



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-deoxyaceticin) 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 Supplemental 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 menstrual 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 isoenzyme 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.

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