

Black cohosh SAP

Science-based support for menopause management*

Black cohosh (*Actaea racemosa*) is native to Canada and the United States. It has been used in traditional medicine to treat a wide range of disorders - from joint pain and rheumatism to menstrual irregularities, childbirth-related complications, and even kidney function.* Its ability to alleviate symptoms of menopause has been studied in randomized controlled clinical trials.* Supplementation with black cohosh has been shown to reduce menopause symptoms such as hot flashes, depression, anxiety, and sleep issues.* A part of this effect can be attributed to the high content of triterpene glycosides in black cohosh, which may help reduce levels of luteinizing hormone and activate dopaminergic receptors.* An added advantage of black cohosh is the fact that it can be used as an alternative to conventional menopause treatments, where estrogen supplementation is not desired or is contraindicated.* Treatment with black cohosh has been found to work well in conjunction with antiestrogen drugs.* There is preliminary but promising data showing a positive correlation between black cohosh supplementation and pregnancy outcomes in cases of PCOS and unexplained infertility. Further research should help corroborate these findings.*

Black cohosh SAP provides high quality black cohosh extract for relief from menopause symptoms.*

ACTIVE INGREDIENTS

Serving size:	Amount per serving	Servings: % Daily value
Black cohosh (<i>Actaea racemosa</i>) root extract, 2.5% triterpene glycosides	40 mg	**

** Daily value not established.

Other ingredients: Vegetable magnesium stearate, microcrystalline cellulose and silicon dioxide in a capsule composed of vegetable carbohydrate gum and purified water.

Contains no: Gluten, soy, wheat, corn protein, eggs, dairy, yeast, citrus, preservatives, artificial colors and flavors, starch or sugar.

This product is non-GMO and vegan friendly.

Black cohosh SAP contains 60 capsules per bottle.

DIRECTIONS FOR USE

Adults: See indication-specific dosages outlined in the indication-specific dosage table

Take 1-2 capsules daily or as directed by your healthcare practitioner.

INDICATIONS

Black cohosh SAP can help:

- Alleviate symptoms of menopause.*
- Reduce severity of hot flashes.*
- Improve quality of sleep.*
- Improve pregnancy rates as an adjuvant in women with PCOS.*

CAUTIONS AND WARNINGS

Consult a healthcare practitioner if symptoms persist or worsen. Consult a healthcare practitioner prior to use if you are breastfeeding, have a liver disorder, or develop symptoms of liver trouble.

CONTRAINDICATIONS

Do not use this product if you are pregnant.

Do not use if seal is broken. Keep out of reach of children.

PURITY, CLEANLINESS, AND STABILITY

All ingredients listed for each Black cohosh SAP lot number have been tested by an ISO 17025 accredited third-party laboratory for identity, potency, and purity.

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Scientific Advisory Panel (SAP):
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Black cohosh (*Actaea racemosa*) is a medicinal plant native to Canada and the eastern United States. Belonging to the Ranunculaceae family, it is also called *Cimicifuga racemosa*, and commonly referred to as wanzenkraut, bugbane, or black snakeroot. [1] It has been used in traditional medicine for a wide variety of ailments, including joint pain and rheumatism, menstrual irregularities, kidney function and even childbirth-related complications. [1] Its ability to ameliorate symptoms of menopause has gained attention in recent times, with clinical trials conducted to successfully support this claim. The supplementation usually consists of an extract of the rhizome of the plant, which is rich in triterpene glycosides that may help to reduce levels of luteinizing hormone and activate dopaminergic receptors, thereby reducing certain symptoms of menopause. [2] Black cohosh may exert an estrogenic effect, which may improve libido and bone mineral density. [2]

Menopause is a natural process, yet a difficult time for many women. It is the end of the menstrual cycle, usually occurring between the ages of 49 and 52 years. [3] Menopause significantly reduces quality of life, with symptoms such as hot flashes, sleep disruption, vaginal dryness, and osteoporosis affecting day-to-day activities. [1,3] Hormone therapy is the most common treatment prescribed for the management of menopausal symptoms, but it is not without some drawbacks. Contraindications such as history of breast or endometrial cancer, thromboembolic disease, hypertension, migraines, and liver disease are the main obstacles in using hormone therapy, and even then, estrogen use is associated with serious adverse events. [1,3] Other non-hormonal drugs such as tamoxifen, clonidine, and venlafaxine have their own side effects such as dry mouth, nausea, drowsiness, or insomnia. [3] Preliminary clinical evidence suggests black cohosh can be a natural alternative to effectively manage menopause symptoms, and although more research will help corroborate this information, data from clinical studies conducted so far is promising.

