



# Dietary Supplement Fact Sheet

## Black Cohosh

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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 [1].
- Although few [adverse events](#) have been reported, long-term [safety data](#) are not available.

### 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 (erroneously reported in the scientific literature as 27-deoxyactein [2]), 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.

### 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 [3]. It was also used for colds, cough, [constipation](#), [hives](#), and backache and to induce [lactation](#) [4]. 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 "macroty" 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) [4].

### 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 [5]. Few were placebo-controlled studies, 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 [6]. 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) [7]. In all groups a modified Kupperman index measuring additional physical symptoms was significantly lower at 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) [8]. 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) [9]. 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](http://www.clinicaltrials.gov) or 1-212-342-0110.)

### 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) [6]. 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 [7].

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; 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 (human breast cancer) cells [14]. In ER-positive breast cancer cell line 435, black cohosh resulted in growth inhibition [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. 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 [8], 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].

A published case of acute hepatitis involved a 47-year-old woman who used black cohosh for symptoms of menopause [23]. She received a liver transplant three weeks after she started taking the herb. The report indicated the dose of black cohosh did not exceed the dosage recommended on the package; but no other dosage information was provided. No other cause for liver disease was found.

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 [24]. 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 [25].

Other cases of adverse outcomes experienced by neonates born to women who reportedly used blue cohosh to induce labor have been published in peer-reviewed journals [26,27].

Liver damage has been reported in a few individuals using black cohosh, but millions of people have taken the herb without apparent adverse health effects [28]. While studies of black cohosh have not provided scientific evidence to show that the herb causes liver damage, one country has added a warning to the label of all products containing black cohosh, stating that it may cause harm to the liver of some individuals and should not be used without medical supervision [29].

In the United States, the U.S. Pharmacopeia (the standards-setting organization for foods and drugs) advises that black cohosh products be labeled with the following cautionary statement: "Discontinue use and consult a healthcare practitioner if you have a liver disorder or develop symptoms of liver trouble, such as abdominal pain, dark urine, or jaundice" [30].

### 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.
- Individuals with liver disorders should avoid black cohosh.
- Individuals who develop symptoms of liver trouble such as abdominal pain, dark urine, or jaundice while taking the supplement should discontinue use and contact their doctor.

### 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](http://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](http://nccam.nih.gov/health/clearinghouse/index.htm)).

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## Glossary

**26-deoxyactein** - A component of black cohosh. It belongs to the family of chemical compounds called triterpene glycosides.

**actein** - A component of black cohosh. It belongs to the family of chemical compounds called triterpene glycosides.

**acute** - Sudden, severe, and not long lasting.

**adverse effect** - An unwanted side effect.

**adverse event** - An unwanted medical problem that occurs during treatment. Adverse events may be unrelated to the treatment or they may be caused by the therapy or procedure. For example, an adverse event may be caused by the toxic effects of a particular drug or dietary supplement or by an interaction with another therapy. Also called adverse effect and side effect.

**alternative medicine** - A group of diverse medical and health care systems, practices, and products that are used in place of conventional medicine.

**American College of Obstetricians and Gynecologists** - A national medical society for obstetricians (doctors who specialize in pregnancy and the delivery of babies) and gynecologists (doctors who specialize in treating diseases of the female reproductive organs).

**antiestrogen** - A substance that blocks the effects of estrogens (a family of hormones that helps develop and maintain female sex characteristics and the growth of long bones).

**black cohosh** - A plant whose rhizome and root are used to relieve hot flashes and other symptoms of menopause. It is not known how black cohosh works or whether it acts like estrogen (a hormone needed to develop and maintain female sex characteristics and the growth of long bones). Historically, black cohosh has been used to treat many medical conditions. Also called black

snakeroot, bugbane, bugwort, rattleroot, rattletop, rattleweed, and macrotys. Latin names: *Actaea racemosa* and *Cimicifuga racemosa*.

**blinding** - A process used in clinical trials to assign individuals to the control group (to receive the standard treatment) or the test group (to receive the new treatment under study) without the individuals or the researchers knowing to which group they have been assigned. Blinding helps ensure that information collected in the study is true and not biased (flawed). In a single-blinded study, the individuals do not know whether the standard treatment or a new treatment is being given. In a double-blinded study, neither the individuals nor the researchers know which treatment is being given.

**blue cohosh** - A plant that has been used to treat menstrual disorders and to start labor. It may be unsafe and should not be confused with black cohosh. Latin name: *Caullophylum thalictroides*.

