progesterone) 0.5 mg/100 mg and 1 mg/100 mg capsules

Presented by: Macy Saunders, MSN, APRN

When: Thursday, December 11, 2025 at 6:15 PM EST

Where: Ruth's Chris Steak House

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Hosted by: Adrienne Soliday at 904-518-9719

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If you would like to join us for this live program,

please RSVP 1 week prior: https://mayne.pharmagin.com/reg/Bijuva-BL200795 or scan:





## Speaker Biography:

Ms. Macy Saunders is an advanced practice nurse practitioner who is passionate about caring for women across the lifespan, though she does have a special place in her heart for providing a safe and comfortable place for girls nervous about seeing an OB/GYN for the first time. Macy is certified through AAFE in aesthetics and offers both Botox and fillers — she loves highlighting natural beauty and making her patients feel their best. You can count on her to always provide compassionate, thorough care. Macy earned her bachelor's in education from Florida State University before pursuing a nursing degree and subsequent master's in nursing from Jacksonville University. When not in the office, you'll find her spending time with her husband and two precious children.

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### IMPORTANT SAFETY INFORMATION FOR BIJUVA® (estradiol and progesterone) 0.5 mg/100 mg and 1 mg/100 mg capsules

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

See full prescribing information for complete boxed warning.

Estrogen Plus Progestin Therapy

- •The Women's Health Initiative (WHI) estrogen plus progestin substudy reported increased risks of pulmonary embolism (PE), deep vein thrombosis (DVT), stroke, and myocardial infarction (MI)
  •The WHI estrogen plus progestin substudy reported increased risks of invasive breast cancer
- •The WHI Memory Study (WHIMS) estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older
- •Do not use estrogen plus progestogen therapy for the prevention of cardiovascular disease or dementia

- Estrogen-Alone Therapy

  There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens
- •The WHI estrogen-alone substudy reported increased risks of stroke and DVT
- •The WHIMS estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

Please see additional Important Safety Information on next page.





#### **IMPORTANT SAFETY INFORMATION** (continued)

#### **INDICATION**

BIJUVA® (estradiol and progesterone) is a combination of an estrogen and progesterone indicated in a woman with a uterus for the treatment of moderate to severe vasomotor symptoms due to menopause.

#### **CONTRAINDICATIONS**

- Undiagnosed abnormal genital bleeding
- Breast cancer or a history of breast cancer
- Estrogen-dependent neoplasia
- Active DVT, PE, or history of these conditions
- Active arterial thromboembolic disease (for example, stroke and MI), or a history of these conditions
- Known anaphylactic reaction, angioedema, or hypersensitivity to BIJUVA
- Hepatic impairment or disease
- Protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders

#### **WARNINGS AND PRECAUTIONS**

- Increased risks of PE, DVT, stroke, and MI are reported with estrogen plus progestin therapy. Should these occur or be suspected, therapy should be discontinued immediately. Manage appropriately any risk factors for arterial vascular disease and/or venous thromboembolism (VTE).
- The WHI substudy of daily estrogen plus progestin after a mean follow-up of 5.6 years reported an increased risk of invasive breast cancer. One large meta-analysis of prospective cohort studies reported increased risks that were dependent upon duration of use and could last up to >10 years after discontinuation of estrogen plus progestin therapy and estrogen-alone therapy. Extension of the WHI trials also demonstrated increased breast cancer risk associated with estrogen plus progestin therapy.
- The use of estrogen-alone and estrogen plus progestin therapy has been reported to result in an increase in abnormal mammograms requiring further evaluation.
- Endometrial hyperplasia (a possible precursor to endometrial cancer) has been reported to occur at a rate of approximately 1 percent or less with BIJUVA. Clinical surveillance of all women using estrogen-alone or estrogen plus progestogen therapy is important. Adequate diagnostic measures should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding with unknown etiology.
- 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.
- In the WHI Memory Study (WHIMS) estrogen plus progestin ancillary studies of postmenopausal women 65 to 79 years of age, there was an
  increased risk of developing probable dementia in women receiving estrogen plus progestin when compared to placebo. It is unknown whether
  these findings apply to younger postmenopausal women.
- Estrogens increase the risk of gallbladder disease.
- Discontinue estrogen if severe hypercalcemia, loss of vision, severe hypertriglyceridemia, or cholestatic jaundice occurs.
- Monitor thyroid function in women on thyroid replacement hormone therapy.

#### **ADVERSE REACTIONS**

The most common adverse reactions ( $\geq$ 3%) with BIJUVA capsules, 0.5 mg/100 mg and 1 mg/100 mg, respectively are breast tenderness (4.0%/10.4%), headache (4.0%/3.4%), nausea (3.5%/2.2%), vaginal bleeding (2.4%/3.4%), vaginal discharge (1.9%/3.4%) and pelvic pain (2.8%/3.1%).

Please note that this information is not comprehensive. Please see Full Prescribing Information, including BOXED WARNING, at BIJUVA.com/pi.pdf.

