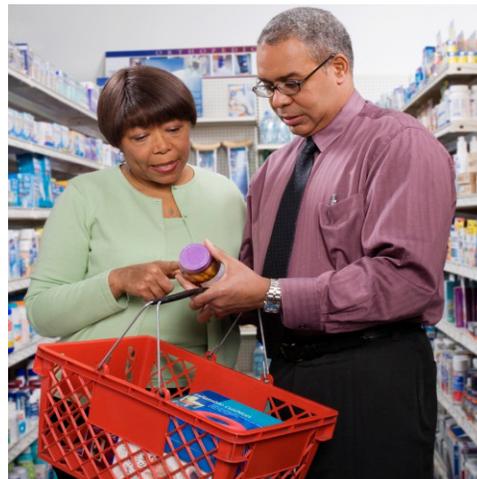




Using Dietary Supplements Wisely



© Comstock/Thinkstock

Like many Americans, you may take dietary supplements in an effort to stay healthy. With so many dietary supplements available and so many claims made about their health benefits, how can you decide whether a supplement is safe or useful? This fact sheet provides a general overview of dietary supplements, discusses safety considerations, and suggests sources for additional information.

Key Points

- Dietary supplements contain a variety of ingredients, such as vitamins, minerals, amino acids, and herbs or other botanicals. Research has confirmed health benefits of some dietary supplements but not others.
- To use dietary supplements safely, read and follow the label instructions, and recognize that “natural” does not always mean “safe.” Be aware that an herbal supplement may contain dozens of compounds and that all of its ingredients may not be known.
- Some dietary supplements may interact with medications or pose risks if you have medical problems or are going to have surgery. Most dietary supplements have not been tested in pregnant women, nursing mothers, or children.
- The U.S. Food and Drug Administration (FDA) regulates dietary supplements, but the regulations for dietary supplements are different and less strict than those for prescription or over-the-counter drugs.
- Tell all your health care providers about any complementary health approaches you use. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care.

Using Dietary Supplements Wisely

About Dietary Supplements

Dietary supplements were defined in a law passed by Congress in 1994 called the Dietary Supplement Health and Education Act (DSHEA). According to DSHEA, a dietary supplement is a product that:

- Is intended to supplement the diet
- Contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and certain other substances) or their constituents
- Is intended to be taken by mouth, in forms such as tablet, capsule, powder, softgel, gelcap, or liquid
- Is labeled as being a dietary supplement.

Herbal supplements are one type of dietary supplement. An herb is a plant or plant part (such as leaves, flowers, or seeds) that is used for its flavor, scent, and/or potential health-related properties. “Botanical” is often used as a synonym for “herb.” An herbal supplement may contain a single herb or mixtures of herbs. The law requires that all of the herbs be listed on the product label.

Research has shown that some uses of dietary supplements are beneficial to health. For example, scientists have found that folic acid (a vitamin) prevents certain birth defects. Other research on dietary supplements has failed to show benefit; for example, several major studies of the herbal supplement echinacea did not find evidence of benefit against the common cold.

Dietary Supplement Use in the United States

According to the 2007 National Health Interview Survey, which included questions on Americans’ use of natural products (not including vitamins and minerals), 17.7 percent of American adults had used these types of products in the past 12 months. The most popular of these products used by adults in the past 30 days were fish oil/omega 3/DHA (37.4 percent), glucosamine (19.9 percent), echinacea (19.8 percent), flaxseed oil or pills (15.9 percent), and ginseng (14.1 percent). National Health and Nutrition Examination Survey (NHANES) data collected from 2003 to 2006 that covered all types of dietary supplements indicate that 53 percent of American adults took at least one dietary supplement, most commonly multivitamin/multimineral supplements (taken by 39 percent of all adults). Women were more likely than men to take dietary supplements.

Federal Regulation of Dietary Supplements

The Federal Government regulates dietary supplements through the FDA. The regulations for dietary supplements are not the same as those for prescription or over-the-counter drugs.

