

DIETARY SUPPLEMENTS

(Sheet 1 of 2)



BASIC INFORMATION

The choice to use a dietary supplement can be a wise decision that provides health benefits. Sometimes, however, these products may not be needed for good health, or they may even create unexpected risks.

DEFINITION OF DIETARY SUPPLEMENTS

- Dietary supplements are defined as products that contain one or more of the following ingredients:
 - a vitamin.
 - a mineral.
 - an herb or other botanical (plant or plant part).
 - an amino acid.
 - a dietary substance used by people to supplement the diet by increasing total dietary intake.
 - a concentrate, metabolite, constituent, and extract, or combination of any of the ingredients listed.
 - intended for ingestion in the form of a capsule, powder, softgel or gelcap, and not represented as a conventional food or as a sole item of a meal or the diet.

PURPOSE OF DIETARY SUPPLEMENTS

Dietary supplements are intended to supplement the diets of some people. They are not meant to replace the balance of the variety of foods important to a healthy diet. While you need nutrients, too much of some nutrients can cause problems.

CAUTIONS

Dietary supplements may not be risk-free in some cases. Use caution if you are pregnant, nursing a baby, or have a chronic medical condition such as, diabetes, hypertension, or heart disease. Be sure to consult your health care provider or pharmacist before buying or taking any supplement.

CHILDREN AND DIETARY SUPPLEMENTS

Vitamin and mineral supplements are widely used and generally safe for children. You may wish to check with your child's health care provider or pharmacist before giving any dietary supplements other than vitamins and minerals to your child.

TALK TO YOUR HEALTH CARE PROVIDER

If you plan to use a dietary supplement in place of drugs or at the same time as any drug, tell your health care provider first. Many supplements contain active ingredients that have strong effects in the body and their safety is not always assured in all users. If you have certain health conditions and take these products, you may be placing yourself at risk.

INTERACTIONS WITH OTHER DRUGS

• Some supplements may interact with prescription and nonprescription drugs. Taking a combination of supplements or using these products together with drugs (both prescription or nonprescription) could, under certain circumstances, produce adverse effects. Some of these interactions could be life-threatening. Ask your health care provider or pharmacist about possible interactions.

• Examples of interactions:

- Coumadin (a prescription drug), ginkgo biloba (an herbal supplement), aspirin, and vitamin E can each thin the blood. Taking any of these products together can increase the potential for internal bleeding.
- Combining St. John's Wort with certain HIV drugs reduces their effectiveness. St. John's Wort may also reduce the effectiveness of prescription drugs for heart disease, depression, seizures, certain cancers, or oral contraceptives.

SURGERY & DIETARY SUPPLEMENTS

Some supplements can have unwanted effects during surgery. It is important to fully inform your health care provider about the vitamins, minerals, herbals, or any other supplements you are taking, especially before elective surgery. You may be asked to stop taking these products at least two to three weeks ahead of the procedure. This will help to avoid potentially dangerous supplement/drug interactions. Interactions could cause changes in heart rate, blood pressure, and increase bleeding. Any of these could adversely affect the outcome of your surgery.

ENSURING THE SAFETY & EFFICACY OF SUPPLEMENTS

Under the 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. Dietary supplement products are not reviewed by the government before they are marketed. The FDA (Food & Drug Administration) does have the responsibility to take action against any unsafe dietary supplement product that reaches the market. If the FDA can prove that claims on marketed dietary supplement products are false and misleading, it may take action against those products.

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(Sheet 2 of 2)

DOES THE INFORMATION FOR THE DIETARY SUPPLEMENT SOUND TOO GOOD TO BE TRUE?

- Do the claims for the product seem exaggerated or unrealistic? While the Web can be a valuable source of accurate, reliable information, it also has a wealth of misinformation that may not be obvious. It is important to know what information about a product is accurate and what is misleading or false. Some advertising can be very convincing.
- Be cautious about information that comes from persons who have no formal training in nutrition or from personal reports. Information may come from store employees, friends, or online chat rooms and message boards. They may talk about incredible benefits or results obtained from using a product. Ask 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 experience and a variety of medical research (not just a single study). Be wary of results claiming a "quick fix." In addition, news stories, about the latest scientific study, especially those on TV or radio, are often too brief. They do not include important details that may apply to you or allow you to make an informed decision.

CONTACT THE MANUFACTURER FOR MORE INFORMATION

- 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 answer your questions. Questions may include:
 1. What information does the firm have to substantiate the claims made for the product? Be aware that sometimes firms supply so-called "proof" of their claims by citing undocumented reports from satisfied consumers, or "internal" graphs and charts that could be mistaken for proven research.
 2. Does the firm have information to share about tests it has conducted on the safety or efficacy of the ingredients in the product?
 3. Does the firm have a quality control system in place to determine if the product actually contains what is stated on the label and is free of contaminants?
 4. Has the firm received any adverse event reports from consumers using their products?

REPORTING ADVERSE EFFECTS

- Adverse effects from the use of dietary supplements should be reported to the FDA. You, your health care provider, or anyone may report a serious adverse event or illness directly to FDA if you believe it is related to the use of any dietary supplement product, by calling FDA at (800) FDA-1088, by fax at (800) FDA-0178 or on-line at www.fda.gov/medwatch/how.htm.
- The FDA would like to know whenever you think a product caused you a serious problem. Report it even if you are not sure that the product was the cause, and even if you do not visit a health care provider or medical clinic. In addition to contacting the FDA on-line or by phone, you may use the form available from the FDA Web site.



NOTIFY OUR OFFICE IF

You have questions about using dietary supplements.

Special notes:

More notes on the back of this page