

What Is the Evidence for Supplement Use for Menopausal Symptoms?

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A high percentage of women are using alternative therapies, particularly botanical dietary supplements to treat conditions that are "gender specific," such as menopause. Recent surveys suggest that the use of botanical dietary supplements among women of the 40-65 year age group may be as high as 80 percent, and in light of the results from the Women's Health Initiative, this trend is likely to continue. Many women are using botanicals as a source of "natural hormones" (commonly referred to as phytoestrogens) for the treatment of menopause. One such product is Actaea (syn. Cimicifuga) racemosa, commonly referred to as black cohosh for the treatment of menopausal symptoms, including hot flashes and vaginal dryness. Much of the published clinical evidence for the safety and efficacy of black cohosh is based on the utilization of a commercial extract, know as "Remifemin." In healthy subjects, this particular extract was superior to placebo, and as effective as daily administrations of low dose conjugated estrogens (0.625 mg/day). However, in breast cancer patients stratified on tamoxifen use, the extract had no effect on menopausal symptoms. Thus, in healthy subjects, this extract may be a safe and effective alternative to estrogen replacement therapy; however, it does not appear to be of benefit for the treatment of hot flashes in women with breast cancer who are currently taking tamoxifen. Trifolium repens (red clover) is another botanical used extensively by women to treat menopausal symptoms. Although red clover appears to be safe, its efficacy for the treatment of menopausal symptoms has not been conclusively demonstrated. Furthermore, red clover contains isoflavone constituents that may mimic some of the effects of steroidal estrogens, raising questions of safety, as long-term safety data on individual isoflavones or isoflavone containing extracts are not available. Considering the widespread use of red clover products for the treatment of menopausal symptoms, further clinical data are urgently needed. Both red clover and black cohosh are currently being investigated in a 1-year phase II clinical trial within the University of Illinois at Chicago (UIC)/National Institutes of Health (NIH) Center for Botanical Dietary Supplements (BDS) Research on Women's Health. The trial will assess the effects of these BDS on the management of hot flashes, but secondary outcomes to be measured include arterial compliance, bone density, and hormonal effects.

References:

Borrelli F, Ernst E. *Cimicifuga racemosa*: a systematic review of its clinical efficacy. Eur J Clin Pharmacol 2002, 58(4):235-41

Jacobson JS et al. Randomized trial of black cohosh for the treatment of hot flashes among women with a history of breast cancer. J. Clin. Oncol., 2001, 19:2739-2745.

Liske E. Therapeutic efficacy and safety of *Cimicifuga racemosa* for gynecological disorders. *Advances in Therapy*, 1998, 15:45-53.

Mahady GB, Fong HHS, Farnsworth NR. Rhizoma Cimicifugae Racemosae. *WHO Monographs* on selected medicinal plants. Volume II, WHO, Geneva, Switzerland, 2002.

Kronenberg F, Fugh-Berman A. Complementary and alternative medicine for menopausal symptoms: a review of randomized, controlled trials. *Ann Intern Med* 2002, 137(10):805-13