



Questions and Answers About Black Cohosh and the Symptoms of Menopause

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This fact sheet provides an overview of the use of black cohosh for menopausal symptoms.

Key points

- Black cohosh is an herb sold as a dietary supplement in the United States.
- Black cohosh is used for hot flashes and other menopausal symptoms.
- Although preliminary evidence is encouraging, the currently available data are not sufficient to support a recommendation on the use of black cohosh for menopausal symptoms. The National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health is funding a rigorous scientific study to determine whether treatment with black cohosh reduces the frequency and intensity of hot flashes and other menopausal symptoms.
- In 2001, the American College of Obstetricians and Gynecologists stated—primarily on the basis of consensus and expert opinion—that black cohosh may be helpful in the short term (6 months or less)

for women with vasomotor symptoms of menopause.

- Although few adverse events have been reported, long-term safety data are not available. Recently, a large study that followed postmenopausal women taking combined estrogen and progestin for an average of 5.2 years showed a small but significant increase in the risk of certain diseases, demonstrating the importance of long-term studies in revealing risks that may not be apparent in shorter studies.

What is black cohosh?

Black cohosh (known as both *Actaea racemosa* and *Cimicifuga racemosa*), a member of the buttercup family, is a perennial plant that is native to North America. Other common names include black snakeroot, bugbane, bugwort, rattleroot, rattletop, rattleweed, and macrotys. Insects avoid it, which accounts for some of these common names.

What are common black cohosh preparations?

Preparations of black cohosh are made from its roots and rhizomes (underground stems). One commercial standardized black cohosh preparation is Remifemin®*, which contains black cohosh extract equivalent to 20 mg of root per tablet. The manufacturer changed the formulation of this preparation from a solution (root extracted with ethanol, 60% by volume) to tablets (root extracted with isopropyl alcohol, 40% by volume), complicating the comparison of research results. Other preparations of black cohosh have been less well studied than Remifemin. Extracts of black cohosh are standardized to 26-deoxyactein content [1], a member of a group of chemicals known as saponins. Commercially available preparations of black cohosh usually contain 1 mg of total triterpene saponins (expressed as 26-deoxyactein) in each 20-mg dose of extract.

* The mention of a specific brand name is not an endorsement of the product.

What are the historical uses of black cohosh?

Black cohosh was used in North American Indian medicine for malaise, gynecological disorders, kidney disorders, malaria, rheumatism, and sore throat [2]. It was also used for colds, cough, constipation, hives, and backache and to induce lactation [3]. In 19th-century America, black cohosh was a home remedy used for rheumatism and fever, as a diuretic, and to bring on menstruation. It was extremely popular among a group of alternative practitioners who called black cohosh "macrotys" and prescribed it for rheumatism, lung conditions, neurological conditions, and conditions that affected women's reproductive organs (including menstrual problems, inflammation of the uterus or ovaries, infertility, threatened miscarriage, and relief of labor pains) [3].

What clinical studies have been done on black cohosh and its effect on menopausal symptoms?

Black cohosh is used primarily for hot flashes and other menopausal symptoms. A number of studies using various designs have been conducted to determine whether black cohosh affects menopausal symptoms [4]. Few studies were placebo controlled, and most assessed symptoms by using the Kupperman index—a scale that combines measures of hot flashes, insomnia, and depression but not vaginal dryness. Those with the best study designs are described below.

A randomized, double-blind, placebo-controlled trial was done in breast cancer survivors because most of

these women experience hot flashes and many use complementary or alternative remedies [5]. The women were over age 18 and had completed breast cancer treatment at least 2 months before the trial; 85 women (69 of whom completed the trial) took one tablet of placebo or 40 mg/day of black cohosh (as 20 mg twice daily) for 2 months to determine the effect on hot flashes, excessive sweating, palpitations, headaches, poor sleep, depression, and irritability [J.S. Jacobson, Columbia University, written communication, 2002]. Fifty-nine subjects were using tamoxifen (an antiestrogen treatment for breast cancer); tamoxifen users were distributed almost equally between the treatment and control groups. The frequency and intensity of hot flashes decreased in both groups, with no statistical difference between the groups; excessive sweating decreased significantly more in the treatment group than the placebo group. Other symptoms improved equally in both groups, and scores on a health and well-being scale did not change significantly in either group.

A 24-week study in 60 women who had undergone hysterectomy but retained at least one ovary compared the effects of 8 mg/day of a black cohosh extract (as four 2-mg tablets daily; isopropanol extract version of Remifemin) with three estrogen regimens: estriol (1 mg/day), conjugated estrogens (1.25 mg/day), and estrogen-progestin therapy (one daily Trisequens® tablet containing 2 mg estradiol and 1 mg norethisterone acetate) [6]. In all groups a modified Kupperman index measuring additional physical symptoms was significantly lower 4, 8, 12, and 24 weeks after treatment began. Black cohosh decreased symptoms similarly to the other treatments, but this study was not placebo controlled.