- Manufacturers of dietary supplements are responsible for ensuring that their products are safe and that the label information is truthful and not misleading. However, a manufacturer of a dietary supplement does not have to provide the FDA with data that demonstrate the safety of the product before it is marketed.¹

¹ “New dietary ingredients” (substances that were not used in dietary supplements before 1994) are an exception to this rule; evidence of their safety must be provided to the FDA before they can be used in dietary supplements.

Using Dietary Supplements Wisely

In contrast, manufacturers of drugs have to provide the FDA with evidence that their products are both safe and effective before the drugs can be sold.

- Manufacturers may make three types of claims for their dietary supplements: health claims, structure/function claims, and nutrient content claims. Some of these claims describe the link between a food substance and a disease or health-related condition; the intended benefits of using the product; or the amount of a nutrient or dietary substance in a product. Different requirements apply to each type of claim. If a dietary supplement manufacturer makes a claim about a product's effects, the manufacturer must have data to support the claim. Claims about how a supplement affects the structure or function of the body must be followed by the words "This statement has not been evaluated by the U.S. Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure, or prevent any disease."
- Manufacturers must follow "current good manufacturing practices" for dietary supplements to ensure that these products are processed, labeled, and packaged consistently and meet quality standards.
- Once a dietary supplement is on the market, the FDA evaluates safety by doing research and keeping track of any side effects reported by consumers, health care providers, and supplement companies. If the FDA finds a product to be unsafe, it can take action against the manufacturer and/or distributor, and may issue a warning or require that the product be removed from the marketplace.

Also, once a dietary supplement is on the market, the FDA monitors product information, such as label claims and package inserts. The Federal Trade Commission (FTC) is responsible for regulating product advertising; it requires that all information be truthful and not misleading.

The Federal Government has taken legal action against dietary supplement promoters or Web sites that promote or sell dietary supplements for making false or deceptive statements about their products or because marketed products have proven to be unsafe. In 2010, an investigation by the U.S. Government Accountability Office found instances in which written sales materials for herbal dietary supplements sold through online retailers included illegal claims that the products could treat, prevent, or cure diseases such as diabetes, cancer, or cardiovascular disease.

Sources of Science-Based Information

It's important to look for reliable sources of information on dietary supplements so you can evaluate the claims that are made about them. The most reliable information on dietary supplements is based on the results of rigorous scientific testing.

To get reliable information on a particular dietary supplement:

- Ask your health care providers. Even if they don't know about a specific dietary supplement, they may be able to access the latest medical guidance about its uses and risks.
- Look for scientific research findings on the dietary supplement. The National Center for Complementary and Integrative Health (NCCIH) and the National Institutes of Health (NIH) Office of Dietary Supplements (ODS), as well as other Federal agencies, have free publications, clearinghouses, and information on their Web sites.

Using Dietary Supplements Wisely

Safety Considerations

If you're thinking about or currently using a dietary supplement, here are some points to keep in mind.

