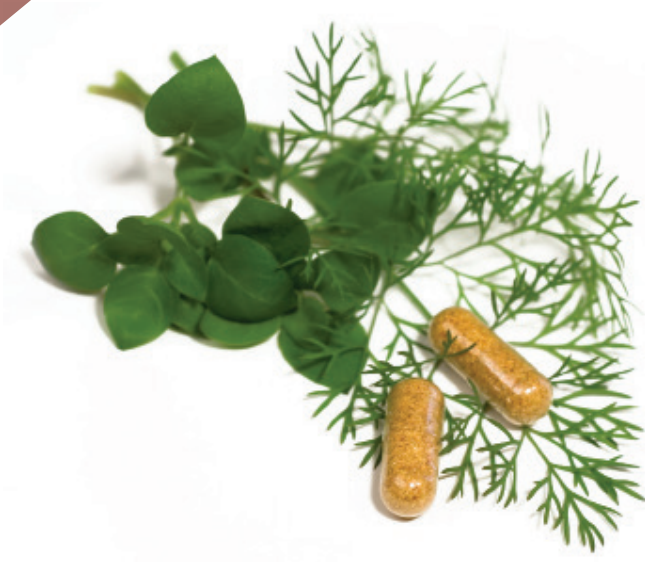
# Herbal Supplements:

## "Natural" Doesn't Always Mean Safe



North American Spine Society
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# Herbal Supplements

People are taking over-the-counter herbs (considered a form of dietary supplement) in greater numbers than ever before. You, or someone you know, may be taking one right now. People take herbs for many reasons from general health improvement to care of chronic conditions, including back pain. According to US News and World Report, Congress' General Accounting Office estimated consumer spending for dietary supplements and functional foods to be about $31 billion in 1999.

## "Natural" Doesn't Always Mean Safe

Like prescription medicines, herbs can have benefits. However, like prescriptions, they can also have unwanted side effects, cause drug interactions and possibly create surgical problems.

Large doses of herbs (the belief that "if one is good, more must be better") can be dangerous. Many herbs have drug-like effects on the body. The many chemical components in herbal products may have varied strengths based on plant genetics, plant parts and growing conditions. Herbs have many components that may also work together differently based on harvesting, processing or packaging. Contamination also can take place during production. For example, heavy metals have been found in some Asian herbal products.

Even herbs that are generally safe can be dangerous or have side effects under the wrong conditions. For instance, herbs can act together

with anesthesia or other medicines commonly used in surgery or affect the operation itself, causing surgical complications.

Drug-herb interactions unrelated to surgery are also common. Many supplements contain active ingredients that have strong biological effects and are not safe for everyone. According to a study in the Journal of the American Medical Association (JAMA), roughly 15 million adults are at risk for possible adverse interactions between prescription medicines and herbs or high dose vitamins.  More than 2900 adverse events related to supplements have been reported to the Food and Drug Administration (FDA), including 104 deaths. The FDA estimates that for each report it receives, there are 100 more it doesn't. Much of the material in this pamphlet can be found in the FDA Center for Food Safety and Applied Nutrition document, Tips for the Savvy Supplement User: Making Informed Decisions and Evaluating Information (see "Sources" at the back of this brochure for the Web site address.)

# Should I Ask My Doctor Before Using a Supplement?

Checking with your doctor before taking a supplement is a good idea, especially for certain people. Dietary supplements including herbs may not be risk-free under certain circumstances. If you are pregnant, nursing a baby or have a chronic medical condition (such as diabetes, hypertension or heart disease) consult your doctor or pharmacist before purchasing or taking any supplement. While vitamin and mineral supplements are widely used and generally considered safe for children, you may wish to check with your doctor or pharmacist before giving these or any other dietary supplement to your child. If you plan to use a dietary supplement in place of drugs or together with any drug, tell your health care provider first. If you have certain health conditions and take these products, you may be placing yourself at risk. Bring your herbal or other dietary supplements with you to doctor visits. Your health care provider can review your supplements with you and tell you about any possible problems or risks.

