



A Field Guide to Herbal Dietary Supplements



A publication of the AHPA Foundation for Education & Research on
Botanicals (AHPA-ERB Foundation)

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Table of contents

Introduction	3
Historical use of herbs	4
Regulation of herbal dietary supplements in the U.S.	5
Contemporary research on herbs	8
Responsible use of herbs	9
Some popular herbs and their uses	10
<i>Black cohosh</i>	11
<i>Echinacea</i>	15
<i>Garlic</i>	19
<i>Ginkgo</i>	23
<i>Ginseng</i>	28
<i>Saw palmetto</i>	32
<i>St. John's wort</i>	36
<i>Valerian</i>	41
For more information	45



Introduction

This *Field Guide to Herbal Dietary Supplements* was prepared by the AHPA Foundation for Education & Research on Botanicals (AHPA-ERB Foundation) to provide information on the general class of herbal products that are marketed in the United States as dietary supplements. The AHPA-ERB Foundation exists to promote education and research on medicinal, therapeutic, and health-promoting herbs.

A conventional field guide to local or regional plants provides information that assists knowledgeable users in identifying plants in their habitats. Field guides do not, however, transform their readers into experts on botanical taxonomy, and it is only through years of practice and actual time in the field that expertise and knowledge can develop. Similarly, readers of this document will be provided with accurate information about herbs and herbal products, which, combined with a commitment to seek out additional references and guidance, will provide a knowledgeable basis for informed decisions on using herbal supplements.

The intention of this document therefore is to provide some basic background for consumers of herbal supplements. This document makes no claims of being a complete collection of herbal knowledge and no small work of this nature could hope to take the place of the vast records, resources, and personal experience needed to learn all there is to know about herbs.

This *Field Guide to Herbal Dietary Supplements* includes a short discussion of the historical use of herbs and of the current regulation of herbal products that are marketed in the United States. There is a section devoted to contemporary research on herbs including the latest scientific findings. Responsible use of herbs is also discussed and brief descriptions are provided for some of the most popular herbs, as well as a listing of sources of credible information for those who wish to learn more.



Historical use of herbs

Throughout time, people around the world have used herbs to address a multitude of health issues. Analyses of archeological sites show that herbs were used long before the beginning of recorded history. Primitive and ancient civilizations throughout the world relied on herbs to provide the benefits that were observed with their use.

The oldest surviving medical documents come from the Ancient Egyptians. Among these is the first document concerned with medicinal herbs, known as the Ebers Papyrus. This text is approximately 3,500 years old, and contains a list of 700 medicinal herbs and includes remedies for many diseases and maladies. Many ancient Chinese documents also classify herbal medicines, and similar records can be found throughout Asia and Europe since recorded history. Other societies, such as Native Americans and indigenous tribes in South America and Africa are also known to have used herbs for centuries.

Today, the World Health Organization estimates that herbal medicine is still the primary source of health care for approximately 80 percent of the world's population. In addition, many of the pharmaceutical preparations used around the world are based on plants. Herbs and herbal products, with their incredibly wide use throughout time and place, continue to provide real health benefits while maintaining a remarkable safety profile.

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Regulation of herbal dietary supplements in the United States

The Food and Drug Administration (FDA) and its predecessor agencies have had jurisdiction over herbal products marketed in the United States for over 100 years. During this time herbs that have been included in conventional foods, such as peppermint tea or vanilla extract, have been regulated as foods, while herbs like digitalis and belladonna, which are recognized as drugs, have been regulated as such. Many other herbs that have long been used for therapeutic purposes or to maintain or promote health have also been broadly sold, but for many years there was no clearly defined regulatory category for these products.

Attempts were made to fill this regulatory gap at the beginning of the 1990s. FDA proposed at that time that herbal “dietary supplements” should be regulated in the same manner as food additives, which is to



say with the same rules that apply to added ingredients like aspartame. But this did not seem like a logical approach for herbs such as chamomile, echinacea, ginseng, and the host of other herbs that have long been used in cultures around the world. Instead, in 1994 the U.S. Congress passed the Dietary Supplement Health and Education Act (DSHEA) that amended the Federal Food, Drug & Cosmetic

Act (FFDCA), to clarify the way in which vitamins, minerals, herbs and specialty supplements are regulated by the federal government. Almost all such products are now marketed in the U.S. as dietary supplements.

The law clarifies that herbal and other dietary supplements should be regulated in many of the same ways as foods. FDA has jurisdiction over how these products are made and labeled, and may seize and detain herbal and supplement products that are adulterated or misbranded. FDA may also forbid the sale of any dietary supplement or ingredient any time that the agency determines that it represents a significant or unreasonable risk. And the law requires that FDA be notified of any “new” dietary ingredients intended for use in supplements.

Federal law also defines the responsibilities of manufacturers and marketers of dietary supplements. Dietary supplements are required to identify every dietary ingredient in the product and to state the quantity of each ingredient or proprietary blend. Claims that are made on a product’s label or labeling are strictly controlled, must be substantiated, and must not claim to diagnose, treat, cure, or prevent any disease (even if there is evidence to support such a “drug claim”). Facilities in which herbal and other dietary supplements are manufactured are held to the high standards of FDA’s Good Manufacturing Practice (GMP) regulation for dietary supplements. Additionally, supplement companies are required by law to tell FDA about any reports of serious adverse events they receive from consumers.

Another important benefit of the Federal law is that it explicitly allows consumers to be provided with balanced scientific information about herbs and other supplement ingredients. Prior to the passage of this law, FDA considered such information to be illegal if it contained any reference to cure, treatment, or prevention of diseases. But the Congress decided that the government “should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers,” and established rules to allow dissemination of truthful and non-misleading publications about ingredients found in dietary supplements.