- **Tell all your health care providers** about any complementary health approaches you use. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care.
- It's especially important to talk to your health care providers if you:
 - Take any medications (whether prescription or over-the-counter). Some dietary supplements have been found to interact with medications. For example, the herbal supplement St. John's wort interacts with many medications, making them less effective.
 - Are thinking about replacing your regular medication with one or more dietary supplements.
 - Expect to have surgery. Certain dietary supplements may increase the risk of bleeding or affect the response to anesthesia.
 - Are pregnant, nursing a baby, attempting to become pregnant, or considering giving a child a dietary supplement. Most dietary supplements have not been tested in pregnant women, nursing mothers, or children.
 - Have any medical conditions. Some dietary supplements may harm you if you have particular medical conditions. For example, by taking supplements that contain iron, people with hemochromatosis, a hereditary disease in which too much iron accumulates in the body, could further increase their iron levels and therefore their risk of complications such as liver disease.
- If you're taking a dietary supplement, **follow the label instructions**. Talk to your health care provider if you have any questions, particularly about the best dosage for you to take. If you experience any side effects that concern you, stop taking the dietary supplement, and contact your health care provider. You can report serious problems suspected with dietary supplements to the U.S. Food and Drug Administration and the National Institutes of Health through the Safety Reporting Portal.
- Keep in mind that although many dietary supplements (and some prescription drugs) come from natural sources, **“natural” does not always mean “safe.”** For example, the herbs comfrey and kava can cause serious harm to the liver. Also, a manufacturer's use of the term “standardized” (or “verified” or “certified”) does not necessarily guarantee product quality or consistency.
- Be aware that **an herbal supplement may contain dozens of compounds** and that all of its ingredients may not be known. Researchers are studying many of these products in an effort to identify what ingredients may be active and understand their effects in the body. Also consider the possibility that what's on the label may not be what's in the bottle. Analyses of dietary supplements sometimes find differences between labeled and actual ingredients. For example:
 - An herbal supplement may not contain the correct plant species.
 - The amounts of the ingredients may be lower or higher than the label states. That means you may be taking less—or more—of the dietary supplement than you realize.
 - The dietary supplement may be contaminated with other herbs, pesticides, or metals, or even adulterated with unlabeled, illegal ingredients such as prescription drugs.

Using Dietary Supplements Wisely

For current information from the Federal Government on the safety of particular dietary supplements, check the “Dietary Supplement Alerts and Safety Information” section of the FDA Web site at www.fda.gov/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/default.htm or the “Alerts and Advisories” section of the NCCIH Web site at nccih.nih.gov/news/.

Dietary Supplements Research at the National Institutes of Health

NCCIH sponsors an array of research to see how dietary supplements might affect the body and tests their use in clinical trials. In fiscal year 2011, NCCIH supported approximately 200 research projects studying dietary supplements.

Also within NIH, ODS focuses specifically on dietary supplements, seeking to strengthen knowledge and understanding of these products by supporting and evaluating research, disseminating results, and educating the public.

NCCIH, ODS, and the National Cancer Institute collaborate to fund dietary supplement research centers focused on botanicals, known collectively as the NIH Botanical Research Centers Program. Scientists at the centers conduct basic research, such as exploring mechanisms of action, on botanicals and help to select products to be tested in clinical trials. The centers are advancing the scientific base of knowledge about botanicals, making it possible to better evaluate their safety and effectiveness.

NCCIH also sponsors a number of other research centers that are studying topics in this field, including antioxidant therapies, botanicals for autoimmune and inflammatory diseases, grape-derived polyphenols for Alzheimer’s disease, and botanicals for pancreatic diseases and for colorectal cancer.

For More Information

NCCIH Clearinghouse

The NCCIH Clearinghouse provides information on NCCIH and complementary and integrative health approaches, including publications and searches of Federal databases of scientific and medical literature. The Clearinghouse does not provide medical advice, treatment recommendations, or referrals to practitioners.

Toll-free in the U.S.: 1-888-644-6226

TTY (for deaf and hard-of-hearing callers): 1-866-464-3615

Web site: nccih.nih.gov

E-mail: info@nccih.nih.gov

PubMed®

A service of the National Library of Medicine, PubMed contains publication information and (in most cases) brief summaries of articles from scientific and medical journals.

Web site: www.ncbi.nlm.nih.gov/pubmed

Using Dietary Supplements Wisely

Office of Dietary Supplements, NIH

ODS seeks to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, supporting research, sharing research results, and educating the public. Its resources include publications (such as *Dietary Supplements: What You Need to Know*), fact sheets on a variety of specific supplement ingredients and products (such as vitamin D and multivitamin/mineral supplements), and the PubMed Dietary Supplement Subset.

