

BIJUVA® 1/100

estradiol (as hemihydrate) and progesterone

Consumer Medicine Information

The Women's Health Initiative (WHI) trial examined the health benefits and risks of combined estrogen plus progestogen therapy (n=16,608) and estrogen-alone therapy (n=10,739) in postmenopausal women aged 50 to 79 years. The estrogen plus progestogen arm of the WHI trial indicated an increased risk of myocardial infarction (MI), stroke, invasive breast cancer, pulmonary embolism and deep vein thrombosis in postmenopausal women receiving treatment with combined conjugated equine estrogens (CEE, 0.625 mg/day) and medroxyprogesterone acetate (MPA, 2.5 mg/day) for 5.2 years compared to those receiving placebo.

The estrogen-alone arm of the WHI trial indicated an increased risk of stroke and deep vein thrombosis in hysterectomised women treated with CEE-alone (0.625 mg/day) for 6.8 years compared to those receiving placebo. Other doses of oral conjugated estrogens with medroxyprogesterone acetate, and other combinations and dosage forms of estrogens and progestogens were not studied in the WHI clinical trials and, in the absence of comparable data, these risks should be assumed to be similar.

Therefore, the following should be given serious consideration at the time of prescribing:

Estrogens with or without progestogens should not be prescribed for primary or secondary prevention of cardiovascular diseases.

Estrogens with or without progestogens should be prescribed at the lowest effective dose for the approved indication.

Estrogens with or without progestogens should be prescribed for the shortest period possible for the approved indication.

For the prevention of osteoporosis, estrogen treatment should be considered in light of other available therapies.

This leaflet provides important information about using BIJUVA 1/100. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BIJUVA 1/100.**

Where to find information in this leaflet:

1. Why am I using BIJUVA 1/100?
2. What should I know before I use BIJUVA 1/100?
3. What if I am taking other medicines?
4. How do I use BIJUVA 1/100?
5. What should I know while using BIJUVA 1/100?
6. Are there any side effects?
7. Product details

1. Why am I using BIJUVA 1/100?

BIJUVA 1/100 contains the active ingredients contain estradiol (as hemihydrate) and progesterone.

BIJUVA 1/100 is a Hormone Replacement Therapy (HRT).

BIJUVA 1/100 is used during continuous combined hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women who still have a uterus with at least 12 months (1 year) since their last natural period.

BIJUVA 1/100 contains two types of female hormones, an estrogen and a progestogen. During menopause, the amount of estrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). BIJUVA 1/100 alleviates these symptoms after menopause.