

## Human-pharmacological investigations during treatment of climacteric complaints with *Cimicifuga racemosa* (Remifemin,):No estrogen-like effects

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Preparations based on extracts of *Cimicifuga racemosa* rootstock have proved worthwhile in therapy of neurovegetative and psychic climacteric complaints. Since binding of plant ingredients (methanolic extract) to estrogen receptors (JARRY et al., 1985) was demonstrated, it was supposed that the efficacy had been due to an estrogen-like effect.

Data of a study performed according to GCP-criteria, which indicated the therapeutical efficacy and tolerability equivalence for two different dosages of a commercial isopropanolic *Cimicifuga racemosa* extract (40 mg vs. 127 mg drug/day during 6 months), show that the supposed estrogen-like effect can, however, no longer be maintained.

The investigations in climacteric patients (n = 152, age: 43 - 60 years) show that the therapy with Remifemin, has no influence on serum concentra-

tions of LH, FSH, SHBG, Prolactin and estradiol. The degree of proliferation of vaginal mucosa does not change in an estrogenic manner while Kupperman Menopause Index is reduced clinically relevant during therapy. This is in accordance with in-vitro-investigations in estrogen-receptor positive mamma-ca cell lines (NESSELHUT et al., 1993) and an experimental study in animals (EINER-JENSEN et al., 1997).

Conclusion:

Therapy with the special *Cimicifuga racemosa* extract of Remifemin® is an effective and safe strategy for treating climacteric complaints. It is of the utmost significance for safe application of the preparation and regarding the applicability in estrogen-dependent basic diseases, that no estrogen-like effect can be derived.