Complementary and Alternative Medicine Patients Are Talking About: Black Cohosh

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Black cohosh (Cimicifuga racemosa) is a plant native to the eastern United States and Canada, originally used by Native Americans as a remedy for menstrual and menopausal symptoms, among other conditions. In Europe, black cohosh root extract has had widespread use for more than half a century for menopausal symptoms (Liske, 1998) and is marketed in Germany as Remifemin® (Schaper & Brummer GmbH & Co. KG, Salzgitter, Germany). Black cohosh is unrelated to blue cohosh or white cohosh.

**Route of administration:** Black cohosh is taken orally as a capsule, fluid extract, tablet, powder, or tincture.

**Dosing and cost:** A variety of factors influence the dosing of black cohosh, such as growing and harvesting conditions, plant parts and extraction methods, and dosage forms selected by manufacturers. Most clinical studies use a specific black cohosh extract standardized to contain 1 mg triterpene glycosides (calculated in the key marker 27-deoxyacetin) per 20 mg tablet with a total dose of 40–80 mg twice daily. An aqueous extract of black cohosh with dosages of 39 mg and 127.3 mg also has been used (Natural Medicines Comprehensive Database, 2005; Thomson Micromedex, 2005). At a dose of 20 mg twice daily of standardized black cohosh, the monthly cost is approximately $15, which is not covered by most prescription plans.

**Indications:** Black cohosh is marketed commercially as an alternative to hormonal therapy in the relief of symptoms associated with menopause, premenstrual syndrome, and dysmenorrhea.

**Regulation:** As a dietary supplement as defined by the Dietary Supplement Health and Education Act of 1994, black cohosh does not fall under postmarket regulation by the U.S. Food and Drug Administration (FDA). The FDA is responsible, however, for taking action against any unsafe products once reported.

**Safety and efficacy:** The pharmacokinetic profile of black cohosh has yet to be investigated, but supplements with the herb appear to have a good safety profile and exhibit modest efficacy when used to alleviate menopausal symptoms, although clinical studies have not extended past six months. Black cohosh was found to be superior to placebo in reducing frequency and severity of menstral migraine headaches (Burke, Olson, & Cusack, 2002). Conflicting clinical evidence exists that black cohosh contains substances with selective estrogen receptor modulator activity. Caution is encouraged when black cohosh is taken concurrently with conventional drugs metabolized by the cytochrome P450 isozyme CYP2D6 because of a recent finding that it demonstrated weak inhibition of CYP2D6 (Gurley et al., 2005). Table 1 offers a summary of the studies.

**Interactions:** Although controversial, black cohosh may have estrogenic effects, thus increasing the risk of metastasis in existing breast cancer or adversely affecting women with hormone-sensitive cancers or conditions (e.g., uterine cancer, uterine fibroids, ovarian cancer, endometriosis) if taken concurrently (Natural Medicines Comprehensive Database, 2005).

**Adverse reactions:** Black cohosh can cause gastrointestinal upset, rash, headache, and dizziness. Case reports of liver failure and autoimmune hepatitis have been linked to the herb, and its use is contraindicated with hypersensitivity, pregnancy, and lactation (Natural Medicines Comprehensive Database, 2005; Thomson Micromedex, 2005).

**Clinical trials:** Currently, no active clinical trials involve black cohosh. Published results are not available yet from a closed 2004 clinical trial sponsored by the North Central Cancer Treatment Group (Physicians Data Query®, 2005).

**Future:** Because of the popularity of black cohosh and its demonstrated clinical efficacy, it likely will continue to be marketed in single and combination products.

Key Patient Teaching Points

- Treatment decisions including black cohosh should be made jointly between healthcare providers and patients, with assessment of potential risks and drug interactions.
- Women with a history of or at risk for developing breast cancer and those with hormone-sensitive conditions (e.g., uterine cancer, uterine fibroids, ovarian cancer, endometriosis) should consider avoiding black cohosh until more clinical information is available.
- Black cohosh should not be combined with hepatotoxic drugs or given to individuals with hepatitis.

