

Dietary Supplements: What You Need to Know

Fact Sheet for Consumers

Many adults and children in the United States take one or more <u>vitamins</u> or other <u>dietary</u> <u>supplements</u>. In addition to vitamins, dietary supplements can contain <u>minerals</u>, <u>herbs</u> or other <u>botanicals</u>, <u>amino acids</u>, <u>enzymes</u>, and many other <u>ingredients</u>. Dietary supplements come in a variety of forms, including tablets, <u>capsules</u>, gummies, and powders as well as drinks and energy bars. Popular supplements include vitamins D and B12; minerals like <u>calcium</u> and <u>iron</u>; herbs such as <u>echinacea</u> and garlic; and products like <u>glucosamine</u>, probiotics, and fish oils.

The Dietary Supplement Label

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

Effectiveness

Some dietary supplements can help you get adequate amounts of <u>essential nutrients</u> 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 eating routine. To learn more about what makes a healthy eating routine, the <u>Dietary Guidelines for Americans (https://www.dietaryguidelines.gov)</u> and <u>MyPlate (https://www.myplate.gov/)</u> are good sources of information.

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

- 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, <u>zinc</u>, <u>copper</u>, <u>lutein</u>, and <u>zeaxanthin</u> (known as an Age-Related Eye Disease Study [AREDS] formula) may slow down further vision loss in people with age-related macular degeneration (AMD).

Many other supplements need more study to determine if they have value. The <u>U.S. Food and</u> <u>Drug Administration</u> (FDA) does not determine whether dietary supplements are effective

before they are marketed.

Safety and Risk

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

You are most likely to have <u>side effects</u> 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 <u>interact</u> with some medicines in ways that might cause problems. Here are a few examples:

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

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 <u>vitamin A</u> can cause headaches and <u>liver</u> damage, reduce bone strength, and cause birth defects. Excess iron causes <u>nausea</u> and vomiting and may damage the liver and other organs.

Be cautious about taking dietary supplements, beyond a standard prenatal supplement, if you are pregnant or <u>nursing</u>. Also, be careful about giving supplements to a child, unless recommended by their health care provider. Many supplements have not been well tested for safety in children and in women who are pregnant or nursing.

If you think that you have had a bad reaction to a dietary supplement, let your health care provider know. They may report your experience to FDA. You may also submit a report directly to FDA by calling 800-FDA-1088 or <u>completing an online form</u>

(https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx?sid=8922afc8-4eef-41c6-a9bd-dfff7c382658). You should also report your reaction to the manufacturer by using the contact information on the product label.

Quality

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. 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:*

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

* Any mention of a specific company, organization, or service does not represent an endorsement by <u>ODS</u>.

Talk with Your Health Care Providers

Tell your health care providers (including doctors, dentists, <u>pharmacists</u>, and dietitians) about any dietary supplements you're taking. 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 website has 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 health care providers to discuss what's best for your overall health.

Keep in Mind

- Consult your health care provider before taking dietary supplements to <u>treat</u> a health condition.
- Get your health care 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 health care provider about any supplements you take.
- Keep in mind the term natural doesn't always mean safe. Some all-natural botanical
 products, for example comfrey and <u>kava</u>, 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 fact sheet and talk to your health care providers to answer these questions:
 - What are its potential benefits for me?
 - Does it have any safety risks?
 - What is the proper dose to take?
 - How, when, and for how long should I take it?

Federal Regulation of Dietary Supplements

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

Medicines must be approved by FDA before they can be sold or marketed. Supplements do not require this approval. Supplement companies are responsible for having <u>evidence</u> 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 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 part or function (like heart health or the immune system). 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 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.

FDA monitors the marketplace for potential illegal products that may be unsafe or make false or misleading claims. The <u>Federal Trade Commission</u>, 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

National Institutes of Health (\underline{NIH}) supports research and provides educational materials on dietary supplements.

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

 PubMed (https://www.ncbi.nlm.nih.gov/pubmed/) contains more than 35 million citations from the scientific literature.
- NIH Health Information (http://health.nih.gov)
 Information about healthy living and wellness from across NIH.

U.S. Food and Drug Administration

<u>FDA (http://www.fda.gov/Food/DietarySupplements)</u> issues rules and regulations and oversees dietary supplement labeling, marketing, and safety. Recall notices are also posted on the FDA webpage or you can <u>subscribe to receive FDA notices of recalls, market withdrawals, and safety alerts (https://www.fda.gov/about-fda/contact-fda/get-email-updates)</u>.

Federal Trade Commission (FTC)

<u>FTC (https://www.ftc.gov)</u> <u>regulates</u> health and safety claims made in advertising for dietary supplements.

U.S. Department of Agriculture (USDA)

<u>USDA (https://www.nutrition.gov)</u> provides information on a <u>variety of food and nutrition topics</u> (https://www.nutrition.gov/topics/dietary-supplements).

