Archives of Internal Medicine Study
Finds One Black Cohosh Effective for Treating Menopausal Symptoms
Other Black Cohosh Studies Showed Mixed or Poor Results

A July 24 review article published in the Archives of Internal Medicine (2006;166:1453-1465) concluded that alternative and complementary therapies are generally ineffective for treating menopause-related symptoms. Among the biologically based studies, only one – on Remifemin® – out of the four black cohosh studies reviewed was shown to be effective.

“A single large trial showed a benefit for vasomotor symptoms with the black cohosh Remifemin (Enzymatic Therapy Inc., Green Bay, Wisconsin) and is consistent with older German studies,” the reviewers wrote, indicating that the remaining three studies showed no benefits from black cohosh. Results from two studies “were confounded by concurrent use of tamoxifen, known to exacerbate hot flashes,” while another used a “more unusual (research) preparation, BN01055.”

“Buyer beware” was the general conclusion of the Archives review, which clearly applies to black cohosh, since recent studies have proven that not all black cohosh products are the same. Most products in the market lack the standardization and research that can ensure efficacy and safety. An article in the Journal of Agricultural & Food Chemistry (2006;54(9):3242-53), reported that three of eleven black cohosh supplements purchased and tested in the United States did not even contain black cohosh (Actaea racemosa syn. Cimicifuga racemosa). Instead, the three contained less expensive extracts of Chinese cimicifuga (specific other Actaea spp.) that do not have all the same chemical compounds or clinical uses as the native North American plant. A fourth product indicated a probable mixture of the two plants.

Remifemin comprises a proprietary, standardized extract (uniform dosage) of pure black cohosh root called RemiSure™. It is the most OB/GYN-recommended, non-prescription menopause brand. The German E Commission has approved the use of 40 mg/ day of black cohosh (Remifemin brand) for six months for relief of menopausal symptoms, as well as for premenstrual syndrome (PMS) and dysmenorrhea.

“Remifemin is clearly the world’s most clinically tested black cohosh product,” said Mark Blumenthal, Founder and Executive Director of the American Botanical Council. “Over 15 clinical trials demonstrate the safety and efficacy of the product, manufactured according to the latest GMPs by Shaper & Bruminer GmbH, a highly respected German phytomedicine company with over 50 years of experience in manufacturing and testing Remifemin. Almost all of the scientific literature on black cohosh was conducted on Remifemin, including recent clinical trials showing no estrogenic activity of the product,” he explained.

“Smart German chemists have been working on Remifemin for over 50 years,” said Yale University School of Medicine Clinical Professor Mary Jane Minkin, MD, who recommends Remifemin as a standard alternative to HRT. “While its mechanism of action is unclear, black cohosh is one of the few products that seems to relieve hot flashes. I talk to everyone about Remifemin along with lifestyle issues like healthy diet and exercise,” she explained. “I respect the personal preferences of my patients, many of whom do not want drug intervention.” Dr. Minkin is author of A Woman’s Guide to Menopause & Perimenopause (Yale University Press, 2005).

Overview of Recent Remifemin Research

While the Archives’ review limits itself only to studies published in the English language, numerous published studies from Europe demonstrate the efficacy and safety of the proprietary Remifemin black cohosh formula. A summary of select research appears below.

Osmers’ randomized, placebo-controlled, double-blind study on 304 patients in Germany (Obstetrics & Gynecology, 2005;105:1074-83) is the large black cohosh research to which the Archives article refers. The results were similar to recent hormone replacement therapy (HRT) study results, showing that Remifemin is a safe and effective alternative to HRT for reducing menopausal symptoms. The study also refuted previously published literature suggesting possible hepatotoxicity – an extremely important point overlooked in the Archives. (Blumenthal, as well as experts from the National Institutes of Health (NIH) who participated in a black cohosh workshop in November 2004, concluded that there is inadequate evidence that black cohosh preparations are causally associated with hepatotoxicity.)

Nappi’s three-month, randomized clinical study (Gynecological Endocrinology. January 2005; 20(1): 30-35) compared Remifemin and
low-dose transdermal estradiol and found them to be comparable in reducing hot flushes and vasomotor symptoms and also in alleviating anxiety and depression.

Geller's (Journal of Women's Health. 2005;14:7) review of literature on botanical and dietary supplements for alleviating menopausal symptoms confirmed that black cohosh (viz. Remifemin) shows "great promise for relief of menopausal symptoms, primarily for treatment of vasomotor symptoms and depression, with an overall positive safety profile."

Liske's six-month, double-blind, placebo-controlled study (J Womens Health Gend Based Med. 2002 Mar;11(2):163-74) showed that Remifemin reduced menopausal symptoms by 70% in 12 weeks, including hot flashes, night sweats, mood swings, irritability, and related occasional sleeplessness. The same study showed Remifemin to be completely hormone-free and without plant-based estrogens that can affect breast and uterine cell growth. It is safe for women with a history of breast cancer who cannot take estrogen.

Vermes' larger study (Advances in Therapy. March/April 2005;22:2:148-154) measured changes in subjective symptoms of menopause among 2,016 women treated with Remifemin. The severity of symptoms was evaluated at the start and end of four, eight, and 12 weeks of treatment with an average decrease in the standard Kupperman Index of 17.64 points after 12 weeks of therapy (P<.001). Based on the weighted symptom scores, the most favorable changes were found in hot flashes (-6.31 points), sweating (-2.86 points), insomnia (-2.27 points), and anxiety (-2.00 points) (P<.001 in each case).

Bodinet's study in 2004 found that Remifemin did not stimulate estrogen-sensitive breast cancer cells in vitro and, in fact, exerted inhibitory effects on cellular proliferation. A previous paper by Freudenstein in 2002 found that Remifemin was not associated with an increased risk of breast cancer in an animal model.

Pockaj's 2004 Mayo Clinic pilot study of menopausal women, including women with a history of breast cancer, found Remifemin use was associated with a 50% daily reduction in hot flashes while having no significant adverse effects. Interestingly, Dr. Pockaj repeated her study in 2005 with a different brand of black cohosh and did not find any beneficial results for the reduction of menopause symptoms.

Remifemin was first introduced to the US market in 1995 by Enzymatic Therapy, Inc., the exclusive distributors of the product in North America and the first to introduce standardization to the US supplement industry. For more info, visit www.remifemin.com.