**breast cancer** - Uncontrolled growth of abnormal cells in the breast.

**caffeic acid** - A component of black cohosh.

**cancer survivor** - A person with cancer, from the time he or she is diagnosed through the balance of his or her life.

**case report** - A detailed record of the diagnosis, treatment, and follow-up of an individual patient. Case reports also contain some information about the patient (such as age, gender, and ethnic origin).

**cell** - The individual unit that makes up the tissues of the body. All living things are made up of one or more cells, which are the smallest units of living structure capable of independent existence.

**cell line** - Cells of a single type that have been adapted to grow and divide in the laboratory and are used in research.

**cimicifugin** - A resin (a component of some plants) found in black cohosh.

**cimicifugoside** - A component of black cohosh. It belongs to the family of chemical compounds called triterpene glycosides.

**clinical trial** - A type of research study that uses volunteers to test the safety and efficacy (the ability to produce a beneficial effect) of new methods of screening (checking for disease when there are no symptoms), prevention, diagnosis, or treatment of a disease. Also called a clinical study.

**columnar cell** - A type of cell that lines the internal and external surfaces of the body.

**complaint** - In medicine, a disorder, disease, or symptom.

**complementary medicine** - A group of diverse medical and health care systems, practices, and products that are used together with conventional medicine.

**complication** - In medicine, an illness or condition that occurs while a patient has a disease. The complication is not a part of the disease, but may be a result of the disease or may be unrelated.

**compound** - In pharmacy, a substance that contains more than one ingredient.

**conjugated estrogen** - A type of female hormone that is made from the urine of pregnant horses or from plants. It is used in estrogen replacement therapy, and to treat the symptoms of menopause, osteoporosis in women who have been through menopause, advanced breast cancer, and some types of advanced prostate cancer.

**consensus** - A general agreement.

**constipation** - A condition in which stool becomes hard, dry, and difficult to pass and bowel movements happen infrequently. Other symptoms may include painful bowel movements and feeling bloated, uncomfortable, and sluggish.

**constituent** - A component, part, or ingredient of a larger whole. For example, valerenic acid and valepotriate are constituents of the dietary supplement valerian.

**control group** - In a research study or clinical trial, the group that does not receive the new treatment being studied. This group is compared with the group that receives the new treatment, to see whether the new treatment works.

**cornification** - The changing of cells that line the internal and external surfaces of the body into an outer layer of flat cells that look like fish scales under a microscope). Also called keratinization.

**cytology** - The study of cells using a microscope (a device that uses a combination of lenses to make enlarged images of tiny objects).

**data** - Facts and information.

**depression** - A serious medical condition that can interfere with an individual's ability to work, study, sleep, and eat. Symptoms include ongoing feelings of sadness and despair, loss of energy, and loss of interest or pleasure in activities that were once enjoyed. A person who has depression may experience changes in eating or sleeping habits, and have thoughts of death or suicide.

**diazepam** - A drug that is used as a sedative and muscle relaxant, and to treat anxiety and epileptic seizures.

**dietary supplement** - A product that is intended to supplement the diet. A dietary supplement contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances) or their components; is intended to be taken by mouth as a pill, capsule, tablet, or liquid; and is identified on the front label of the product as being a dietary supplement.

**diuretic** - A drug or other substance that increases the amount of urine made by the body.

**dose** - The amount of medicine or other substance taken at one time or over a specific period of time.

**double-blind** - Describes a clinical trial in which neither the researcher nor the patient knows which of several possible therapies the patient is receiving.

**drug** - Any substance (other than food) that is used to prevent, diagnose, treat, or relieve symptoms of a disease or abnormal condition. Also, a substance that alters mood or body function or that can be habit-forming or addictive, especially a narcotic.

**endometrium** - A layer of tissue that lines the uterus.

**epithelium** - A thin layer of tissue that covers organs, glands, and other structures within the body.

**ER-negative** - Estrogen receptor negative (ER-). Having to do with breast cancer cells that do not have a protein (a receptor molecule) to which estrogen will attach. Breast cancer cells that are ER- do not need the hormone estrogen to grow and usually do not respond to hormone (antiestrogen) therapy that blocks these receptor sites.

