

# Safety

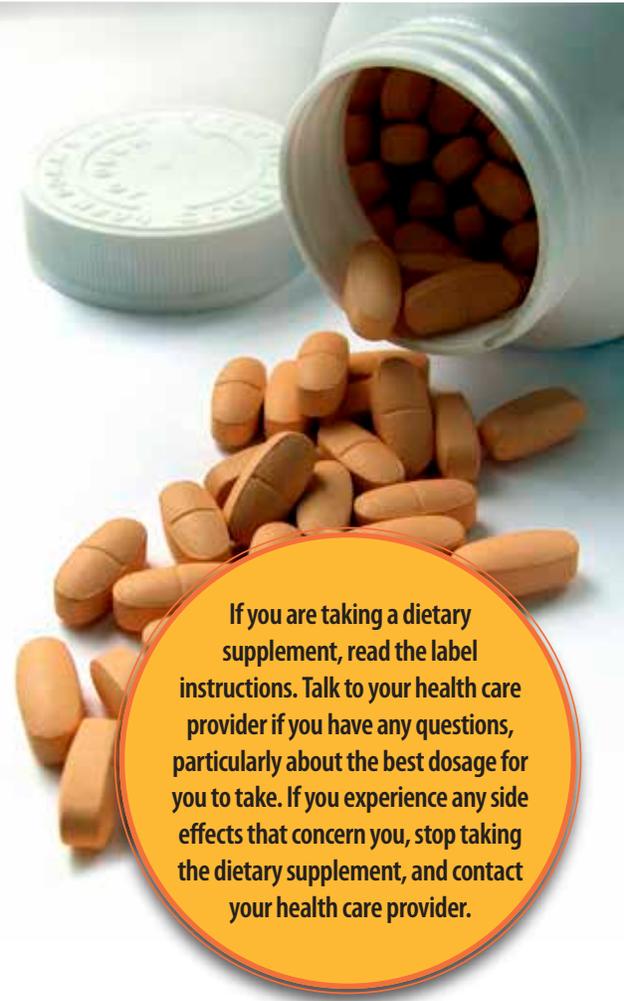
## Considerations

### FOR DIETARY SUPPLEMENTS

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

Tell your health care providers about any complementary and alternative practices you use, including dietary supplements. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care. It is especially important to talk to your health care provider if you are:

- Thinking about replacing your regular medication with one or more dietary supplements.
- Taking any medications (whether prescription or over-the-counter), as some dietary supplements have been found to interact with medications.
- Planning to have surgery. Certain dietary supplements may increase the risk of bleeding or affect the response to anesthesia.
- Pregnant or nursing a baby, or are considering giving a child a dietary supplement. Most dietary supplements have not been tested in pregnant women, nursing mothers, or children.



**If you are taking a dietary supplement, read 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.**

### A Note on “Natural” Supplements

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 its active ingredients may not be known. Researchers are studying many

of these products in an effort to identify active ingredients 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:

- A herbal supplement may not contain the correct plant species.
- The amount of the active ingredient 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 ingredients such as prescription drugs.

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### Considerations

#### FOR DIETARY SUPPLEMENTS

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The Federal Government regulates dietary supplements through the U.S. Food and Drug Administration (FDA). The regulations for dietary supplements are not the same as those for prescription or over-the-counter drugs. *In general, the regulations for dietary supplements are less strict.*

- A manufacturer does not have to prove the safety and effectiveness of a dietary supplement before it is marketed.
- A manufacturer is permitted to say that a dietary supplement addresses a nutrient deficiency, supports health, or is linked to a particular body function (e.g., immunity), if there is research to support the claim. Such a claim 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 are expected to follow certain “good manufacturing practices” (GMPs) to ensure that dietary supplements are processed consistently and meet quality standards.
- Once a dietary supplement is on the market, the FDA monitors safety. If it 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 a number of dietary supplement promoters or Web sites that promote or sell dietary supplements because they have made false or deceptive statements about their products or because marketed products have proven to be unsafe.

### What's Considered A Supplement?

The Dietary Supplement Health and Education Act (DSHEA) is a federal law that defines dietary supplements and sets product-labeling standards and health claim limits. DSHEA defines supplements and outlines quality, safety, and efficacy regulations that are different from those for drugs. 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)
- A plant or part of a plant used for its flavor, scent, or potential therapeutic properties.
- Includes flowers, leaves, bark, fruit, seeds, stems, and roots, 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