U.S. Department of Health and Human Services (HHS)

HHS provides <u>wellness information</u>, <u>personal health tools</u>, <u>and health news</u> (<u>https://www.healthfinder.gov</u>).

Disclaimer

This fact sheet by the National Institutes of Health (NIH) Office of Dietary Supplements (ODS) provides information that should not take the place of medical advice. We encourage you to talk to your health care providers (doctor, registered dietitian, pharmacist, etc.) about your interest in, questions about, or use of dietary supplements and what may be best for your overall health. Any mention in this publication of a specific product or service, or recommendation from an

organization or professional society, does not represent an endorsement by ODS of that product, service, or expert advice.

Glossary

adverse event

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

age-related macular degeneration

AMD. An eye disease that results in a loss of central, "straight-ahead" vision. AMD is the leading cause of vision loss in older Americans.

amino acid

A chemical building block of protein.

antioxidant

A substance that protects cells from damage caused by free radicals (compounds formed during the metabolism of oxygen). It may help prevent the development of some chronic diseases such as cancer. Antioxidants include beta-carotene; lutein; lycopene; vitamins A, C, and E; selenium; and zinc.

binder

An inactive ingredient (one that has no medicinal effect on the body, such as starch, salt, or sugar) used to hold together the contents of a pill or tablet.

botanical

Having to do with plants or plant parts, or dietary supplement products made from plants. calcium

A mineral found throughout the body. Calcium is needed for healthy bones and teeth, for nerves and enzymes to function properly, and for blood clotting. Calcium is found in some foods, including milk, yogurt, and cheese, and in Chinese cabbage, kale, broccoli and fortified foods, such as many drinks, tofu, and cereals.

cancer

A group of diseases in which cells divide abnormally and without control, and spread to nearby tissues and other parts of the body. Without treatment, cancer can stop organs from working normally, damage body systems, and cause the patient to die. Cancer may be caused by multiple factors, such as radiation, sunlight, tobacco, certain viruses, and poisonous chemicals; however, the cause of many cancers is unknown.

capsule

A gelatin shell containing a dose of medicine, a vitamin, or other dietary supplement. chemotherapy

A chemical that kills bacteria, viruses, fungi, or tumor cells. It usually refers to drugs used in cancer treatment.

control

In a clinical trial, the group of participants that does not receive the new treatment being studied. This group is compared with the group receiving the new treatment, to see whether the new treatment works. In an observational study, the controls are participants who do not have a particular health condition; the control group is compared with the group of participants who do have the condition to see if certain factors (such as diet, activity level, or use of dietary supplements) may be associated with developing or

preventing the condition.

copper

In nutrition, a mineral the body needs (along with iron) to make red blood cells. Copper also helps keep the immune system, blood vessels, nerves, and bones healthy. Copper is found in some foods, including oysters and other shellfish, whole grains, beans, nuts, potatoes, organ meats, dark leafy greens, and dried fruits.

cure

To heal or restore health; a treatment to restore health.

diagnose

The process of using signs and symptoms to identify a disease.

dietary supplement

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

dose

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

drug

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

echinacea

A plant that is native to North America. Traditionally, it has been used for colds, flu, and other infections.

effectiveness

In medicine, the ability of an intervention (for example, a drug, surgery, or a dietary supplement) to produce the desired beneficial effect under the usual conditions of care by a health care provider.

enzyme

A protein that speeds up chemical reactions in the body.

essential

In nutrition, essential nutrients are ones that we must consume for good health because our bodies cannot make them. Essential nutrients include vitamins and minerals.

evidence

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

Federal Trade Commission

FTC. A federal agency that protects consumers by preventing deceptive and unfair business practices. This includes unfair or deceptive advertising and marketing practices.

filler

An inactive ingredient (one that has no medicinal effect on the body, such as lactose or starch) that is used to provide consistency and uniformity in the size and weight of a pill or tablet.

folic acid

The form of folate (a B vitamin occurring naturally in food) that is manufactured and used in supplements and fortified foods.

Food and Drug Administration

FDA, Department of Health and Human Services. FDA is the Federal government agency responsible for ensuring that foods and dietary supplements are safe, wholesome and sanitary, and that drugs, medical devices, cosmetics, and food are honestly, accurately and informatively represented to the public. FDA regulates dietary supplements under a different set of regulations than those covering conventional foods and drug products (prescription and over-the-counter). The dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to get FDA approval before producing or selling dietary supplements.

glucosamine

Glucosamine sulfate is found naturally in the fluid that surrounds your joints. It is also made from the shells of shrimp, lobsters, and crabs, and can be made in the laboratory. Some people use glucosamine to help prevent arthritis pain.

herb

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

ingredient

In a dietary supplement, an ingredient is a component of the product, such as the main nutrient (vitamin, mineral, herb, amino acid, or enzyme) or any binder, color, filler flavor, or sweetener. In herbal supplements, the common name and Latin name (the genus and species) of the plant is given in the ingredient list. On a dietary supplement label, the ingredients are listed by weight, with the ingredient used in the largest amount first on the list and the ingredient used in the least amount at the end of the list.