ER-positive - Estrogen receptor positive (ER+). Having to do with breast cancer cells that have a protein (a receptor molecule) to which estrogen will attach. Breast cancer cells that are ER+ need the hormone estrogen to grow and will usually respond to hormone (antiestrogen) therapy that blocks these receptor sites.

estradiol - A form of the hormone estrogen.

estriol - A form of the hormone estrogen.

estrogen - A hormone (a chemical made by the body that controls the actions of certain cells or organs) that is needed to develop and maintain female sex characteristics and the growth of long bones. Estrogens are also made in the laboratory and are used in birth control and to treat symptoms of menopause, menstrual disorders, and osteoporosis.

estrogen receptor binding assay - ER binding assay. A laboratory test to determine the presence of a protein found on cells of female reproductive tissue, some other tissues in the body, and some cancer cells. The hormone estrogen will attach (bind) to the receptors inside the cells and may cause the cells to grow.

ethanol - A type of alcohol. Also called ethyl alcohol or grain alcohol.

evidence - Information used to support the use of a particular screening procedure, treatment, or preventive measure. In medicine, evidence needed to determine effectiveness is provided by laboratory research, clinical trials, and other studies.

expert opinion - In medicine, the judgment of a respected healthcare professional, based on clinical experience or reports of expert committees. Expert opinions are important when results of controlled clinical trials and other scientific studies are not available to provide health care recommendations.

extract - A substance made by soaking an herb in a liquid that removes specific types of chemicals. The liquid can be used as is or evaporated to make a concentrate or a dry extract for use in capsules or tablets.

follicle-stimulating hormone - FSH. A hormone made by the pituitary gland (an organ at the base of the brain) that is used in reproduction and in making estrogen and sperm.

Food and Drug Administration - FDA. The FDA is an organization in the federal government responsible for protecting public health by assuring the safety and efficacy of drugs and medical devices, and the safety of cosmetics, dietary supplements, and the food supply. FDA regulates dietary supplements under a different set of regulations than those covering conventional foods and drug products (prescription and over-the-counter). The dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to get FDA approval before producing or selling dietary supplements.

fukinolic acid - A component of black cohosh.

gastric - Having to do with the stomach.

gynecologic - Having to do with the female reproductive tract (including the cervix, endometrium, fallopian tubes, ovaries, uterus, and vagina).

Hamilton anxiety scale - A rating system that is used to measure the severity of the symptoms of anxiety (including worrying, restlessness, fearfulness, trouble sleeping, poor concentration or memory, depression, aches and pains, shortness of breath, nausea, sweating, and impotence).

health care provider - A person who supplies health care services. Health care providers include individuals with professional training (including doctors, nurses, technicians, and aides).

hepatitis - A group of diseases in which the liver becomes enlarged and inflamed, causing fever, nausea, vomiting, abdominal pain, and dark urine.

herb - A plant used in cooking, in tea, and for medicinal purposes.

hives - Raised red bumps or patches on the surface of the skin that come and go and itch, burn, or sting. They are usually caused by an allergic reaction to drugs, food, or insect bites. Also called urticaria.

home birth - Having a baby in the home rather than at a birthing center or hospital.

home remedy - A traditional treatment that uses certain foods or common substances that may have medicinal properties or cause a placebo effect. Examples include chicken soup (for colds and flu), certain teas (for headache, fever, or stomach ache), and duct tape (for broken bones and plantar warts).

hormone - A group of chemicals made by glands in the body. Hormones circulate in the bloodstream and control the actions of certain cells or organs. Some hormones can also be manufactured.

hot flash - A sudden, temporary onset of body warmth, flushing, and sweating (often associated with menopause).

hysterectomy - Surgery to remove the uterus. A partial hysterectomy is removal of the uterus only. A total hysterectomy is removal of the uterus and part or all of the cervix.

in vitro - In the laboratory (outside the body).

incidence - The number of new cases of a disease diagnosed in a specific group of people during a specific period of time. For example, the annual incidence of childhood cancer is 14.6 cases per 100,000 children aged birth to 14 years.

infertility - The inability to produce children.

inflammation - Redness, swelling, pain, and/or a feeling of heat in an area of the body. It is a protective reaction to injury, disease, or irritation of tissues.

insomnia - Difficulty in going to sleep or in getting enough sleep.

isoferulic acid - A component of black cohosh.

isopropanol - A substance used to kill germs and as a solvent to dissolve other substances into a solution. Also called isopropyl alcohol and rubbing alcohol.

isopropyl alcohol - A substance used to kill germs and as a solvent. Also called isopropanol and rubbing alcohol.