### Some dietary supplements may interact with prescription and over-the-counter medicines

Combining supplements or using supplements together with medicines (prescription or over-the-counter) could under certain circumstances produce undesirable effects, some life-threatening. Be alert to warnings about these products, whether taken alone or in combination. For example, Coumadin (a prescription medicine), gingko biloba (an herb), aspirin

(an over-the-counter drug) and vitamin E (a vitamin) can each thin the blood, and taking any of these products together can increase the potential for internal bleeding. Combining St. John's Wort with certain HIV drugs significantly reduces their effectiveness. St. John's Wort may also reduce the effectiveness of prescription drugs for heart disease, depression, seizures, certain cancers or birth control pills.

### Some dietary supplements can have unwanted effects during surgery

It is important to tell your doctor about vitamins, minerals, herbs or any other supplements you are taking, especially before surgery. You may be asked to stop taking these products at least 2-3 weeks before an operation to avoid potentially dangerous supplement/drug interactions—such as changes in heart rate, blood pressure and increased bleeding—that could negatively affect your surgery.

### Other Safety Tips…

- Do not take larger than recommended doses of herbs.
- Elderly people should not take herbs without the approval of a doctor. It is a good idea for everyone to check with their health care provider before taking dietary supplements.
- Avoid long term use of herbs (more than several weeks).
- Take time to study about your supplements so you know about them and can avoid problems.

# Reporting Adverse Effects

Adverse effects from using dietary supplements should be reported to MedWatch (the program for reporting problems with FDA-regulated products) You, your health care provider, or anyone may report a serious adverse event or illness to the FDA if you believe it is related to the use of any dietary supplement product. The FDA would like to know when you think a product caused a serious problem, even if you are not sure that the product was the cause or do not visit a doctor or clinic. In addition to telling FDA online or by phone, you may use the MedWatch form available from the FDA Web site.

Telephone: 1-800-FDA-1088

Fax: 1-800-FDA-0178
(using a MedWatch reporting form)

Online: http://www.fda.gov/medwatch/how.htm

# Possible Side Effects and Interactions

This list is a sample and does not contain all herbs that may cause the listed or other conditions or hazards. All herb use should be approved by a health care provider.

## Possible Risk of Increased Bleeding (Especially with Surgery)

Chamomile
Dong Quai
Feverfew
Fish Oil
Garlic
Ginger
Gingko
Ginseng
St. John's Wort
Vitamin E

## May Worsen Swelling (Edema) and/or High Blood Pressure (Hypertension)

Celery
Dandelion
Elder
Goldenseal
Guaiacum
Juniper

## Interacts with Nonsteroidal Antiinflammatory Drugs (prescription and over-the-counter pain relievers including aspirin, Advil®, Motrin® and Aleve®)

Feverfew
Gingko
Ginseng
St. John's Wort
Uva-Ursi

# More Information About Supplements

Who is responsible for safety and effectiveness of dietary supplements?

By law, manufacturers of dietary supplements are responsible for making sure their products are safe before they go to market. They are also responsible for making sure that the claims on their labels are accurate and truthful. The government does not review dietary supplements before they are marketed, but the FDA is responsible for taking action against any unsafe supplement product that reaches the market.

## Searching the Internet for Information

When searching the Web for information on dietary supplements, try using directory sites of respected organizations rather than blind searches with a search engine. Ask yourself these questions:

- Who operates the site?
  Is the site run by the government, a university, or a reputable medical or health-related association (eg, American Medical Association, American Diabetes Association, American Heart Association, National Institutes of Health, National Academies of Science, or the US Food and Drug Administration)? Is the information written or reviewed by qualified health professionals, experts in the field, academic world, government or the medical community?
- What is the purpose of the site?
  Is the purpose of the site to objectively educate the public or just to sell a product? Be aware of practitioners or organizations whose main interest is selling products, either directly or through linked sites. Commercial sites should clearly distinguish scientific information from advertisements, but do

not always do so. Most nonprofit and government sites contain no advertising, and access to the site and materials is usually free.

- What is the source of the information and does it have any references?
  Has the study been reviewed by recognized scientific experts and published in reputable peer-reviewed scientific journals, like the New England Journal of Medicine? Does the information say "some studies show…" or does it tell where the study is listed so that you can check the authenticity of the references? For example, can the study be found in the National Library of Medicine's database of literature citations (PubMed link-http://www.ncbi.nlm.nih.gov/PubMed/)?
- Is the information current?
  Check to see when the material was posted or updated. Often new research or other findings are not reflected in old material, eg, side effects or interactions with other products or new evidence that might have changed earlier thinking. Ideally, health and medical sites should be updated frequently.
- How reliable is the Internet or e-mail solicitations?
  While the Internet is a rich source of health information, it is also an easy way to spread myths, hoaxes and rumors about supposed news, studies, products or findings. To avoid such hoaxes, be skeptical and watch for very emphatic language with UPPERCASE LETTERS and lots of exclamation points!!!! Beware of such phrases as: "This is not a hoax" or "Send this to everyone you know."