The discussion presented above addresses only the regulation of herbs and other supplements by FDA. As with any other industry, however, companies that make and sell supplements must conform with the regulations of many other federal agencies, as well as state and local jurisdictions. For example, the Federal Trade Commission enforces the laws that govern advertising of all consumer goods, and companies in the herbal business must comply with these. Marketers of organic herbal products must be familiar with rules maintained by the U.S. Department of Agriculture, and manufacturers of herbal extracts need to be in compliance with the legal guidelines set by the Tax and Trade Bureau. The list goes on and on—the Department of Transportation rules apply to all interstate shipments; U.S. Customs and Border Protection governs imports; the Occupational Safety and Health Administration protects workers in all trades; etc.

In conclusion, manufacturers and marketers of herbal supplements are subject to extensive federal laws and regulations. Each of these federal agencies is responsible for enforcing their rules so that the needs of consumers are properly met, and so that companies that do not follow the rules do not gain an advantage over those that do. The laws that are currently in place in the U.S. were designed to ensure that safe and beneficial dietary supplements, including herbal products, are available to well-informed consumers for use when making their own self-care choices. Responsible manufacturers and marketers will continue to provide these products and the citizens of the United States will continue to enjoy the health freedom which they demand and deserve.

Contemporary research on herbs

Because herbs have been used successfully since ancient times, modern researchers worldwide are interested in using current scientific protocols to quantify their effectiveness.

In recognition of the importance of herbs for health, the National Center for Complementary and Alternative Medicine (NCCAM) was created and funded by Congress, and is dedicated, in part, to investigating complementary and alternative healing practices through scientific experimentation and research. NCCAM and another government agency, the Office of Dietary Supplements, currently fund five Research Centers focused on botanicals. The centers' research includes the effects of botanicals on immune function, inflammatory diseases, women's health issues, age-related diseases, and metabolic syndrome. The centers are expected to advance the scientific base of knowledge about botanicals, including issues of their safety, efficacy, and biological activity.

Another NCCAM objective is to publicize this information, which is achieved through conferences, educational programs, exhibits, and their web site. Additionally, thousands of science-based, clinical studies are performed every year on a wide variety of herbs and herbal products.

Scientific inquiries continue to develop our knowledge of the benefits of plants and often validate the observations made over the past centuries.

Responsible use of herbs

Plants that enjoy broad culinary and therapeutic usage are generally safe. We can flavor our food with any number of herbs to make a meal more flavorful. We can appreciate a delicious cup of peppermint leaf or ginger root tea, or benefit from the soothing properties of marshmallow root or the inner bark of slippery elm. We can take an herbal supplement containing milk thistle seed extract or saw palmetto berries, or any number of the other herbs. Although allergies and reactions have been recorded for a few herbs that are widely used in foods and supplements, such individual concerns are also seen with many foods, and do not diminish the safety profile of the many herbs that are generally recognized as safe.

On the other hand, and as everyone knows, some plants are highly toxic, even deadly. Every ten-year-old hiker knows to stay away from poison ivy when walking in the woods. The death sentence imposed on Socrates by an Athenian jury 2,400 years ago was carried out with a fatal dose of poison hemlock.

Responsible and informed use by consumers is essential to ensure that herbal products maintain their established safety profile. Be sure to follow label directions or the recommendation of your healthcare provider for any herbal product. And remember to tell your healthcare provider that you're using an herbal supplement. The effect of a pharmaceutical drug you are taking may be either increased or decreased in the presence of other factors in your diet, including herbal use.





Some popular
herbs and
their uses





Capsule



Tablet



Tincture



Root

Black cohosh

Actaea racemosa
(synonym: *Cimicifuga racemosa*)

Source

Black cohosh, a member of the buttercup family, is found in rich woods of the eastern deciduous forests from southern Ontario south to Georgia, west to Arkansas, and north to Wisconsin. Most of the root is wild-harvested. Some is grown commercially in Europe.

Traditional Use

Among Native Americans and early settlers in North America, black cohosh root was an important folk medicine for menstrual irregularities and as an aid in childbirth. It served as the main ingredient in Lydia Pinkham's famous patent medicine known as "Vegetable Compound," used by women in the nineteenth century for menstrual stress and nervous tension. Adopted in medical practice in the early nineteenth century, it had a great reputation as an anti-inflammatory for arthritis and rheumatism; for normalizing suppressed or painful menses; and for relieving pain after childbirth. It was also used for nervous disorders. The root was an official drug in the *U.S. Pharmacopoeia* from 1820 to 1926.

Current Status

Black cohosh root is approved for use in Germany for the treatment of premenstrual symptoms, painful or difficult menstruation, and for menopausal symptoms such as hot flashes. A number of pharmacological studies also suggest a mild sedative and anti-inflammatory activity. Compounds in the root, a group of related triterpene glycosides, have been associated with black cohosh's biological activity. As ovarian function declines during menopause, estrogen production also declines and luteinizing hormone (LH) increases. These changes are sometimes associated with hot flashes. In one study an alcohol extract of black cohosh lowered LH in both animals and women, reducing hot flashes (Düker, et al., 1991).



In recent years scientists have focused on conducting clinical studies investigating the therapeutic benefits and safety of black cohosh alone, against placebo and in comparison with convention drugs such as hormone replacement therapy (HRT). At least twenty such studies have been published, and additional clinical studies are currently underway, including studies funded by the National Institutes of Health (NIH) at both Columbia University and the University of Illinois at Chicago. Some studies have been criticized because of lack of rigor in study design and because the duration of the studies was relatively short; conducted for six months or less. Different types of preparations used in various studies may have also led to conflicting results. A recent randomized, multicenter, double-blind, placebo-controlled clinical study enrolled 304 menopausal women, who took a 40 mg daily dose of a German black cohosh preparation. The results showed that black cohosh did produce significant benefits with no adverse side effects, especially in women in early stages of menopause (Osmers, et al., 2005). To date, at least fourteen positive clinical studies support the effectiveness and

safety of black cohosh preparations in treating hot flashes, perspiration and mood swings associated with menopausal symptoms.

