

SAVE IN ACUTE AND LONG-TERM TREATMENT OF SYMPTOMS IN PERIMENOPAUSAL WOMEN

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Background: ERr 731® (the special extract from the roots of *Rheum rhaponticum*) has been demonstrated as being a safe herbal extract to reduce menopausal symptoms. Results of previous publications show that ERr 731® is very well tolerated with only a few transient and mild-to-moderate adverse events (AEs). The objective of this report was to demonstrate in a confirmatory study the safety of ERr 731® in acute and long-term treatment of climacteric complaints in perimenopausal women.

Hypothesis: ERr 731® is safe and very well tolerated in acute and long-term treatment of climacteric complaints.

Study Design: A 12-week, multicenter, double-blind randomized controlled trial (DB) followed by a 1-year open-label observational phase (OS).

Methods: During the RCT, 112 symptomatic perimenopausal women were randomized to receive ERr 731® or placebo for 12 weeks. For the OS, 89 women from the RCT (44 from the ERr 731® arm and 45 from the placebo arm) agreed to take ERr 731® for 1 year. Safety parameters that were investigated included endometrial biopsy, vaginal smear, mammography, and laboratory safety parameters, as well as AEs.

Results: No endometrial hyperplasia, no increase in breast density, breast tenderness, and no clinically relevant increase in liver enzymes and other safety parameters were observed in both DB and OS. Differences between the treatment groups were not found. There were no serious AEs during DB and OS. All AEs were assessed as mild to moderate. Merely one patient during the DB experienced AEs that were assessed as being possibly related to ERr 731®. By the end of OS, all AEs had stopped. No causal relationship was reported between any AE and ERr 731®.

Conclusion: The results of the DB and OS confirmed ERr 731® to be safe in the acute and long-term treatment of climacteric symptoms in perimenopausal women.