CLIMACTERIC SYMPTOMS OF MENOPAUSE

There is a strong and growing body of evidence that suggests the ability of black cohosh to manage several symptoms of menopause. In a randomized, double-blind, placebo-controlled study conducted with 304 women, administration of 40 mg of black cohosh extract showed significant improvement in their menopause symptoms, especially hot flashes. The effect was more prominent in women in early stages of these symptoms. [4] Another prospective study looking at the overall quality of life showed that supplementation with 40 mg of black cohosh extract to 122 postmenopausal women significantly improved their global quality of life, with particular improvement in scores related to the 'psychic', 'sexuality', and 'menopause and health' domains. [5] Since hot flashes appear to be one of the main manifestations of menopausal symptoms, studies have focused on addressing this symptom. Hot flashes are a part of a larger occurrence of vasomotor symptoms, which have been linked to poor endothelial function. [6] It is possible that improvement of endothelial function in postmenopausal women may address the symptom of hot flashes, but also vasomotor symptoms and cardiovascular health at large. A randomized, double-blind, placebo-controlled trial with 62 participants showed that administration of 106 mg/day of black cohosh (containing 4 mg of triterpene glycosides) for 28 days can improve endothelial function by increasing flow mediated dilation of the brachial artery and improving arterial elasticity. [7] Another prominent disrupting symptom of menopause is the poor quality of sleep. Supplementation with 40 mg of crude black cohosh delivering 5 mg of extract per day over 6 months showed an improvement in sleep quality in a study conducted with 48 postmenopausal women. Waking after sleep onset reduced by 15%, and the participants receiving black cohosh also showed improvement in vasomotor and physical domains of quality of life. [8]

ALTERNATIVE TO CONVENTIONAL MENOPAUSE TREATMENTS

A comparison between black cohosh and transdermal estradiol showed that black cohosh could be used as an alternative therapy to transdermal estradiol since it has comparable results. In a randomized trial, 64 postmenopausal women were administered either 40 mg black cohosh or 25 µg of transdermal estradiol for 3 months. Both treatments showed significant and similar reduction in frequency of hot flashes, depression, and anxiety. Black cohosh-treated participants even showed increased

levels of HDL compared to their estradiol-treated counterparts. [9] These results are certainly worth investigating further since conventional hormone therapy is not always the best alternative, especially in contraindicated conditions such as a history of breast cancer. In fact, black cohosh proved to be compatible for use with antiestrogen tamoxifen, used post breast cancer treatment. In a prospective study conducted with 50 breast cancer patients undergoing tamoxifen treatment, administration of 2.5-10 mg black cohosh per day reduced overall menopause rating scores, especially hot flashes, sweating, anxiety, and sleep issues. There was no effect observed on musculoskeletal and urogenital complaints and hence a higher dose of black cohosh needs to be investigated to address these symptoms. [10] Another study compared the effect of black cohosh with fluoxetine, an antidepressant commonly used for the treatment of depression and hot flashes in postmenopausal women. When a dose of 40 mg/day of black cohosh was compared with 20 mg/day of fluoxetine for 6 months in 120 postmenopausal women, fluoxetine showed greater improvement in depression, but black cohosh was more effective than fluoxetine in reducing hot flashes and night sweats. [11]

PCOS AND PREGNANCY

Due to the phytoestrogenic nature of black cohosh, it has been tested as a supportive therapy in female infertility occurring from unknown causes, or common conditions such as polycystic ovary syndrome. A randomized trial (n=119) looked at supplementation with 120 mg/day of black cohosh along with clomiphene citrate, a common drug used to treat infertility in women. Supplementation with black cohosh showed improved serum levels of estradiol, luteinizing hormone, and a thicker endometrium. [12] This trial was followed up with another randomized trial (n=194) where a similar treatment of 120 mg of black cohosh with clomiphene citrate showed improved endometrial thickness, serum estradiol, luteinizing hormone, and progesterone. [13] Both trials showed an improvement in the pregnancy rates in the black cohosh-treated group compared to the group treated with clomiphene citrate alone. [12,13] Further placebo-controlled and blinded trials are required to confirm these findings. The results show promise in the ability of black cohosh to work with conventional infertility treatments.

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INDICATION SPECIFIC DOSAGE SUMMARY BASED ON HUMAN CLINICAL RESEARCH#

#Please note these suggestions are guidelines based on the clinical studies. Evidence for efficacy and safety have been qualitatively (study quality in terms of study design, sample size, appropriate methods of analysis, use of appropriate placebo/control, bias etc) assessed and have been rated using a 5 star ★ rating classification.