Black cohosh has been widely used in Europe for over 50 years, with experience in millions of menopausal cases. As many as 10 million monthly units of one German black cohosh preparation alone were sold in Germany, Australia and the United States ten years ago. Now black cohosh is the eighth best-selling herb in the American market, with sales increasing significantly after mid-2003 when a large government-sponsored trial (Women's Health Initiative) on hormone replacement therapy (HRT) was discontinued after these conventional treatments were shown to increase unacceptable adverse effects in menopausal women. Efficacy and safety are generally confirmed by the long-term clinical experience, as well as recent controlled clinical studies with black cohosh.

Preparations

In the American market preparations available include tablets, capsules, tinctures, and the dried root. Standardized products are also available.

Dose

Traditionally, a decoction of 0.3–2 g (up to ½ teaspoonful) of the dried cut-and-sifted root is used. Tablets containing 20 mg of a standardized extract are taken twice per day (or per label instructions) in Germany. Most clinical studies have been conducted with a German extract, named Remifemin®. In Germany use is limited to six months at a time, with pauses in between to see if menopausal symptoms return. Follow label instructions for commercial products. Generally, it must be taken for a minimum of four weeks before results are seen.

Cautions

No contraindications or drug interactions are reported, though some women have experienced a low incidence of transient mild adverse effects including upset stomach, headache, dizziness, breast pain, and weight problems from use of black cohosh preparations. Furthermore, the most recent evidence suggests the black cohosh is not estrogenic (Mahady, 2005). Recent reports of liver toxicity associated with black cohosh led the Australian Therapeutic Goods Association to react by

requiring a warning “Black cohosh may harm the liver in some individuals. Use under the supervision of a healthcare professional.” In all but one of the obscure clinical case reports, those who experienced liver problems were taking other substances that could have led to liver problems. The NIH held a one-day “Workshop on the Safety of Black Cohosh in Clinical Studies” in November of 2004 that reconfirmed the relative safety of black cohosh given the millions of doses consumed for decades, and no understanding of how it could be dangerous (details online at: http://nccam.nih.gov/news/pastmeetings/blackcohosh_mtnngsumm.htm). Nevertheless, future NIH-sponsored clinical trials on the herb will include testing parameters for liver function. Objective information on black cohosh can also be found at the NIH Office of Dietary Supplements website: <http://ods.od.nih.gov/>. Search for black cohosh under the “health information” setting. For more detailed studies, search PubMed, the database of the world’s largest medical library, the National Library of Medicine at NIH, at the following link: www.ncbi.nlm.nih.gov/entrez/query.fcgi

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Capsule



Tablet



Tincture/
liquid



Tea

Echinacea

Echinacea angustifolia

Echinacea pallida

Echinacea purpurea

Sources

Echinacea, also known as purple coneflower, is the root or above-ground parts (harvested in flower) of three species of large, robust daisylike plants of the aster family. *Echinacea angustifolia* and *E. pallida* are harvested from the prairies of the Midwestern United States. Some commercial cultivation of these two species has developed. *E. purpurea*, also native to the Midwest, is the most widely used species of the three. Most of the world's supply of *E. purpurea* is from cultivated sources.

Traditional use

Native Americans of the prairie used echinacea for more medicinal purposes than they did any other plant, for everything from colds to cancer. It entered formal medicine in 1895, becoming the best-selling American medicinal plant prescribed by physicians into the 1920s. Later replaced by antibiotics in the United States, it has enjoyed continuous popularity in Europe. In 1993, German physicians prescribed

echinacea more than 2.5 million times. Traditionally, herbalists consider it a blood purifier and aid to fighting infections.

Current Status

Today most consumers use echinacea to avoid colds and other upper respiratory tract infections and to help heal infections. Echinacea enhances the particle ingestion capacity of white blood cells and other specialized immune system cells, thus increasing their ability to attack foreign invaders, such as cold or flu viruses. A recent study (Agnew, et al., 2005) found that echinacea may also induce an immune response by stimulating an increase in white blood cell activity and counts. An

antioxidant effect was also observed. Besides stimulating a healthy immune system to deal more effectively with invading viruses, it helps accelerate healing if infection already exists.

Over two-dozen clinical studies have investigated the therapeutic benefits and safety of various echinacea species, plant parts, types of preparations and dosage regimes. Barnes, et al. (2005), reviewed the chemistry, pharmacology and clinical prop-

erties of the three most commonly used echinacea species. They state that evidence from preclinical studies support some of the traditional and modern uses, particularly the immunostimulant properties. Although most clinical trials of echinacea preparations have reported positive effects in the prevention and treatment of upper respiratory tract infections, some well-publicized recent studies have produced mixed results. These authors suggest that different types of patients groups, and various preparations and dosage regimens result in a non-definitive evidence of effectiveness. Another recent meta-analysis of echinacea preparations findings supports the results of randomized, double-blind, placebo-controlled clinical trials that report the efficacy of



echinacea preparations for the prevention of spontaneous colds (Schoop, et al., 2006).

The best-studied echinacea is a preparation made from the fresh expressed juice of *E. purpurea* used in various product forms continuously in Germany since 1939. No single chemical component has been identified as causing echinacea's medicinal action, but it may involve flavonoids, essential oils, polysaccharides, caffeic acid derivatives, alkalamides, and other compounds.

More clinical studies are needed to determine clear therapeutic indications, the best preparations, and the most effective dosage.

Preparations

Echinacea products include tablets, capsules, and liquids such as tinctures, extracts, and the expressed juice of the fresh flowering plant, on which most research has been done. Some products are standardized to a variety of different chemical components.