A randomized, double-blind, placebo-controlled trial in 80 menopausal women compared 8 mg/day of a black cohosh extract (as two 2-mg tablets of Remifemin twice daily) with placebo or conjugated estrogens (0.625 mg/day) [7]. At 12 weeks, scores on the Kupperman index and the Hamilton anxiety scale were significantly lower in the treated groups than in the placebo group; the scores of participants using black cohosh were somewhat better than the scores of those receiving the estrogen treatment. This is one of the few studies in which hot flashes were scored separately from other symptoms. Daily hot flashes decreased from 4.9 to 0.7 in the black cohosh group, 5.2 to 3.2 in the estrogen group, and 5.1 to 3.1 in the placebo group.

A randomized, 12-week study of 55 menopausal women compared an ethanolic extract of black cohosh (40 drops twice daily) with conjugated estrogens (0.6 mg/day) or diazepam (2 mg/day) [8]. Regardless of the treatment, all symptoms improved as measured by the Kupperman index, a depression scale, and an anxiety scale. However, this was not a blinded, placebo-controlled trial and diazepam is not a usual treatment for menopausal symptoms.

Although some study results suggest that black cohosh may help relieve menopausal symptoms, other study results do not. Studies of black cohosh have yielded conflicting data, in part because of lack of rigor in study design and short study duration (6 months or less). In addition, interpretation of these studies is complicated by the fact that different amounts of black cohosh from different sources were used in the various studies and their outcome measures were different. To provide more definitive evidence on the effects of black cohosh on menopausal symptoms, NCCAM is funding a 12-month, randomized, placebo-controlled study to determine whether treatment with black cohosh is effective in reducing the frequency and intensity of menopausal hot flashes. The study will also assess whether black cohosh reduces the frequency of other menopausal symptoms and improves quality of life. The study will examine the possible mechanisms of action of black cohosh. (Women who are interested in participating in the study, which is at Columbia University in New York City, can find out more at www.clinicaltrials.gov or 1-212-342-0110.)

In 2001, the American College of Obstetricians and Gynecologists stated—primarily on the basis of consensus and expert opinion—that black cohosh may be helpful in the short term (6 months or less) for

women with vasomotor symptoms of menopause [9].

How does black cohosh work?

How black cohosh works is not known. The possibility that black cohosh exhibits estrogenic activity has been studied but the evidence is contradictory [10-18].

A compound recently identified in black cohosh—fukinolic acid—was shown to have estrogenic activity in vitro [10]. Other active compounds appear to include triterpene glycosides (including actein and cimicifugoside), resins (including cimicifugin), and caffeic and isoferulic acids [19].

- **Effect on hormone levels**

Women who have reached menopause generally have lower levels of estrogen and higher levels of two other hormones—luteinizing hormone (LH) and follicle-stimulating hormone (FSH)—than do women who menstruate. Three of four studies show that black cohosh does not affect LH or FSH.

A study of 150 perimenopausal and postmenopausal women using two different doses of black cohosh (Remifemin tablets, 39 or 127.3 mg/day) found that 6 months of treatment caused no changes in LH, FSH, prolactin, estradiol, or sex-hormone-binding globulin [20]. Another trial of black cohosh in women with breast cancer found small but insignificant changes in LH levels (in 18 subjects) and FSH levels (in 33 subjects) [5]. In the third study, Remifemin (8 mg/day given as four 2-mg tablets) did not affect LH or FSH levels in 15 women who had undergone a hysterectomy who were part of a study comparing black cohosh with several estrogens [6].

The fourth study, which found an effect of black cohosh on LH levels, was a trial in 110 women with menopausal symptoms. Participants treated with Remifemin (8 mg/day) for 8 weeks had significantly lower average LH levels than did a control group (FSH levels were unchanged) [11]. However, the report of this study does not include the participants' hormone levels before the study began, so the two groups may have had different LH levels initially.

In vitro studies used to examine the effect of black cohosh have given contradictory results. Black cohosh had no activity in estrogen receptor (ER) binding assays in Ishikawa (endometrial) and S30 (breast cancer) cell lines [12]. It did not show potent ER binding activity; it slightly enhanced the growth of ER-positive breast cancer cells (T47D) but was not tested on ER-negative cells [13]. In another study black cohosh inhibited the growth of T47D cells [14]. Black cohosh inhibited growth of ER-positive breast cancer cell line 435 [15]. In ER-positive breast cancer cell line MCF-7, it inhibited estradiol-induced stimulation of cell proliferation in one study [21] but isolated constituents of black cohosh increased proliferation in another [10].

