



THE ISOPROPANOLIC CIMICIFUGA RACEMOSA EXTRACT ICR IS SAFE FOR BREAST AND UTERINE TISSUE

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Context & Objective: With an increasing demand for non-hormonal treatment of climacteric complaints, the use of *Cimicifuga racemosa* herbal medicinal products (MP) is gaining popularity in healthy patients as well as in patients with hormone-dependent tumors. We analyzed the relevant clinical data of the best studied MP (iCR extract) for safety at estrogen-sensitive tissue.

Methods: Publications from 1997-2017 (e.g. from MEDLINE, EMBASE, BIOSIS, EMBASE Alert) were collected and analyzed for iCR's safety at estrogen-sensitive tissue.

Patients, Interventions & Main Outcome Measures: Altogether 2,488 patients were treated with iCR extract in 21 clinical studies (thereof 10 randomized controlled trials) with relevance for the safety at estrogen-sensitive tissue. Results are reported with focus on examination of hormones, breast, uterus, tumor risk and recurrence.

Results: The intake of iCR extract does not influence hormone levels. A 6-month iCR treatment affects neither mammographic breast tissue density nor breast epithelial cell proliferation. Two further studies with 6-month treatment duration (one with 12-month follow-up) found no impact of iCR use on breast ultrasound findings. A large case-control study sponsored by the German Cancer Aid e.V. shows that iCR therapy is associated with a reduced risk for breast cancer. Breast cancer survivors taking iCR have a significantly better recurrence-free survival compared to non-iCR users. iCR extract does not increase endometrial thickness and does not cause postmenopausal vaginal bleeding. 3-month iCR treatment significantly decreases myoma volume compared to tibolone. In endometriosis patients treated with goserelin, iCR add-back therapy does not influence the endometrium. Women who were treated surgically for endometrial cancer do not experience recurrences or changes in CA 125 during 6 months of therapy with iCR and after 1 year follow-up.

Conclusions: Treatment of climacteric symptoms with iCR extract is safe at estrogen-sensitive tissue not only in otherwise healthy patients but also in women with hormone-dependent tumors. Some clinical results suggest additional beneficial effects of iCR for patients suffering from myoma or breast cancer.

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