Dose

A dose of 60 drops of *E. purpurea* root tincture three times a day is equivalent to 1 g of the dried root three times a day. The World Health Organization and the Canadian Natural Health Products Directorate suggest a dosage equivalent to at least 3 g per day. Several negative clinical studies have used the lower dose of 900 mg per day, which was established by German health officials in the early 1990s. Rather than being used continuously like vitamin C to prevent colds, echinacea is often used as needed at the onset of symptoms or in early stages of infection. To support the immune system on an ongoing basis, some herbalists recommend "pulsing," which is to take echinacea usually for two weeks, followed by a resting period of one week. This is based on theory, rather than clinical studies. Other herbalists recommended using it during the entire cold and flu season. For commercial products, please follow manufacturer's label instructions

Cautions

Persons who are allergic to the pollen of other members of the aster family, such as ragweed, may also be allergic to echinacea. Such allergies are rare. The German government recommends that nonspecific

immunostimulants, including echinacea, should not be used in cases of impaired immune response (involving diseases of the immune system itself) including tuberculosis, multiple sclerosis, and HIV infection. This is based on the theoretical concept that immunostimulants should not be used when autoimmune disease is present.

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Capsule



Tablet



Tincture

Garlic

Allium sativum

Source

Few herbs are as closely tied to the human experience as garlic. It is a member of the lily family, and is unknown in the wild. Garlic has actually evolved under cultivation during the past 5,000 years.

Traditional Use

Garlic has been used as food and medicine since the age of the Egyptian pharaohs. The Greek historian and traveler Herodotus (484–425 B.C.) wrote that inscriptions on an Egyptian pyramid recorded the quantities of garlic consumed by the laborers. The Roman naturalist Pliny the Elder (A.D. 23–79) declared that garlic has powerful properties, and is of great benefit against changes of water and of residence. He recommended it to treat asthma, suppress coughs, and expel intestinal parasites, but noted some drawbacks (other than garlic breath): garlic dulled the sight, caused flatulence, injured the stomach if taken in excess, and caused thirst. In China, garlic was traditionally used for fevers, dysentery, and intestinal parasites. In 1858, the French microbi-

ologist Louis Pasteur (famous for “pasteurization”) first reported on garlic’s antibacterial activity.

Current Status

In the past 30 years, garlic has been the subject of over 3,000 scientific studies. Well-documented health benefits include reducing cholesterol and triglycerides in the blood (while increasing high-density lipoproteins, so-called good cholesterol), reducing blood pressure, improving circulation, and helping to prevent yeast infections, colds, and flu. Garlic has also shown potential benefit in supporting the health of people with diabetes, as well as cancer preventative potential, among many other benefits. Garlic has good antibacterial, antifungal, antiparasitic, antioxidant, anti-inflammatory, and immunostimulant properties. At least nine epidemiological studies suggest that garlic significantly decreases the incidence of cancer, especially cancers of the gastrointestinal tract, among those who consume it regularly.

Nearly 3,000 patients have been involved in 18 clinical studies on the use of 600–900 mg of garlic powder to reduce blood lipids over a one- to four-month period. When taken together, the studies show an average reduction of 9–12 percent of total serum cholesterol, and a reduction of 13 percent of triglycerides, compared with placebo. It is considered a useful therapeutic tool for patients with milder forms of hyperlipidemia.

The news media has focused on studies showing garlic may not have as much value as was once thought in helping to prevent cardiovascular risks. A 2000 review of 13 clinical trials on about 800 people reported that garlic preparations did reduce total cholesterol more than placebo, but their data analysis found that the reduction was 4–6 percent, rather than the 9–12 percent reduction commonly stated in the herb literature (Stevinson, et al., 2000).

Despite the controversy, positive studies seem not to be reported in the media. Garlic studies have been shown not only to reduce cholesterol, but also thin the blood and reduce arterial plaque. A recent study found that eating the equivalent one garlic clove a day (3 g) for several months had a significant blood-thinning effect (Ali and Thompson, 1995). A recent study by German researchers (Seigel, et al., 2005)

found that a leading German garlic product not only helped to reduce the formation of molecular complexes that lead to the building of arterial plaque, but also help to reduce or reverse existing plaque. A 2006 study (Rassoul, et al., 2006), found that a water soluble garlic extract helped to significantly decrease the formation of molecules that create adhesion of plaque building substances in arterial walls. Therefore, the benefits do not involve just one mechanism of action. Still various reviews of garlic studies point out methodology flaws of positive clinical studies, and generally agree that more, better designed clinical studies involving larger numbers of patients over a longer period of time should be conducted to reveal garlic's cardiovascular benefits.

More than 30 controlled clinical studies involving over 45,000 subjects have been published on garlic. Although positive studies on garlic's health benefits are voluminous, these studies are rarely reported by the media. The degree of benefit may be debated, but the fact that garlic is at least beneficial is well-supported.

When garlic is cut or crushed, it produces sulfur compounds, such as allicin, because a sulfur-containing amino acid, alliin, comes into contact with the enzyme allinase. Garlic has an extremely complex chemistry, with more than 160 compounds identified from its bulbs and essential oil.

If your food should be your medicine, garlic should be part of your diet.

Preparations

Garlic is available in many product forms, including, of course, fresh and dried garlic, as well as capsules, "odorless" garlic tablets, and aged garlic extracts.

Dose

One average-sized clove of fresh garlic may be chewed daily as a general preventive. Add raw garlic to cooked foods at the end of cooking to retain sulfur compounds and volatile constituents. According to German health authorities, the daily dose is 4 g of fresh garlic. Processed garlic products should deliver at least 5 mg of allicin daily. Clinical and pharmacological studies since 1988 show that 900 mg of powdered garlic standardized to 0.6 percent allicin per 100 mg (equivalent to 5.4 mg

allicin) daily may lower cholesterol. For commercial products, please follow manufacturer's label instructions.

Cautions

Rare cases of allergic reactions to garlic have been reported. Some individuals experience heartburn or flatulence from consuming it. Garlic's blood thinning capability has been found to potentiate the action of the prescription blood thinner warfarin, therefore it should be used under medical supervision when such drugs are used, and should be avoided before surgery.

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Capsule



Tablet

Ginkgo

Ginkgo biloba

Sources

Ginkgo products come from the leaves of the only surviving member of the ginkgo family, a living fossil more than 200 million years old. Most commercial leaf production is from plantations in South Carolina, France, and China.