Kupperman index - A rating scale that is used to measure the severity of the symptoms of menopause, including hot flashes, tingling or crawling skin, difficulty sleeping, nervousness, melancholy, dizziness, weakness, joint or muscle pain, headache, and

abnormal heart beat.

labor - The process of childbirth.

laboratory test - A medical procedure that involves testing a sample of blood, urine, tissue, or other substance collected from the body. Tests can help determine a diagnosis, plan treatment, check to see whether treatment is working, or monitor a disease over time.

lactation - The processes of making milk in the breast and supplying it to an infant.

liver - A large organ located in the right upper abdomen. It stores nutrients that come from food, makes chemicals needed by the body, and breaks down some medicines and harmful substances so they can be removed from the body.

lot - A batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or, an amount produced in a unit of time or quantity.

luteinizing hormone - LH. A hormone made in the brain that is important for the release of an egg from an ovary during the menstrual cycle and in making the hormones testosterone and estrogen.

malaise - General discomfort that may be an early symptom of illness.

malaria - A serious, sometimes fatal disease that is caused by a parasite and spread by infected mosquitoes. It causes fatigue, high fever, sweating, shaking chills, and anemia. Malaria is common in parts of Asia, Africa, Central and South America, the Pacific islands, and areas of the Caribbean.

mechanism of action - The means by which a substance (such as a dietary supplement) is able to produce an effect in the body.

medicinal - Having to do with the abilities of medicine to prevent and cure.

menopause - The time of life when a woman's menstrual periods stop. A woman is in menopause when she hasn't had a period for 12 months in a row. Also called "change of life."

menstruation - Periodic discharge of blood and tissue from the uterus. From puberty until menopause, menstruation normally occurs about every 28 days, except when a woman is pregnant.

microscopic - Too small to be seen without a microscope.

milligram - mg. A measure of weight. It is a metric unit of mass equal to 0.001 gram (it weighs 28,000 times less than an ounce).

miscarriage - The natural loss of a fetus before 20 weeks of pregnancy. Also called spontaneous abortion.

National Center for Complementary and Alternative Medicine - NCCAM. An organization of the federal government that provides funding for research, training, and education in complementary and alternative medicine (CAM); and studies ways to use evidence-based CAM practices in conventional medicine. NCCAM is one of 27 Institutes and Centers that make up the National Institutes of Health.

National Institutes of Health - NIH. The main organization in the federal government responsible for conducting and supporting medical research. It is composed of 27 Institutes and Centers that provide financial support to researchers in the United States and throughout the world to investigate ways to prevent, treat, and cure common and rare diseases. NIH is part of the US Department of Health and Human Services.

neonate - An infant during the first month of life after birth.

neurologic - Having to do with nerves and the nervous system.

norethisterone acetate - A substance used in oral contraceptives (birth control pills) and as a treatment for endometriosis (a condition in which tissue that is normally found inside the uterus grows elsewhere in the abdomen).

outcome - A specific endpoint measured in a clinical trial. Examples include weight loss, cholesterol levels, severe toxicity, worsening of disease, and death.

ovariectomy - To remove one or both ovaries (the female reproductive organs in which eggs are made and stored).

ovary - One of a pair of female reproductive glands in which the eggs (ova) are formed and stored. The ovaries are located in the pelvis, one on each side of the uterus.

palpitation - A fluttering sensation in the chest, usually caused by a forceful or irregular heart beat.

peer-reviewed journal - A scholarly or scientific publication in which an article is reviewed by a board of experts before it is published. The board members determine the accuracy of the article and approve or reject it.

perimenopausal - The time of life near menopause when a woman's menstrual periods become irregular.

placebo - An inactive substance or treatment that has no effect on the body and that ideally looks, smells, and tastes the same as, and is given the same way as, the active drug or treatment being tested. The effects of the active substance or treatment are compared to the effects of the placebo.

placebo-controlled - Refers to a method of studying a drug or dietary supplement in which a placebo (an inactive ingredient) is given to one group of participants, and the drug or dietary supplement being tested is given to a second group of participants. Results from the two groups are compared to see if the drug or dietary supplement being tested works better than the placebo.

postmenopausal - Having to do with the time after menopause. The time in a woman's life when menstrual periods stop permanently is called menopause ("change of life").

postterm baby - A baby born after the normal 42 weeks of pregnancy.

preparation - A mixture made for medicinal use.

prescription - A written order from a health care provider for medicine, other therapy, or tests.

progesterin - A natural or laboratory-made substance that has some or all of the biologic effects of progesterone, a female hormone.

prolactin - A hormone made by the pituitary gland (an organ located at the base of the brain) and important for making breast milk and in ovulation (the release of an egg from an ovary during the menstrual cycle).

proliferation - Multiplying or increasing in number. In biology, cell proliferation occurs by a process called cell division.

prudent - Wise; using good judgment.

quality of life - The overall enjoyment of life, a sense of well-being, and the ability to carry out routine activities.

**randomization** - When referring to an experiment or clinical trial, the process by which animal or human subjects are assigned by chance to separate groups that compare different treatments or other therapies. Randomization gives each participant an equal chance of being assigned to any of the groups.

