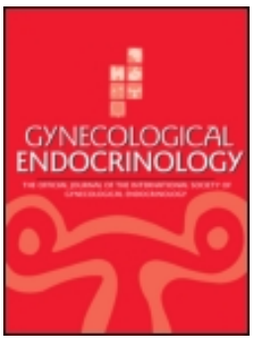

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Endometrial safety of Femoston®

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Estrogen replacement therapy increases the risk of endometrial hyperplasia and cancer, the reduction of which depends upon supplementation with progestogen. In combined hormone replacement therapy, an estrogen antagonist (progestin) is added sequentially to the estrogen treatment. Histologically, adequate progestogen response results in the disappearance of mitosis in the glandular component of the endometrium, together with a secretory transformation, or atrophic aspect, of the mucosa. Femoston® is a combined sequential treatment using 2 mg/day 17β-estradiol supplemented with 10 mg dydrogesterone (daily for 14 days every 28 days). The safety of Femoston® therapy has been assessed in 2 studies; a dydrogesterone dose–ranging study (5–20 mg dydrogesterone) and a 1-year treatment study using 10 mg dydrogesterone.

In the dose–ranging study, final endometrial histology was available for 286 women who had received at least three cycles, and 271 women who had received at least six cycles, of sequential treatment. Adequate progestational response of the endometrium was found in 94% of women in the 5 mg dydrogesterone group (lower 95% CL: 85.2); 97% in the 10 mg group (lower 95% CL: 91.6); 98% in the 15 mg group (lower 95% CL: 93.6) and 98% in the 20 mg group (lower 95% CL: 90.9). Thus, in all groups, the response rate was ≥ 94%, whilst the lower 95% CL remained above 90% in all but the 5 mg dydrogesterone group. From these data it was considered that sequential 10 mg/day dydrogesterone is the optimum dose to oppose daily 2 mg/day estradiol and confers sound endometrial protection.

In the long-term 2 mg estradiol/10 mg dydrogesterone endometrial safety study, final endometrial histology was evaluable for 146 of the 150 patients who received treatment for 1 year. The success rate for progestational response in this sample was 97%.

These two studies confirm the safety, as determined by endometrial histology, of Femoston® therapy. The combination of both these hormones within a single Femoston® tablet should also allay fears regarding increased risk of endometrial hyperplasia and neoplasia through patient non-compliance with estrogen/progestogen therapy.

Femoston®: effects on bone and quality-of-life

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Depletion in ovarian follicles at the time of the menopause, with the subsequent decline in peripheral estrogen levels, can result in the emergence of a complex syndrome, having both physical and psychological components, including climacteric symptomatology and an increased risk of osteoporotic fracture. Evidence is accumulating which confirms that hormone replacement therapy (HRT) relieves the acute symptoms of estrogen deficiency and reduces some long-term effects of estrogen depletion.

Femoston® is a new oral sequential hormone replacement whereby 2 mg of micronised 17β-estradiol is taken daily, together with 10 mg of dydrogesterone (an orally active pure progestogen), daily for two out of every four weeks. Femoston® has been shown to have beneficial effects on the acute symptoms of the climacteric, on bone, and on quality-of-life. In a long-term study of 186 post-menopausal women who received Femoston® for 1 year, De Jonge *et al.* (1993) showed a clear reduction in the percentage of women bothered by hot flushes, night sweats, attacks of diaphoresis and sleeping disturbances after six weeks, and also throughout the remainder of the study. In addition, the number of women bothered by vaginal dryness and dyspareunia also decreased over the treatment period.

The bone sparing effects of Femoston® have also been demonstrated. Haenggi *et al.* (1993) showed that, compared with untreated controls, Femoston® significantly increased bone mineral density (BMD)