Contact the manufacturer for more information about the specific product you are purchasing
If you cannot tell whether the product you are purchasing meets the same standards as those used in the research studies you read about, check with the manufacturer or distributor. Ask to speak to someone who can address your questions, some of which may include:

- What information does the firm have to substantiate the claims made for the product? Be aware that sometimes firms provide so-called “proof” of their claims by citing undocumented reports from satisfied consumers or “internal” graphs and charts that could be mistaken for evidence-based research.

- Does the firm have information to share about tests it has conducted on the safety or efficacy of the ingredients in the product?

- Does the firm have quality control systems in place to determine if the product actually contains what is stated on the label and is free of contaminants?

- Has the firm received any adverse event reports from consumers using their products?

# Additional Safety Tips

- Ask yourself: Does it sound too good to be true? Do claims for the product seem exaggerated and unrealistic? Are simple conclusions drawn from a complex study to sell a product? While the Web can be a valuable source of accurate, reliable information, it also has a wealth of misinformation that may not be obvious. Learn to distinguish hype from evidence-based science. Nonsensical jargon can sound very convincing. Also, be skeptical about anecdotal information from people who have no formal training in nutrition or herbal supplements, or from personal testimonials (eg, from store employees, friends or on-line chat rooms and message boards) about incredible benefits or results. Question these people about their training and knowledge in nutrition or medicine.

- Think twice about chasing the latest headline. Sound health advice is generally based on a body of research, not a single study. Be wary of results claiming a “quick fix” that depart from previous research and scientific beliefs. Keep in mind science does not advance by dramatic breakthroughs, but by taking many small steps, slowly building toward agreement. Also, news stories about the latest scientific study, especially on TV or radio, are often too short to include important details that may apply to you or allow you to make an informed decision.

- Check your assumptions about these statements:

Even if a product may not help me, it at least won't hurt me. Don't assume this is always true. When consumed in high enough amounts, for a long enough time, or together with certain other substances, all chemicals can be toxic. This includes nutrients, plant components and other biologically active ingredients.

When I see the term "natural," it means that a product is healthful and safe. Consumers can be misled if they assume this term assures wholesomeness, or that these food-like substances have milder effects, which makes them safer than drugs. The term "natural" on labels is not well defined and sometimes used vaguely to suggest unproven benefits or safety. For example, many weight loss products claim to be "natural" or "herbal," but this doesn't necessarily make them safe. Their ingredients may act together with drugs or may be dangerous for people with certain medical conditions.

A product is safe when there is no cautionary information on the product label. Dietary supplement manufacturers may not necessarily include warnings about potential adverse effects on the labels of their products. If consumers want to know about the safety of a specific supplement, they should contact the manufacturer of that brand directly. It is the manufacturer's responsibility to determine that the supplement it produces or distributes is safe and that there is substantiated evidence that the label claims are truthful and not misleading.

A recall of a harmful product guarantees that all such harmful products will be immediately and completely removed from the marketplace. A product recall of a dietary supplement is voluntary and while many manufacturers do their best, a recall does not necessarily remove all harmful products from the marketplace.

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# Notes

# Notes


## DISCLAIMER

The information provided in this document should be considered a general overview. It is not all-inclusive and is provided for information and education only. This document should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any treatment is to be made by the physician in light of circumstances presented by the patient and the needs and resources particular to the locality or institution. Some herbs listed have multiple species (eg, ginseng). Different species may have different properties and produce different effects and interactions. This list contains a range of potential interactions. Patient consumption of herbs should be investigated on a case-by-case basis, in each case examining and researching the specific product/species the patient is taking. NASS encourages spine care providers and patients to educate themselves about alternative therapies commonly used.

Information provided is based on literature searches in December 2001 and January 2002 and reviews of relevant Web sites and documents, including those of the US government and other associations. NASS disclaims any and all liability for injury or other damages resulting to any individual and for all claims that may arise out of the use of techniques discussed.