**regimen** - A treatment plan that specifies the dosage, schedule, and duration of treatment.

**regulate** - To govern, make uniform, and bring under the control of a rule, principle, or legal system. In the United States, the FDA has the authority to regulate dietary supplements.

**reproductive organ** - A sex organ. In females, reproductive organs include the ovaries, fallopian tubes, uterus, cervix, and vagina. In males, reproductive organs include the prostate, testes, and penis.

**resin** - A substance found in some plants.

**rheumatism** - A group of disorders characterized by inflammation or pain in the body's connective tissues (bone and cartilage).

**rhizome** - A horizontal stem that grows shallowly underground. At nodes along the rhizome, below-ground roots and above-ground shoots grow into new plants. Examples include strawberries and many types of grasses.

**rigorous** - Accurate, precise, and without deviation from standards.

**risk** - The chance or probability that a harmful event will occur.

**root** - A part of a plant that is below ground.

**safety data** - Information about unwanted symptoms or diseases related to the use of drugs, medical devices, dietary supplements, food, and cosmetics.

**saponin** - A substance found in some plants. Saponins may help lower cholesterol and may have anticancer effects.

**scale** - A standardized tool used to measure or rate. For example, specific scales are used to measure a person's quality of life and the severity of pain.

**scientific study** - A method of gaining knowledge by making observations, proposing educated guesses (hypotheses) to explain the observations, and testing the hypotheses in ways that have reproducible results.

**sex hormone binding globulin** - SHBG. A protein made by the liver that carries a male hormone (testosterone) and a female hormone (estradiol, a form of estrogen) through the blood to body tissues. Estrogen causes levels of SHBG to increase; testosterone causes levels of SHBG to decrease.

**solution** - A liquid in which another substance has been dissolved or mixed.

**squamous cell** - A type of cell that covers the inside and outside surfaces of the body. Squamous cells are flat cells that look like fish scales under a microscope. They are found in tissues that form the surface of the skin, the lining of hollow organs (such as the uterus), and passages of the respiratory tract (nose, throat, windpipe, and lungs) and digestive tract (mouth, esophagus, and rectum).

**standardization** - A process manufacturers may use to ensure batch-to-batch consistency of their products and to provide a measure of quality control. Dietary supplements are not required to be standardized in the United States. Some manufacturers use the term incorrectly or to mean different things and the presence of the word "standardized" on a supplement label does not necessarily indicate a level of product quality.

**statistical difference** - A mathematical measure of variation between groups that is greater than what might be expected to happen by chance alone.

**statistically significant** - In medicine, a mathematical measure of difference between two or more groups receiving different treatments that is greater than what might be expected to happen by chance alone.

**study design** - A plan for collecting and using information to properly test an educated guess (hypothesis).

**symptom** - An indication of disease that an individual can feel, but that cannot be measured objectively by a health care professional. Examples include headache, fatigue, indigestion, depression, and pain.

**tamoxifen** - A drug used to treat breast cancer and to prevent cancer in women who have a high risk of developing breast cancer. Tamoxifen blocks the effects of the hormone estrogen in the breast. It belongs to the family of drugs called antiestrogens.

**tissue** - A group or layer of cells in a living organism that work together to perform a specific function.

**transplant** - The replacement of tissue with tissue from the person's own body or from another person.

**triterpene** - A chemical compound found in some plants.

**triterpene glycoside** - A family of chemicals found in some plants. Examples of triterpene glycosides are acetin, cimicifugoside, and 26-deoxyacetin, which are components of the herb black cohosh.

**uterus** - The small, hollow, pear-shaped organ in a woman's pelvis in which a fetus develops.

**vagina** - The muscular canal between the uterus and the outside of the body.

**vasomotor** - Having to do with the narrowing and widening of blood vessels.

**volume** - The amount of space taken up by a substance; the amount of space a container can hold.

**well-being** - The state of feeling healthy, happy, and content. Well-being is affected by things such as physical and mental health, income, education, social support, attitude, values, stress, security, and other qualities of life.

## Disclaimer

The mention of a specific brand name is not an endorsement of the product. For general information on herbs and botanicals and their use as dietary supplements, please see General Background Information About Dietary Supplements

(<http://ods.od.nih.gov/factsheets/generalbackground.html>) and Background Information About Botanical Dietary Supplements

(<http://ods.od.nih.gov/factsheets/botanicalbackground.html>) from the Office of Dietary Supplements (ODS) and the National Center for Complementary and Alternative Medicine (NCCAM), available at [ods.od.nih.gov](http://ods.od.nih.gov) and [nccam.nih.gov](http://nccam.nih.gov). 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.

## About ODS

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.

## General Safety Advisory

- The information in this document 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.

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