

IMPORTANT RISK INFORMATION

Most important information you should know about BIJUVA™ (estradiol and progesterone) capsules:

- Do not use estrogens with or without progestogens to prevent heart disease, heart attacks, strokes, or dementia (decline of brain function).
- Taking estrogens with progestogens may increase your chances of getting heart attacks, strokes, breast cancer, or blood clots.
- Taking estrogens with progestogens may increase your chance of getting dementia, based on a study of women 65 years of age or older.
- Taking estrogen-alone may increase your chance of getting cancer of the uterus.
- Taking estrogen-alone may increase your chances of getting strokes or blood clots.
- Taking estrogen-alone may increase your chance of getting dementia, based on a study of women 65 years of age or older.
- You and your healthcare provider should talk regularly about whether you still need treatment with BIJUVA.

DO NOT USE BIJUVA IF YOU

- Have had your uterus (womb) removed (hysterectomy). BIJUVA contains progesterone to decrease the chance of getting cancer of the uterus. If you do not have a uterus, you do not need progesterone and you should not take BIJUVA.
- Have any unusual vaginal bleeding. Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb). Your healthcare provider should check any unusual vaginal bleeding to find out the cause.
- Currently have or have had certain cancers. Estrogens may increase the chances of getting certain types of cancers, including cancer of the breast or uterus. If you have or have had cancer, talk with your healthcare provider about whether you should take BIJUVA.
- Currently have or have had blood clots.
- Had a stroke or heart attack.
- Currently have or have had liver problems.
- Have been diagnosed with a bleeding disorder.
- Are allergic to BIJUVA or any of its ingredients.

WARNINGS

Ask a doctor before use if you:

- Have high levels of fat in your blood (triglycerides).
- Have any unusual vaginal bleeding.
- Have certain medical conditions that may become worse while you are taking BIJUVA, such as: asthma (wheezing); diabetes; epilepsy (seizures); migraine; a genetic problem called porphyria; lupus; hypertension (high blood pressure); have high calcium in your blood; endometriosis; angioedema (swelling of face or

tongue); problems with your heart, liver, thyroid or kidneys.

- Are going to have surgery or will be on bed rest.
- Are pregnant or think you may be pregnant. BIJUVA is not for pregnant women.
- Are breastfeeding.

Tell your doctor or pharmacist about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

WHEN USING BIJUVA, YOU MAY HAVE

- Breast tenderness • Headache • Vaginal bleeding • Vaginal discharge • Pelvic pain

Call your doctor right away if you get any of the following warning signs:

- New breast lumps
- Unusual vaginal bleeding
- Changes in vision or speech
- Sudden new severe headaches
- Severe pains in your chest or legs with or without shortness of breath, weakness and fatigue
- Vomiting

USE

BIJUVA is a prescription medicine that contains two hormones, estrogen and progesterone. BIJUVA is used after menopause to reduce moderate to severe hot flashes in women with a uterus.

The risk information provided here is not complete. To learn more, review the BIJUVA Patient Information and talk about BIJUVA with your healthcare provider or pharmacist. The FDA-approved product labeling, including Patient Information, can be found at www.BIJUVA.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [MedWatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088. You may also report side effects to TherapeuticsMD® at 1-888-228-0150.