**References**


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<th>Authors</th>
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<td>Burke et al., 2002</td>
<td>Summary of evidence of potential use and efficacy of a combination product containing black cohosh for the prevention of menstral migraine headaches in women</td>
<td>Frequency of menstrual migraine headaches and overall frequency of migraine headaches, doses of conventional medications (triptans), and analgesics were recorded in daily diaries for women (N = 49) randomized to two groups over a 24-week period. The treatment group (n = 25) received a combination product containing phytoestrogens (soy extract, dong quai, and black cohosh) in tablet form taken twice daily. The placebo group (n = 24) took identical-looking tablets twice daily.</td>
<td>Twice-daily oral dosing of the combination product containing phytoestrogens was significantly superior to placebo in reducing frequency and severity of menstrual migraine headaches, with effects beginning after one month of treatment. Five adverse events involving three symptoms (nausea, diarrhea, or pruritis) were reported. The authors recommended larger studies evaluating phytoestrogens, alone and in combination, for the treatment of migraine headaches.</td>
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<td>Hernandez Munoz &amp; Pluchino, 2003</td>
<td>Summary of evidence of effectiveness of a formulation of black cohosh for the treatment of hot flashes</td>
<td>Breast cancer survivors were randomized to receive tamoxifen alone (20 mg daily, n = 46) and tamoxifen plus a formulation of Cimicifuga racemosa (20 mg tablet twice daily for 60 days, n = 90) to evaluate the effect of a formulation of black cohosh on the frequency and intensity of hot flashes for two months. The manufacturer of the product stated that the preparation should not be given to women with estrogen-dependent tumors.</td>
<td>The number of severe hot flashes in the women in the tamoxifen-alone group (73.9%) was significantly greater than the number of severe hot flashes in the women in the tamoxifen plus black cohosh group (24.4%). The authors asserted that although the combination therapy may reduce hot flashes, the results are limited by a short study time.</td>
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<td>Jacobson et al., 2001</td>
<td>Summary of evidence of efficacy, safety, and side-effect profile of black cohosh for the treatment of hot flashes</td>
<td>In a two-arm, double-blind, placebo-controlled study, breast cancer survivors were randomized to receive black cohosh (dose not stated, 1 tablet twice daily, n = 42) or placebo (n = 43) plus tamoxifen (n = 59) or minus tamoxifen (n = 26) for two months. Patients were asked to record the frequency and intensity of hot flashes in a diary. Luteinizing hormone (LH) and follicle-stimulating hormone (FSH) levels were drawn at baseline and study completion.</td>
<td>The treatment and placebo groups reported reduced number and intensity of hot flashes. The treatment group (black cohosh and no tamoxifen) reported a continued decline in hot flash intensity throughout the study, although the number was not statistically significant (n = 9). No significant changes in hormonal levels were observed overall; however, tamoxifen users had lower FSH and LH levels than nontamoxifen users. Thirteen adverse events were reported.</td>
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<td>Liske et al., 2002</td>
<td>Summary of evidence of efficacy and safety of black cohosh at varying doses</td>
<td>Perimenopausal and postmenopausal women (N = 152) were randomized to receive two doses of black cohosh (39 mg daily dose, n = 76; 127.3 mg daily dose, n = 76) over 24 weeks. Physiologic effects (vaginal cytology measures and hormone levels) were obtained at intervals. Patients were asked to complete symptom scales at intervals.</td>
<td>No dose-dependent effect between the standard dose (39 mg) and the higher dose (127.3 mg) was found, implying that the standard dose is sufficient for the relief of menopausal symptoms. No difference was found in vaginal cytology or hormonal levels between groups, therefore not supporting an estrogenic effect.</td>
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<td>Wuttke et al., 2003</td>
<td>Summary of evidence of efficacy of black cohosh on menopausal symptoms and bone metabolism</td>
<td>Postmenopausal women (N = 62) were randomized to receive black cohosh (40 mg daily), conjugated estrogens 0.6 mg, or placebo over a three-month period. Measures of bone degradation, endometrial thickness, and vaginal cytology were obtained at intervals. Patients were asked to complete menopause rating scales at intervals and maintain a diary.</td>
<td>Black cohosh was superior to placebo and equal to conjugated estrogen in reducing menopausal symptoms. Serum markers of bone metabolism were similar between treatment groups. Endometrial thickness increased in the conjugated estrogen group, but no change occurred from baseline in the black cohosh group. The authors believe that the data support the theory that black cohosh contains substances with selective estrogen receptor modular activity.</td>
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