

Dietary Supplements



Dietary Supplements can be beneficial to your health — but taking supplements can also involve health risks. The U.S. Food and Drug Administration (FDA) does not have the authority to review dietary supplement products for safety and effectiveness before they are marketed.

You've heard about them, may have used them, and may have even recommended them to friends or family. While some dietary supplements are well understood and established, others need further study. Read on for important information for you and your family about dietary supplements.

Before making decisions about whether to take a supplement, talk to your healthcare provider. They can help you achieve a balance between the foods and nutrients you personally need.

What are dietary supplements?

Dietary supplements include such ingredients as vitamins, minerals, herbs, amino acids, and enzymes. Dietary supplements are marketed in forms such as tablets, capsules, softgels, gelcaps, powders, and liquids.

What are the benefits of dietary supplements?

Some supplements can help assure that you get enough of the vital substances the body needs to function; others may help reduce the risk of disease. But supplements should not replace complete meals which are necessary for a healthful diet – so, be sure you eat a variety of foods as well.

Unlike drugs, **supplements are not permitted to be marketed for the purpose of treating, diagnosing, preventing, or curing diseases.** That means supplements should not make disease claims, such as “lowers high cholesterol” or “treats heart disease.” Claims like these cannot be legitimately made for dietary supplements.

Are there any risks in taking supplements?

Yes. Many supplements contain active ingredients that have strong biological effects in the body. This could make them unsafe in some situations and hurt or complicate your health. For example, the following actions could lead to harmful – even life-threatening – consequences.

- Combining supplements
- Using supplements with medicines (whether prescription or over-the-counter)
- Substituting supplements for prescription medicines
- Taking too much of some supplements, such as vitamin A, vitamin D, or iron

Some supplements can also have unwanted effects *before, during, and after* surgery. So, be sure to inform your healthcare provider, including your pharmacist about any supplements you are taking.

Some Common Dietary Supplements

- Calcium
- Echinacea
- Fish Oil
- Ginseng
- Glucosamine and/or Chondroitin Sulphate
- Garlic
- Vitamin D
- St. John's Wort
- Saw Palmetto
- Ginkgo
- Green Tea

Note: These examples do not represent either an endorsement or approval by FDA.

Who is responsible for the safety of dietary supplements?

FDA is not authorized to review dietary supplement products for safety and effectiveness before they are marketed.

The manufacturers and distributors of dietary supplements are responsible for making sure their products are safe BEFORE they go to market.

If the dietary supplement contains a NEW ingredient, manufacturers must notify FDA about that ingredient prior to marketing. However, the notification will only be reviewed by FDA (not approved) and only for safety, not effectiveness.

Manufacturers are required to produce dietary supplements in a quality manner and ensure that they do not contain contaminants or impurities, and are accurately labeled according to current Good Manufacturing Practice (cGMP) and labeling regulations.

If a serious problem associated with a dietary supplement occurs, manufacturers must report it to FDA as an adverse event. FDA can take dietary supplements off the market if they are found to be unsafe or if the claims on the products are false and misleading.

How can I find out more about the dietary supplement I'm taking?

Dietary supplement labels must include name and location information for the manufacturer or distributor.

If you want to know more about the product that you are taking, check with the manufacturer or distributor about:

- Information to support the claims of the product
- Information on the safety and effectiveness of the ingredients in the product.

How can I be a smart supplement shopper?

Be a savvy supplement user. Here's how:

- When searching for supplements on the internet, use noncommercial sites (e.g. National Institutes of Health, FDA, and United States Department of Agriculture) rather than depending on information from sellers.
- If claims sound too good to be true, they probably are. Be mindful of product claims such as "works better than [a prescription drug]," "totally safe," or has "no side effects."
- Be aware that the term *natural* doesn't always mean *safe*.
- Ask your healthcare provider if the supplement you're considering would be safe and beneficial for you.
- Always remember – safety first!

Report Problems to FDA

Notify FDA if the use of a dietary supplement caused you or a family member to have a serious reaction or illness (even if you are not certain that the product was the cause or you did not visit a doctor or clinic).

Follow these steps:

1. Stop using the product.
2. Contact your healthcare provider to find out how to take care of the problem.
3. Report problems to FDA in either of these ways:
 - Contact the **Consumer Complaint Coordinator** in your area. Locate a coordinator here: <http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators>
 - File a safety report online through the **Safety Reporting Portal** at: <http://www.safetyreporting.hhs.gov>



To learn more about dietary supplements, visit: <http://www.fda.gov/Food/DietarySupplements/default.htm>