

Dietary Supplements: What You Need to Know

Many adults and children in the United States take one or more vitamins or other dietary supplements. In addition to vitamins, dietary supplements can contain minerals, herbs or other botanicals, amino acids, enzymes, and many other ingredients. Dietary supplements come in a variety of forms, including tablets, capsules, gummies, and



powders, as well as drinks and energy bars. Popular supplements include vitamins D and B12; minerals like calcium and iron; herbs such as echinacea and garlic; and products like glucosamine, probiotics, and fish oils.

The Dietary Supplement Label

Products sold as dietary supplements come with a Supplement Facts label that lists the active ingredients, the amount per serving (dose), as well as other ingredients, such as fillers, binders, and flavorings. The manufacturer suggests the serving size, but you or your healthcare provider might decide a different amount is more appropriate for you.

Effectiveness

Some dietary supplements can help you get adequate amounts of essential nutrients if you don't eat a nutritious variety of foods. However, supplements can't take the place of the variety of foods that are important to a healthy diet. To learn more about what makes a healthy diet, the Dietary Guidelines for Americans (http://health.gov/dietaryguidelines) and ChooseMyPlate (http://www.choosemyplate.gov) are good sources of information.

Some dietary supplements can improve overall health and help manage some health conditions. For example:

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- Calcium and vitamin D help keep bones strong and reduce bone loss.
- Folic acid decreases the risk of certain birth defects.
- Omega-3 fatty acids from fish oils might help some people with heart disease.
- A combination of vitamins C and E, zinc, copper, lutein, and zeaxanthin (known as AREDS) may slow down further vision loss in people with age-related macular degeneration (AMD).

The U.S. Food and Drug Administration (FDA) does not determine whether dietary supplements are effective before they are marketed. Therefore, advertised claims for some supplements might not be backed by scientific evidence.

Safety and Risk

Many supplements contain active ingredients that can have strong effects in the body. Always be alert to the possibility of unexpected side effects, especially when taking a new product.

You are most likely to have side effects from dietary supplements if you take them at high doses or instead of prescribed medicines, or if you take many different supplements. Some supplements can increase the risk of bleeding or, if taken before surgery, can change your response to anesthesia. Supplements can also interact with some medicines in ways that might cause problems. Here are a few examples:

- Vitamin K can reduce the ability of the blood thinner Coumadin® to prevent blood from clotting.
- St. John's wort can speed the breakdown of many medicines and reduce their effectiveness (including some antidepressants, birth control pills, heart medications, anti-HIV medications, and transplant drugs).
- Antioxidant supplements, such as vitamins C and E, might reduce the effectiveness of some types of cancer chemotherapy.

Manufacturers may add vitamins, minerals, and other supplement ingredients to foods you eat, especially breakfast cereals and beverages. As a result, you may get more of these ingredients than you think, and more might not be better. Taking more than you need costs more and might also raise your risk of side effects. For example, too much vitamin A can cause headaches and liver damage, reduce bone

strength, and cause birth defects. Excess iron causes nausea and vomiting and may damage the liver and other organs.

Be cautious about taking dietary supplements if you are pregnant or nursing. Also, be careful about giving supplements to a child, unless recommended by their healthcare provider. Many supplements have not been well tested for safety in pregnant women, nursing mothers, or children.

If you think that you have had a serious reaction from a dietary supplement, let your healthcare provider know. He or she may report your experience to the FDA. You may also submit a report directly to the FDA by calling 800-FDA-1088 or completing an online form (http://www.fda.gov/Safety/MedWatch/HowToReport). You should also report your reaction to the manufacturer by using the contact information on the product label.

Quality

The FDA has established good manufacturing practices (GMPs) that companies must follow to help ensure the identity, purity, strength, and composition of their dietary supplements. These GMPs can prevent adding the wrong ingredient (or too much or too little of the correct ingredient) and reduce the chance of contamination or improper packaging and labeling of a product. The FDA periodically inspects facilities that manufacture supplements.

Several independent organizations offer quality testing and allow products that pass these tests to display a seal of quality assurance that indicates the product was properly manufactured, contains the ingredients listed on the label, and does not contain harmful levels of contaminants. These seals do not guarantee that a product is safe or effective. Organizations that offer quality testing include:

- U.S. Pharmacopeia
- ConsumerLab.com
- NSF International

Keep in Mind

 Consult your healthcare provider before taking dietary supplements to treat a health condition.