Traditional Use

Ginkgo leaf is a relatively new herbal medicine, used in China only since the fifteenth century. The leaves were traditionally used for “benefiting the brain,” treatment of lung disorders, relief of cough and asthma symptoms, and diarrhea. The leaf tea was applied externally to treat sores of the skin and remove freckles.

Current Status

Ginkgo leaf extracts are among the better selling herbal medicines in Europe. Most research has focused on the use of these complex extracts to increase circulation to the extremities as well as the brain,

especially in the elderly. Clinical use is supported by more than 400 scientific studies conducted since the late 1950s. Ginkgo extract has also been studied for the treatment of ringing in the ears (tinnitus), male impotence, degenerative nerve conditions such as multiple sclerosis, and other diseases. It has shown potential to relieve difficulties with short-term memory, attention span, and mood in early stages of Alzheimer's disease by improving oxygen metabolism in the brain, among other mechanisms. The vast majority of studies have involved German extracts including EGb 761 (Wilmar Schwabe, Karlsruhe, Germany) and LI 1370 (Lichtwer Pharma, Berlin).

A 1996 prospective, randomized, double-blind, placebo-controlled multicenter study looked at the effect of EGb 761 in the treatment of outpatients with pre-senile and senile primary degenerative dementia associated with Alzheimer's. It looked at the effects on 216 patients over a 24-week period. Three established psychiatric evaluation criteria were used to assess the patient's response. After 24 weeks, information was available on 156 patients, including 79 in the treatment group, and 77 in the placebo group. Twenty-eight percent of patients in the treatment group responded positively to the ginkgo leaf extract, compared with 10 percent in the placebo group (Kanowski, et al., 1966).

The first large-scale American clinical study on ginkgo was published in 1997 by the *Journal of the American Medical Association*. It focused on the effects of ginkgo leaf extracts in improving the short-term memory of early diagnosed Alzheimer's syndrome. The 52-week trial, in the end, evaluated data on 202 patients diagnosed with either Alzheimer type dementia or multi-infarct dementia. Patients received 40-mg tablets before each primary meal per day, delivering a total daily dose of 120 mg of the extract, EGb 761. The researchers concluded that the *Ginkgo biloba* leaf extract, EGb 761, was safe and both stabilizing, and in a significant number of patients, improved cognitive performance and social functioning of demented patients (LeBars, et al., 1997). Ginkgo extract's usefulness has been attributed to various neurological and metabolic effects.

Other clinical studies have shown mixed or negative results such as Solomon, et al. (2002), which showed negative results for memory loss

and early stages of Alzheimer's dementia. The designed outcome was based on measuring the claims for which ginkgo was being marketed. Other examples, both pro and con, can be cited. One aspect usually lost in the clinical debate is the cost and safety benefits of ginkgo versus other treatment options. In recent years cholinesterase (ChE) inhibitors are the drugs of choice for dementias of Alzheimer's type. Various prescription ChE inhibitors currently in use, adverse drug reactions cause 10 times more adverse reactions than ginkgo and cost at least five times more. (Schulz, 2003).

Most of the focus on ginkgo leaf extracts is related to its use in improving memory function in early stages of age-related problems. A recent review of the benefits of ginkgo extracts in healthy people suggests that evidence is growing for safety and efficacy of ginkgo extract to enhance performances on tasks assessing different aspects of memory, attention, and the speed of processing abilities. (Crews, et al., 2005, Blumenthal, 2005). To date more than 140 clinical trials document the safety and efficacy of ginkgo extracts.



Ginkgo's effects have been attributed to compounds called flavonol glycosides, as well as unique compounds—ginkgolides—which are potent inhibitors of a platelet-activating factor involved in the development of inflammatory, cardiovascular, and respiratory disorders. The ginkgolides' activity helps explain the herb's broad-spectrum biological effects.

Another important effect is strong antioxidant activity. With its ability to “scavenge” reactive oxygen forms known as free radicals, ginkgo leaf extract directs antioxidant effects to the brain, central nervous system, and cardiovascular system. This is one of the mechanisms that make it promising in treatment of age-related declines of brain function.

Preparations

Ginkgo is one of the few herbs that uses highly standardized products to achieve predictable results. Nearly all studies have been conducted on a highly concentrated ginkgo leaf extract standardized to 24 percent flavonol glycosides, further calibrated for six percent ginkgolides, with potentially toxic ginkgolic acid removed. The results of studies on the complex leaf extract do not apply to the dried leaf or leaf tea.

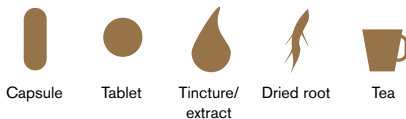
Dose

For predictable results with standardized ginkgo leaf extracts, the dose is very specific and cannot be translated into kitchen measures. Typical dosage ranges for ginkgo leaf extract are 120–160 mg daily (divided into three doses). Some German physicians prescribe 240 mg daily doses. Ginkgo is generally used for six to eight weeks before results are evident. For commercial products, please follow manufacturer's label instructions.

Cautions

Some individuals have shown hypersensitivity to ginkgo leaf extracts including rare cases of gastrointestinal upset, headaches, or skin allergies. In such cases, use of ginkgo should be discontinued. Ginkgo has also been associated with blood-thinning, and should not be used in conjunction with blood-thinning drugs except under a physician's care.

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Ginseng

Panax quinquefolius

(American ginseng)

Panax ginseng (Asian ginseng)

Sources

Ginseng is the root of two different herbs from opposite sides of the world—American ginseng and Asian ginseng. American ginseng is wild-harvested and grown in North America. Asian ginseng, which includes both Korean and Chinese ginseng, is cultivated in China, Korea, and Japan.

Traditional Use

According to Harvard University botanist Shiu Ying Hu, the earliest mention of ginseng is in the 2,000-year-old herbal of Shen Nong: “It is used for repairing the five viscera, quieting the spirit, curbing the emotion, stopping agitation, removing noxious influence, brightening the eyes, enlightening the mind and increasing wisdom. Continuous use leads one to longevity with light weight.” Ginseng use is little changed in 2,000 years.

