



Rx Only

Elestrin™

estradiol gel 0.06%

NEW



Effective low dose estrogen therapy approved for the treatment of moderate-to-severe vasomotor symptoms associated with menopause

| Trade Name | NDC | Unit Size | Amerisource | Bergen | Cardinal | McKesson | Kinray | HD Smith |
|--------------------------|--------------|-----------|-------------|--------|----------|----------|--------|----------|
| Rx Only Elestrin™ | 0482-4900-02 | 1 bottle | 5002142 | 592042 | 3980547 | 1641943 | 133256 | 2073716 |

Please see Important Product Safety Information on next page.
Visit www.elestrin.com/Package%20Inserts.pdf or call 1-800-929-9300 for Full Prescribing Information.

Manufactured for:

KENWOOD THERAPEUTICS
A DIVISION OF BRADLEY PHARMACEUTICALS, INC.

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EQ4402W-R1

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Important Product Safety Information

Close clinical surveillance of all women taking estrogens is important. Adequate diagnostic measures should be undertaken to rule out malignancy in cases of undiagnosed persistent or recurring abnormal vaginal bleeding.

Long-term continuous administration of estrogen, with or without progestin, has shown an increased risk of endometrial, breast and ovarian cancers.

Estrogens with or without progestins should not be used for the prevention of cardiovascular disease or dementia. An increased risk of developing probable dementia in postmenopausal women 65 years of age or older was reported with estrogen-alone use, as well as, in combination with progestin.

Estrogen-alone therapy has been associated with an increased risk of stroke and deep vein thrombosis. Estrogen plus progestin therapy has been associated with an increased risk of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli and deep vein thrombosis. Estrogens should be discontinued immediately if any of these events occur or are suspected.

Estrogen with or without progestin should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the patient.

An increase in gallbladder disease requiring surgery in postmenopausal women receiving estrogens has been reported. Estrogen therapy may lead to severe hypercalcemia in patients with breast cancer and bone metastases. Retinal vascular thrombosis has been reported in patients receiving estrogens.

Estrogen products should not be used in women with undiagnosed abnormal genital bleeding; known, suspected or history of breast cancer; known or suspected estrogen-dependent neoplasia; active or history of deep vein thrombosis or pulmonary embolism; active or recent (within the past year) arterial thromboembolic disease (e.g., stroke, myocardial infarction); liver dysfunction or disease; known or suspected pregnancy.

Blood pressure should be monitored during estrogen use. Caution should be exercised in patients with hypertriglyceridemia, impaired liver function or a history of cholestatic jaundice, conditions that might be influenced by fluid retention, hypocalcemia, asthma, diabetes mellitus, epilepsy, migraine, porphyria, systemic lupus erythematosus, and hepatic hemangiomas. Patients dependent on thyroid hormone replacement therapy may require increased doses of such therapy. The addition of progestin should be considered in patients with residual endometriosis post-hysterectomy. Concomitant application of sunscreen and **Elestrin™** to the same site for more than 7 days should be avoided.

The most frequently reported adverse events in clinical trials were nasopharyngitis, breast tenderness, upper respiratory tract infection, and metrorrhagia.

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