

**Efficacy and safety of standard versus low-dose Femarelle (DT56a) for the treatment of menopausal symptoms.**

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**OBJECTIVE:** In a previous study treatment with a daily standard dose of Femarelle (644 mg/day) resulted in a significant elevation in bone mineral density (BMD) while a reduced dose resulted in a decrease in BMD. The aim of the current study was to examine the efficacy and safety of the two doses of Femarelle in the treatment of menopausal symptoms. **MATERIALS AND METHODS:** Eighty healthy postmenopausal women were randomly allocated to receive either the standard dose (SD) or low dose (LD) of Femarelle (644 mg/day vs 344 mg/day). A detailed medical history was taken on enrollment, followed by a physical examination, pelvic ultrasound, and sex hormone and lipid profiles. A detailed Kupperman index for each patient was completed. These measures were repeated every three months for 12 months. **RESULTS:** In both groups there was a significant reduction in the Kupperman index following 12 weeks of treatment, which was sustained throughout the 12 months of treatment ( $p < 0.01$ ). Seventy-six percent of the patients in the SD group reported a decrease in vasomotor symptoms and seventy eight % in the LD group (NS). This decrease was sustained following 12 months of treatment. There was no change in TSH and sex hormone levels or endometrial thickness during the study period. **CONCLUSIONS:** In the current study we found that menopausal symptoms were reduced similarly by LD and SD, however for the combined treatment of menopausal symptoms and osteoporosis the standard dosage of 644 mg/day of Femarelle is needed.