Current Status

In the last 40 years, Asian ginseng (but not so much American ginseng) has been extensively studied. Ginseng is an adaptogen. The late I.I. Brekhman, the leading Russian researcher on ginseng, described an “adaptogen” as an innocuous substance that causes minimal disorders of an organism’s function. It must have a “nonspecific action” that normalizes body functions, irrespective of the condition or disease. And an adaptogen must be safe. Adaptogens are essentially general tonics.

At least 16 European clinical studies showed that standardized extracts decreased reaction time to visual and auditory stimuli; increased respiratory performance, alertness, power of concentration, and grasp of abstract concepts; and improved visual and motor coordination. Sometimes conflicting results indicate the need for further clinical studies, especially on products with well-defined levels of active compounds. More than 60 clinical studies have been carried out on a European dry extract of Asian ginseng, standardized to 4 percent ginsenosides, widely considered the most relevant biologically active group of compounds. In addition to clinical studies on its adaptogenic effects, other human studies have explored ginseng’s value in cancer prevention, diabetes, fatigue, immunostimulation, menopausal symptoms, male reproduction and respiratory effects (Blumenthal, et al., 2003).

American ginseng, although less well studied, has been the subject of recent clinical trials showing potential benefit in the supportive treatment of type 2 diabetes. Additional clinical studies have explored its use for athletic performance and reflexes. Clearly, more studies are needed. Like its Asian counterpart, it has been shown to be an effective antioxidant.

Ginseng is also a nonspecific immunostimulant, similar to echinacea.



There are at least 40 active chemicals called ginsenosides in Asian ginseng. American and Asian ginsengs contain some of the same, as well as different, ginsenosides, which helps to explain their different actions as expressed in Traditional Chinese Medicine (TCM). Milder American ginseng helps to reduce the heat of the respiratory and digestive systems, whereas the stronger Asian ginseng is a heat-raising tonic for the blood and circulatory systems.

In Germany, Asian ginseng products may be labeled as tonics to treat fatigue, reduced work capacity, lack of concentration, and convalescence.

Preparations

Asian ginseng is available as whole root, powder, and in various forms including “white” and “red” ginseng. White ginseng is simply the dried root; steaming the roots for three hours, then drying them, makes translucent, rust-colored “red” ginseng; it is considered stronger than white ginseng. Product forms include tinctures, capsules, tablets, teas, and extracts. Asian ginseng products standardized to contain 4–7 percent ginsenosides are widely sold and may produce more reliable effects than other forms. American ginseng is generally available as the whole or powdered root, as well as standardized extracts.

Dose

The German Commission E monograph on ginseng recommends a daily dosage of 1–2 g of Asian ginseng root, divided into three portions. TCM prescribes 1–9 g of Asian ginseng or 2–9 g of American ginseng. Higher dosages may be prescribed by healthcare practitioners as needed. For standardized products, 100 mg one or two times a day is the usual recommended dose. For commercial products, please follow manufacturer’s label instructions.

Cautions

Use at normal dosage levels is generally not associated with side effects; however, some persons have experienced over stimulation or gastrointestinal upset and some women have reported breast tenderness or menstrual problems with long-term use. If you have high blood pressure, use ginseng with caution. Avoid ginseng during pregnancy. Possible drug interactions have been suggested for phenelzine (an

MAO inhibitor), the blood thinner warfarin, and the HIV drug zidovudine. Discuss ginseng use with your physician if these or similar drugs have been prescribed. As ginseng may lower blood glucose, diabetic patients should discuss insulin dose with their physicians.

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Capsule



Tablet



Tincture

Saw palmetto

Serenoa repens

Source

Saw palmetto products are made from the fruit of a small shrub in the palm family native to the southeastern United States from South Carolina to southern Mississippi and throughout Florida. Most of the fruit is wild-harvested in Florida.

Traditional Use

Saw palmetto was introduced into medicine by J.B. Read, of Savannah, Georgia, in an 1879 issue of the *American Journal of Pharmacy*: “By its peculiar soothing power on the mucous membrane, it induces sleep, relieves the most troublesome coughs, promotes expectoration, improves digestion, and increases fat, flesh and strength. Its sedative and diuretic properties are remarkable.”

The first mention of its use for prostate problems is an “original communication” in the July 1892 issue of *The New Idea* that stated, “It also exerts a great influence over the organs of reproduction, mamma, ovarium, prostate, tests [sic], etc. Its action on them is a vitalizer, and is

said to be the greatest known, tending to increase their activity and add greatly to their size.”

Current Status

Saw palmetto preparations are used by more than 2 million men in America as an alternative and primary solution for benign prostatic hyperplasia (BPH), a benign (non-malignant) enlargement of the prostate that eventually affects more than half of men over 50 years of age. Pressure of the enlarged prostate on the bladder may cause many of these men to awaken four or five times a night with an urge to urinate and decreased urinary flow and volume. Twenty of at least 25 clinical studies on saw palmetto preparations show that it decreases symptoms associated with BPH, especially reducing the urge to urinate during the night. Components of fat-soluble extracts of the fruit reduce prostate size and inhibit inflammation. A French double-blind clinical trial involving 110 BPH patients, published in 1984, reported that saw palmetto reduced the number of times patients had to urinate at night by more than 45 percent and increased urinary flow rate by more than 50 percent. Painful or difficult urination was significantly reduced in the treatment group as compared to the placebo group. More than 3,000 patients have now been evaluated in clinical trials.

A 1996 major multi-center study was published in the journal *The Prostate* comparing the use of Permixon® (a European saw palmetto extract available composed of 90 percent free and 7 percent esterified fatty acids) with the convention drug finasteride (Proscar®) in the treatment of 1,098 patients diagnosed with BPH. It was given to patients for 26 weeks at a dose of 160 mg (two times a day morning and evening). Head to head, the researchers concluded that both treatments do relieve symptoms of BPH in about two-thirds of patients.