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Indication	Suggested dosage	Supporting evidence and study outcomes	Study design	Outcomes measures/selection criteria for studies	Safety	Evidence quality rating
Menopause Symptoms						
Climacteric symptoms ¹ (Climacteric symptoms: Menstrual bleeding disorders; vegetative symptoms; psychosomatic symptoms; somatotrophic changes; and metabolic changes)	1 capsule/day for 12 weeks	Reduction in climacteric symptoms, especially hot flashes. More benefit in early climacteric phase*	Randomized, multi-centre, double-blind, placebo-controlled trial (n=304), dose 40 mg/day for 12 weeks	Improvement in menopause symptoms as per Menopause Rating Scale I	No significant adverse events	★★★★★
Endothelial function ²	2-3 capsules/day for 28 days	Significant increase of flow-mediated dilation of brachial artery by improved elasticity of the brachial artery*	Prospective, randomized, double-blind, placebo-controlled trial (n=62), dose 106 mg/day with 4 mg of triterpene glycosides for 28 days	Flow mediate dilation of right brachial artery, blood pressure	No adverse events	★★★★★
Sleep quality ³	1 capsule/day for 6 months	Significantly different polysomnographic changes- improved sleep efficiency, reduced wake after sleep onset by 15%.* Improved sleep quality index. Improved vasomotor and physical domains*	Randomized, double-blind, placebo-controlled trial (n=48), dose 40 mg crude (5 mg extract)/day for 6 months	Polysomnography and Pittsburg Sleep Quality Index, Menopause-specific Quality of Life questionnaire, estradiol and follicle stimulating hormone tests	No adverse events	★★★★★
Climacteric symptoms ⁴	1 capsule/day for 3 months	Improved global quality of life, Improved Z scores for 'menopause and health', 'psychic', and 'sexuality' domains*	Prospective study, n=122, dose 40 mg/day for 3 months	Cervantes HR-QoL scale global quality of life scores, domains- menopause and health, psychic, couple relationship and sexuality	No adverse events	★★★
Climacteric symptoms ⁵	1 capsule/day for 3 months	Reduction in hot flashes, depression, anxiety by both treatments. Increase in HDL with black cohosh treatment only. Black cohosh considered valid alternative dose to transdermal estradiol*	Randomized, n=64, dose 40 mg black cohosh or 25 µg low dose transdermal estradiol for 3 months	Frequency of hot flashes, vasomotor and urogenital symptoms, anxiety and depression, hormonal parameters, lipid profile, endometrial thickness	No adverse events	★★★

Climacteric complaints in breast cancer patients ⁶	0.5-1 capsule/day for 6 months	Reduction in overall menopause rating scale scores, especially hot flashes, sweating, sleep problems, and anxiety*	Prospective study with (n=50) breast cancer patients, dose 1-4 tablets, 2.5 mg for 6 months, in addition to tamoxifen treatment	Climacteric complaints on menopause rating scale at 1, 3, 6 months	22 patients reported adverse events not linked to treatment. Black cohosh tolerated well by 90% of participants	★★★
Hot flashes ⁷	1 capsule/day for 6 months	Significant reduction in monthly scores for hot flashes and night sweats.* Black cohosh more effective in treatment compared to fluoxetine for hot flashes*	Prospective study, n=120, dose 40 mg/day compared to 20 mg fluoxetine for 6 months	Severity of hot flashes, Kupperman index, Beck's depression scale, RAND 36 quality of life questionnaire	Mild adverse effects, less than fluoxetine-dyspepsia, constipation, tiredness, allergy, irritability	★★★

PCOS and Pregnancy

Conception and pregnancy rates ⁸	3 capsules/day for 12 days	Higher estradiol and luteinizing hormone levels.* Higher levels of endometrium thickness, progesterone and pregnancy rate*	Randomized trial (n=119) dose 120 mg/day black cohosh (day 1-12) with clomiphene citrate treatment (day 3-7). Followed by intercourse and HCG injection	Serum luteinizing hormone and estradiol, follicle stimulating hormone, progesterone, pregnancy rates	No adverse events	★★★
Conception and pregnancy rates with PCOS ⁹	3 capsules/day from start of treatment till pregnancy test	Increased endometrial thickness, estradiol, luteinizing hormone and progesterone, higher pregnancy rate*	Randomized trial (n=194) dose 120 mg/day black cohosh (day 1-pregnancy test) with clomiphene citrate treatment (day 3-7)	Serum estradiol, progesterone, pregnancy rates	No adverse events	★★★

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