Generic Name:
Estradiol and progesterone capsules
Trade Name:
Bijuva
Company:
TherapeuticsMD
Notes:

FDA approved Bijuva (TherapeuticsMD), the first bioidentical oral hormone combination of estradiol and progesterone (1-mg/100-mg capsule) to treat moderate to severe hot flashes in women with a uterus.

Approval was based on the Phase III Replenish Trial, in which Bijuva demonstrated a statistically significant reduction from baseline in both the frequency and severity of hot flashes compared with placebo, while reducing the risks to the endometrium.

The most common adverse reactions (?3%) were breast tenderness, headache, vaginal bleeding, vaginal discharge, and pelvic pain. No clinically significant changes were found in lipid, coagulation, or glucose parameters compared with placebo, and no unexpected safety signals were noted.

The recommended dosage is one tablet orally each evening with food.

Bijuva comes with a boxed warning; see the prescribing information for more information.

The drug will be available in the United States in the second quarter of 2019.

Medication Monitor Categories:
New Drug Approvals