The conventional drug, finasteride, produced a significant decrease in prostate volume size. The saw palmetto product did not reduce prostate size, suggesting different mechanisms of action for the efficacy of both. One of the known side effects of finasteride is decreased libido and impotence. The saw palmetto product produced fewer complaints of decreased libido or impotence.

This study confirms that the saw palmetto product is equally effective as the conventional drug in relieving symptoms of benign prostatic hyperplasia while producing fewer side effects. That's a winner for a head to head test of a conventional drug with a phytomedicine population (Carraro, et al., 1996).

A 2006 study published in the *New England Journal of Medicine* found no significant difference between those taking saw palmetto pills and those taking a placebo in 225 men with moderate to severe symptoms of BPH. Given the study design, the results might have been predicted. Both the German government's official monograph on saw palmetto and the World Health Organization's saw palmetto monograph recommend saw palmetto for the treatment of mild to moderate cases of BPH. Therefore, it might be expected that men with advanced BPH, for which saw palmetto is not recommended, would not respond to the treatment. No such distinction of this important difference was generally reported in the media, which chose instead to use the conclusions of the authors of the study "saw palmetto did not improve symptoms or objective measures of benign prostatic hyperplasia" without distinction of the important detail that advanced cases were treated in the study. It is interesting to note as well that the placebo group had significantly higher rate of adverse effects.

German health authorities allow saw palmetto fruit preparations for difficulty of urination in early stages of BPH.

Preparations

The dried fruit is available in whole or ground form, as well as in capsules, tablets, and tinctures. Benefits are most likely to be achieved with standardized products made with fat-soluble carriers containing high levels of certain fatty acids.

Dose

Traditionally, standardized preparations are taken one or two times a day for a daily dose of 320 mg. A recent clinical trial compared a twice-daily dose of 160 mg with a one-time-a-day dose of 320 mg. One hundred and thirty-two patients were randomized into two groups. No significant differences were found between the two dosage regimes, so it seems 320 mg once a day is an appropriate dosage. The equivalent of 1–2 g ($\frac{1}{2}$ –1 tsp.) of the dried fruit is the average daily dose of other preparations. For commercial products, please follow manufacturer's label instructions.

Cautions

Few side effects or contraindications besides rare stomach upset have been reported. The primary condition for which the fruit is used, BPH, can only be diagnosed by a physician, so consult one for proper examination and treatment.

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Capsule



Tablet



Tincture/
extract



Tea

St. John's wort

Hypericum perforatum

Source

St. John's wort products are made from the dried herb or flowering tops of a member of the St. John's wort family, native to Europe and naturalized in Asia, Africa, North America, South America, and Australia. In 1793 the first recorded specimen in the United States was collected in Pennsylvania. Commercial supplies come from plants cultivated and wild-harvested in Chile, the United States, and Europe.

Traditional Use

St. John's wort has interested herbalists since the first-century Greek physicians Galen and Dioscorides recommended it as a diuretic, wound-healing herb, and treatment for menstrual disorders. During the Middle Ages, remarkable, even mystical, properties were attributed to it—St. John's wort was thought to be best if harvested on St. John's Day (June 24). In nineteenth-century America, physicians used it for wound healing, especially for lacerations involving damaged nerve tissue, and as a diuretic, astringent, and mild sedative. Externally,

St. John's wort oil is used for the treatment of wounds, abrasions, nerve pain, and first-degree burns.

Current Status

St. John's wort emerged as one of the most popular selling herbs in the United States thanks to a segment aired June 27, 1997, on an ABC News 20/20 program, which reported that St. John's wort outsold Prozac® by more than twenty-to-one in Germany. Then, in 2000, a letter-to-the-editor in the British medical journal, *The Lancet*, warned of possible drug interactions between St. John's wort and a drug used for the treatment of AIDS and a drug used to help the body not reject transplanted organs. Consequently, St. John's wort became an obsession with conventional medical researchers—along with other herb-drug interactions. Of 727 references to St. John's wort on all scientific topics at the PubMed database of the National Institutes of Health recently, 173 papers dealt with the topic of St. John's wort's safety. In a recent article (Schulz, 2006) analyzing safety data on St. John's wort in more than 14,000 patients, the incidence of adverse effects was ten times less compared with conventional antidepressant drugs.

Like grapefruit juice, St. John's wort interferes with the enzyme system involved in the metabolism of about 50 percent of prescription drugs. St. John's wort increases the metabolizing activity of this system and therefore lowers the concentration in the blood stream of these prescription drugs, including birth control pills. This reduces their therapeutic activity and is actually the opposite of what grapefruit juice is known to do. Grapefruit juice can greatly increase the level of these same prescription drugs in the blood stream, putting people at risk of overdose after drinking just one glass of juice a day. The bottom line: if you use St. John's wort (or drink grapefruit juice), have your physician check the literature to see if the activity of any prescribed drug might be affected.

Over three-dozen controlled clinical studies involving more than 3,000 patients diagnosed with mild to moderate depression have been documented. In all but a handful of studies, positive results were reported. In most of the studies, St. John's wort was significantly better than placebo, and just as effective as conventional antidepressant drugs for



mild to moderate depression with far fewer and less serious side effects. Clinical studies on St. John's wort's benefits for severe depression, predictably, have produced negative results. It has never been a phytomedicine indicated for major depression. It has always been used *only* for mild to moderate depression. Further, lest we

be too critical of St. John's wort in these trials, one third of studies on pharmaceutical antidepressant drugs fail to show a significant benefit.

In various clinical studies, patients who took St. John's wort extracts felt significant improvement in depressive mood indicators such as feelings of sadness, hopelessness, helplessness, and uselessness, as well as fear and difficult or disturbed sleep. Few significant side effects were observed. Researchers conclude that St. John's wort extract, compared with synthetic antidepressants, produced side effects of minor significance and can be recommended for the treatment of mild and moderate depression (Roder, et al., 2006, Whiskey, et al., 2001).