- Get your healthcare provider's approval before taking dietary supplements in place of, or in combination with, prescribed medicines.
- If you are scheduled to have any type of surgical procedure, talk with your healthcare provider about any supplements you take.
- Keep in mind the term "natural" doesn't always mean safe. Some all-natural botanical products, for example, like comfrey and kava, can harm the liver. A dietary supplement's safety depends on many things, such as its chemical makeup, how it works in the body, how it is prepared, and the amount you take.
- Before taking any dietary supplement, use the information sources listed in this brochure and talk to your healthcare providers to answer these questions:
 - What are its potential benefits for me?
 - Ones this product have any safety risks?
 - What is the proper dose to take?
 - How, when, and for how long should I take it?

Talk with Your Healthcare Providers

Tell your healthcare providers (including doctors, pharmacists, and dietitians) about any dietary supplements you're taking so that you can discuss what's best for your overall health. They can help you determine which supplements, if any, might be valuable for you.

Keep a complete record of any dietary supplements and medicines you take. The Office of Dietary Supplements (ODS) provides a useful form, "My Dietary Supplement and Medicine Record

(https://ods.od.nih.gov/pubs/DietarySupplementandMedicineRecord.pdf)," that you can print and fill out at home. For each product, note the name, the dose you take, how often you take it, and the reason for use. You can share this record with your healthcare providers to discuss what's best for your overall health. When you see your healthcare provider, you can also bring the products you take.

Federal Regulation of Dietary Supplements

Dietary supplements are products intended to supplement the diet. They are not medicines and are not intended to treat, diagnose, mitigate, prevent, or cure diseases. The FDA is the federal agency that oversees both supplements and medicines, but the FDA regulations for dietary supplements are different from those for prescription or over-the-counter medicines.

Medicines must be approved by the FDA before they can be sold or marketed. Supplements do not require this approval. Supplement companies are responsible for having evidence that their products are safe, and the label claims are truthful and not misleading. However, as long as the product does not contain a "new dietary ingredient" (one introduced since October 15, 1994), the company does not have to provide this safety evidence to the FDA before the product is marketed.

Dietary supplement labels may include certain types of health-related claims. Manufacturers are permitted to say, for example, that a supplement promotes health or supports a body function (like immunity or heart health). These claims must be followed by the words, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Manufacturers must follow GMPs to ensure the identity, purity, strength, and composition of their products. If the FDA finds a dietary supplement to be unsafe, it may remove the product from the marketplace or ask the manufacturer to voluntarily recall the product.

Once a dietary supplement is on the market, the FDA monitors information on the product's label and any package insert to make sure that the information is accurate and that any claims made are truthful and not misleading. The Federal Trade Commission, which monitors product advertising, also requires information about a supplement product to be truthful and not misleading.

The federal government can take legal action against companies and websites that sell dietary supplements when the companies make false or deceptive statements about their products, if they promote them as treatments or cures for diseases, or if their products are unsafe.

Federal Government Information Sources on Dietary Supplements

NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health supports research and provides educational materials on dietary supplements.

- Office of Dietary Supplements (http://ods.od.nih.gov)
 ODS provides accurate and up-to-date scientific information about dietary supplements.
- National Center for Complementary and Alternative Medicine (http://nccam.nih.gov)
 NCCIH also provides scientific information about dietary supplement
- National Library of Medicine (http://www.nlm.nih.gov)
 Medline Plus (http://medlineplus.gov)
 PubMed (http://www.pubmed.gov)
- NIH Health Information (http://health.nih.gov)

U.S. FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration (http://www.fda.gov/Food/DietarySupplements) issues rules and regulations and oversees dietary supplement labeling, marketing, and safety. Recall notices are also posted on the FDA webpage or you can subscribe to receive FDA notices of recalls, market withdrawals, and safety alerts (https://updates.fda.gov/SubscriptionManagement).

FEDERAL TRADE COMMISSION

The Federal Trade Commission (http://www.ftc.gov) regulates health and safety claims made in advertising for dietary supplements.

U.S. DEPARTMENT OF AGRICULTURE

The U.S. Department of Agriculture (http://www.nutrition.gov) provides information on a variety of food and nutrition topics (http://fnic.nal.usda.gov).

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

The U.S. Department of Health and Human Services provides wellness information, personal health tools, and health news (http://www.healthfinder.gov).









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