Web site: www.ods.od.nih.gov

E-mail: ods@nih.gov

PubMed Dietary Supplement Subset: ods.od.nih.gov/Research/PubMed_Dietary_Supplement_Subset.aspx

U.S. Food and Drug Administration (FDA)

The FDA oversees the safety of many products, such as foods, medicines, dietary supplements, medical devices, and cosmetics. Its series of consumer updates includes the publication FDA 101: *Dietary Supplements* (www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm050824.pdf).

Toll-free in the U.S.: 1-888-463-6332

Web site: www.fda.gov

Center for Food Safety and Applied Nutrition (CFSAN)

Part of the FDA, CFSAN oversees the safety and labeling of supplements, foods, and cosmetics. It provides information on dietary supplements. Online resources for consumers include *Tips for Dietary Supplement Users: Making Informed Decisions and Evaluating Information*.

Toll-free in the U.S.: 1-888-723-3366

Web site: www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/

Safety Reporting Portal

The Safety Reporting Portal allows consumers, manufacturers, health care professionals, researchers, and public health officials to file reports on serious problems suspected with dietary supplements to the U.S. Food and Drug Administration and the National Institutes of Health.

Report adverse events at www.safetyreporting.hhs.gov

Federal Trade Commission

The FTC is the Federal agency charged with protecting the public against unfair and deceptive business practices. A key area of its work is the regulation of advertising (except for prescription drugs and medical devices).

Toll-free in the U.S.: 1-877-382-4357

Web site: www.ftc.gov

Using Dietary Supplements Wisely

NIH National Library of Medicine's MedlinePlus

To provide resources that help answer health questions, MedlinePlus brings together authoritative information from NIH as well as other Government agencies and health-related organizations.

Web site: www.medlineplus.gov

Information on dietary supplements: www.nlm.nih.gov/medlineplus/dietarysupplements.html

Dietary Supplements Labels Database

The Dietary Supplement Label Database—a project of the National Institutes of Health—has all the information found on labels of many brands of dietary supplements marketed in the United States. Users can compare the amount of a nutrient listed on a label with the Government's recommended amounts.

Web site: www.dsld.nlm.nih.gov/dsld/

Key References

Barnes PM, Bloom B, Nahin RL. Complementary and alternative medicine use among adults and children: United States, 2007. *CDC National Health Statistics Report* #12. 2008.

Dietary supplements. U.S. Food and Drug Administration Web site. Accessed at www.fda.gov/Food/DietarySupplements on December 20, 2012.

Dietary supplements: what you need to know. NIH Office of Dietary Supplements Web site. Accessed at ods.od.nih.gov/HealthInformation/DS_WhatYouNeedToKnow.aspx on December 20, 2012.

Gahche J, Bailey R, Burt V, et al. *Dietary Supplement Use Among U.S. Adults Has Increased Since NHANES III (1988-1994)*. NCHS Data Brief No. 61, April 2011. Centers for Disease Control and Prevention Web site. Accessed at <http://www.cdc.gov/nchs/data/databriefs/db61.pdf> on December 20, 2012.

Kutz GD. *Herbal Dietary Supplements. Examples of Deceptive or Questionable Marketing Practices and Potentially Dangerous Advice*. Testimony Before the Special Committee on Aging, U.S. Senate (May 26, 2010) by the Managing Director of Forensic Audits and Special Investigations. U.S. Government Accountability Office Web site. Accessed at <http://www.gao.gov/new.items/d10662t.pdf> on December 20, 2012.

U.S. Food and Drug Administration. *Tainted Products Marketed as Dietary Supplements*. U.S. Food and Drug Administration Web site. Accessed at <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM236998.pdf> on December 20, 2012.

Using Dietary Supplements Wisely

This publication is not copyrighted and is in the public domain.

Duplication is encouraged.

NCCIH has provided this material for your information. It is not intended to substitute for the medical expertise and advice of your primary health care provider. We encourage you to discuss any decisions about treatment or care with your health care provider. The mention of any product, service, or therapy is not an endorsement by NCCIH.

U.S. Department of Health & Human Services • National Institutes of Health • National Center for Complementary and Integrative Health

nccih.nih.gov