Preparations

The dried herb and flowering tops may be made into tea or soaked in olive oil (imparting a red pigment, hypericin, to the oil) and used for external applications. Products standardized to contain 0.2 to 0.3 percent hypericin are commonly available. While most products are standardized to hypericin, other components, such as hyperforin, could be involved in antidepressant action. Some evidence suggests flavonoid components could also be involved in its action. Capsules, tablets, tinctures, extracts, and other products are also found in the American market.

Dose

A daily dose of 2–4 g ($\frac{1}{2}$ –1 tsp) of the dried herb (containing 0.2–1.0 mg hypericin) is used in tea. Extracts standardized to 0.3 percent hypericin are taken in doses of 300 mg three times a day to deliver 1 mg of hypericin daily. Other products are standardized to hyperforin at 2–4.5 percent. For commercial products, please follow manufacturer's label instructions.

Cautions

St. John's wort may result in significant interactions with prescription drugs, and should not be taken at the same time as other antidepressants, coumarin-type anticoagulants, the immunosuppressants such as cyclosporine and tacrolimus, certain HIV drugs, birth control pills, and certain drugs used in chemotherapy. Reported cases of interaction are rare and, with medical supervision, easily avoided (Schulz, 2006).

Hypericin from the flowers may cause light-skinned animals that consume the plant to break out in hives or blisters upon exposure to sunlight, a reaction called photodermatitis. If you have fair skin, be aware of this potential problem, especially if you are likely to be exposed to bright sunlight after taking the herb. At least one woman who frequented tanning salons while taking St. John's wort developed severe photodermatitis. She did not tell her physician she was taking St. John's wort, so he attributed the reaction to other causes. Since St. John's wort is a "natural product," the woman could not conceive of it having side effects. If you are taking St. John's wort, avoid sun bathing and the tanning salon. Yes, herbs are natural. Treat nature with respect.

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Valerian

Valeriana officinalis

Sources

Valerian is the root of a perennial member of the valerian family found in eastern, southeastern, and east-central Europe, to south Sweden and the Southern Alps. It escaped from cultivation in the northeastern United States and is commercially grown in Europe, the United States, and elsewhere.

Traditional Use

Valerian, not a major medicinal plant of the ancient classical authors, was best known to them as a diuretic and treatment for menstrual difficulties. The Greek physician Galen used it for epilepsy in children and adults. An Italian nobleman, Fabio Colonna, born in 1567, suffered from epilepsy and found Galen's reference. He took valerian himself and claimed it completely restored his health. His words stimulated interest in the plant as a sedative. Use of valerian to relieve spasms and as a sleep aid evolved in the seventeenth and eighteenth centuries. Valerian was an official remedy in the *U.S. Pharmacopoeia* from 1820 to 1936.

Current Status

Valerian is widely used in Europe as a mild nerve sedative and sleep aid for insomnia, excitability, and exhaustion. Experimental studies have shown that it depresses the central nervous system and relieves muscle spasms. Its sedative action is attributed to a number of chemical fractions, with no single compound emerging as the active principle.

In the 1980s, Swiss researchers were the first to perform clinical studies on the effects of valerian water extracts on sleep patterns. Sleep quality was assessed by the patients and by laboratory measures. The time taken to fall asleep was reduced, especially in older patients and insomniacs. Dream recall and nocturnal movement were apparently not affected. No hangover effect, a common complaint among users of synthetic sedatives, was reported the following morning (Chauffard, 1982; Leathwood, et al., 1982).



Upwards of 30 clinical studies are published on the benefits of valerian preparations for the treatment of anxiety, sleep disorders, and mood. The majority of these studies show that valerian is more effective than placebo in improving sleep in cases of sleep disturbances. Valerian has also been studied in combination products, along with hops (*Humulus lupulus*), lemon balm (*Melissa officinalis*), St. John's wort (*Hypericum perforatum*), hawthorn (*Crataegus laevigata*), and other herbs. Valerian is generally used for treatment of acute insomnia. However, a 1996 study involving 121 patients who were administered a valerian extract for 4 weeks using four different rating scales found significant differences between placebo and treatment groups after the four-week period. A statistically significant difference was observed by patients and physicians after fourteen days, suggesting valerian's benefits are enhanced if used for two to four weeks to improve daily mood and sleep disturbance patterns (Vorbach, 1996).

German health authorities allow use of valerian in sedative and sleep-inducing preparations, for states of excitation, and for difficulty in falling asleep due to nervousness. Valerian provides an excellent example of the benefits and complexities of developing effective drugs based on plant extracts or whole parts rather than single isolated components. While various valepotriates, valerenic acid and other components have been suggested as possible active compounds for *Valeriana* species, no single compound or group of compounds has been proven responsible for the activity of this widely used phytomedicine (Houghton, 1988).

Given its history of use, positive pharmacological, chemical and clinical studies, and its wide therapeutic use as a sleep aid particularly in Europe, valerian is one of the most accepted phytomedicines from a scientific and clinical viewpoint

Preparations

Dried valerian root is available in whole, cut-and-sifted, and powdered form for teas, capsules, tablets, tinctures, extracts, and other preparations. Some products are standardized to contain at least 0.5 percent essential oil.

Dose

The standard daily dose is 2–3 g (about ½ tsp) of the root divided into two or three doses each day. Products standardized to 0.5 percent essential oil may be taken at a dose of 300–400 mg per day. As a sleep aid, valerian is taken one hour before bedtime. For commercial products, please follow manufacturer's label instructions.

Cautions

Some individuals may experience temporary stomach upset. Compounds called valepotriates have been shown to destroy and cause mutations in animal cells. Despite these findings, valerian is generally considered safe. Although official texts do not caution against using valerian during pregnancy and lactation; avoid it to be on the safe side. Animal studies suggest that if valerian is taken with sedatives, it may increase their effect, therefore such use should be avoided.

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For more information

For more information on herbs visit:

The American Herbal Products Association
www.ahpa.org

The Dietary Supplement Information Bureau
www.supplementinfo.org

PubMed, a service of the National Library of Medicine
www.pubmed.gov

HerbMed®—an interactive, electronic herbal database
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