- **Effect on the vagina**

Because of the marked changes in hormone levels in women who have achieved menopause, numerous modifications occur in the structure and activity of vaginal and uterine tissues, which may cause vaginal dryness and reduced sexual responsiveness. Microscopically, vaginal cells look

different after menopause because of decreased estrogen. Studies have been mixed on whether black cohosh affects vaginal epithelium. One placebo-controlled, double-blind trial of black cohosh showed estrogenic changes in vaginal epithelium of menopausal women [7], but another study of two Remifemin doses (39 or 127.3 mg/day) found that 6 months of treatment in perimenopausal and menopausal women caused no changes in vaginal cytology [20].

- **Effect on the uterus**

Menopause is associated with a thinning of the uterine lining (the endometrium). No human studies have adequately evaluated the effect of black cohosh on uterine endometrium.

When uterine weight of immature female mice and growth of ER-positive breast cancer cells (MCF-7) were used to measure the estrogenic effect of black cohosh, black cohosh caused an increase in uterine weight and growth of cancer cells in culture, which the authors said reflected an estrogenic effect [16]. Black cohosh did not exhibit estrogenic effects in a study that measured uterine weight in immature mice and vaginal cell cornification (conversion of cells from columnar to squamous) in ovariectomized rats [17].

What is the regulatory status of black cohosh in the United States?

In the United States, black cohosh is sold as a dietary supplement, and dietary supplements are regulated as foods, not drugs. Manufacturers do not have to provide the Food and Drug Administration (FDA) with evidence that dietary supplements are effective or safe before marketing. Because dietary supplements are not always tested for manufacturing consistency, the composition may vary considerably from lot to lot.

Can black cohosh be harmful?

Black cohosh can cause stomach discomfort and headaches [10]. Clinical trials comparing estrogens with black cohosh preparations have shown a low incidence of adverse effects associated with black cohosh; headaches, gastric complaints, heaviness in the legs, and weight problems were the main adverse effects noted [22].

Black cohosh usually has not been used for long periods, and published studies have followed women for only 6 months or less. Recently, a large study that followed postmenopausal women taking combined estrogen and progestin for an average of 5.2 years showed a small but significant increase in the risk of certain diseases, demonstrating the importance of long-term studies in revealing risks that may not be apparent in shorter studies [23]. If black cohosh is estrogenic, long-term use may adversely affect uterine or breast tissue. No studies have been published on long-term safety in humans, particularly regarding abnormal stimulation of cells in the endometrium or breast.

There is a case report of neurological complications in a postterm baby after labor induction with a mixture of black cohosh and blue cohosh (*Caullophylum thalictroides*) during a home birth [24].

Who should not take black cohosh?

- The use of black cohosh during pregnancy has not been rigorously studied. Thus, it would be prudent

for pregnant women not to take black cohosh unless they do so under the supervision of their health care provider.

- Women with breast cancer may want to avoid black cohosh until its effects on breast tissue are understood.

Does black cohosh interact with any drugs or laboratory tests?

Although black cohosh has not been reported to interact with any drugs or to influence laboratory tests, this has not been rigorously studied.

What are some additional sources of information on black cohosh?

Medical libraries are one source of information about medicinal herbs. Others include Web-based resources such as CAM on PubMed available at www.nlm.nih.gov/nccam/camonpubmed.html and the NCCAM Clearinghouse (call toll-free 1-888-644-6226 or go to nccam.nih.gov/health/clearinghouse/index.htm).

For general information on herbs and botanicals and their use as dietary supplements, please see Dietary Supplements: Background Information (<http://ods.od.nih.gov/factsheets/generalbackground.html>) and Botanical Dietary Supplements: Background Information (<http://ods.od.nih.gov/factsheets/botanicalbackground.html>) from the Office of Dietary Supplements (ODS), available at ods.od.nih.gov.

General safety advisory for consumers

- The information in this fact sheet does not replace medical advice.
- Before taking an herb or a botanical, consult a doctor or other health care provider-especially if you have a disease or medical condition, take any medications, are pregnant or nursing, or are planning to have an operation.
- Before treating a child with an herb or a botanical, consult with a doctor or other health care provider.
- Like drugs, herbal or botanical preparations have chemical and biological activity. They may have side effects. They may interact with certain medications. These interactions can cause problems and can even be dangerous.
- If you have any unexpected reactions to an herbal or a botanical preparation, inform your doctor or other health care provider.

Disclaimer

The mention of a specific brand name is not an endorsement of the product. Reasonable care has been taken in preparing this fact sheet and the information provided herein is believed to be accurate. However, this information is not intended to constitute an "authoritative statement" under Food and Drug Administration rules and regulations.

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About ODS and NCCAM

The mission of the Office of Dietary Supplements (ODS) is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the U.S. population.

The National Center for Complementary and Alternative Medicine (NCCAM) is dedicated to exploring complementary and alternative healing practices in the context of rigorous science, training complementary and alternative medicine researchers, and disseminating authoritative information to the public and professionals.

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