interaction

A change in the way a dietary supplement acts in the body when taken with certain other supplements, medicines, or foods, or when taken with certain medical conditions. Interactions may cause the dietary supplement to be more or less effective, or cause effects on the body that are not expected.

iron

In nutrition, a mineral the body needs to make red blood cells, proteins, and enzymes; and for the control of cell growth and cell specialization. Iron is found in some foods, including red meats, fish, poultry, lentils, and beans.

kava

The root of this plant has been used in traditional medicine to relieve stress, anxiety, tension, sleeplessness, and problems of menopause. The US Food and Drug Administration advises users that products containing kava may cause severe liver damage. Also called kava kava, intoxicating pepper, rauschpfeffer, tonga, and yangona. Latin name: *Piper methysticum*.

label

When referring to dietary supplements, information that appears on the product container, including a descriptive name of the product stating that it is a "supplement"; the name and place of business of the manufacturer, packer, or distributor; a complete list of ingredients; and each dietary ingredient contained in the product. Supplements must also include directions for use, nutrition labeling in the form of a Supplement Facts panel that identifies each dietary ingredient contained in the product and the serving size, amount, and active ingredients.

liver

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

lutein

A substance found in egg yolk and colorful fruits and vegetables such as spinach, kale, collard greens, broccoli, peas, brussels sprouts, kiwi, and red seedless grapes. Lutein is a carotenoid the body cannot use to make vitamin A. It is being studied in the prevention of certain eye diseases (age-related macular degeneration and cataracts).

mineral

In nutrition, an inorganic substance found in the earth that is required to maintain health. mitigate

To make milder or less painful.

National Institutes of Health

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

nausea

The uneasy feeling of having an urge to throw up (vomit).

nursing

Breastfeeding.

nutrient

A chemical compound in food that is used by the body to function and maintain health. Examples of nutrients include proteins, fats, carbohydrates, vitamins, and minerals.

Office of Dietary Supplements

ODS, Office of Disease Prevention, Office of Director, National Institutes of Health, Department of Health and Human Services. ODS strengthens knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the US population.

omega-3 fatty acid

A main component of fats used by the body for energy and tissue growth. Omega-3s are essential fatty acids in the human diet; they are found in fish oil and certain plant and nut oils.

pharmacist

A person licensed to make and dispense (give out) prescription drugs and who has been taught how they work, how to use them, and their side effects.

prescription

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

prevent

To stop from happening.

regulate

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

risk

The chance or probability that a harmful event will occur. In health, for example, the chance that someone will develop a disease or condition.

scientific literature

Published peer-reviewed original research in the sciences and social sciences.

transplant

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

treat

To care for a patient with a disease by using medicine, surgery, or other approaches.

vitamin

A nutrient that the body needs in small amounts to function and maintain health. Examples are vitamins A, C, and E.

vitamin A

A general term for a group of compounds that includes provitamin A carotenoids (found in foods that come from plants) and retinol (preformed vitamin A found in foods that come from animals). The body can use retinol to make retinal and retinoic acid (other forms of vitamin A). Vitamin A plays an important role in vision, bone growth, reproduction, immunity, cell development, and skin health. Vitamin A is found in some foods, including eggs, liver, fortified milk, cheese, leafy green vegetables (such as spinach, kale, turnip greens, collards, and romaine lettuce), broccoli, dark orange fruits and vegetables (such as apricots, carrots, pumpkin, sweet potatoes, papaya, mango, and cantaloupe), and red bell pepper.

vitamin D

A nutrient that is obtained from the diet and can be made in the skin after exposure to sunlight. Vitamin D acts as a hormone. It helps to form and maintain strong bones, maintain normal blood levels of calcium and phosphorus, and increase calcium absorption; it also helps to maintain a healthy immune system and control cell growth. Vitamin D is found in some foods, including some types of fatty fish, and milk and breakfast cereals that are fortified with vitamin D.

vitamin K

A nutrient needed by the body to function and stay healthy. It helps form blood clots and maintain strong bones. Vitamin K is found in some foods, including green leafy vegetables, broccoli, liver, and vegetable oils. It is also made by bacteria that live in the large intestine.

zeaxanthin

A substance found in corn, leafy green vegetables, persimmons, tangerines, seeds, and egg yolk. It is a carotenoid the body cannot use to make vitamin A. It is being studied in the prevention of certain eye diseases (age-related macular degeneration and cataracts).

zinc

A mineral found in most cells of the body. It helps enzymes work properly, helps maintain a healthy immune system, helps maintain the senses of taste and smell, and is needed for wound healing, making DNA, and normal growth and development during pregnancy, childhood, and adolescence. Zinc is found in some foods, including oysters, red meat, poultry, beans, nuts, certain seafood, whole grains, fortified breakfast cereals, and dairy products.

Updated: January 4, 2023 <u>History of changes to this fact sheet</u>