

Dietary Supplements:

What Pharmacists

Should Know



Dietary supplements are taken for a variety of reasons. Some dietary supplements can help consumers meet the daily requirements of essential nutrients or can help improve or maintain their overall health. **But supplements may also come with health risks, especially from combining dietary supplements with medications or other supplements.**

So, it is important for pharmacists to be prepared to counsel consumers when they are considering taking dietary supplements.

Dietary supplements can contain ingredients such as:

- Vitamins
- Minerals
- Herbs
- Botanical extracts and constituents
- Amino Acids
- Enzymes
- Live microbials (commonly referred to as “probiotics”)

Dietary supplements come in a variety of forms such as tablets, capsules, softgels, gel caps, liquids, gummies, powders, and bars.

Dietary Supplements Defined

A dietary supplement is a product that is ingested and is intended to add to or “supplement” the diet. A dietary supplement is not intended to be a substitute for conventional food or meals. Conventional food should always be the primary source of nutrients.



Regulation of Dietary Supplements

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the manufacturers and marketers of dietary supplements are responsible for ensuring that the products they sell are safe and lawful.

Unlike FDA’s role in regulating prescription drugs, FDA does not have the authority to approve dietary supplements (for safety or efficacy) or their labeling before they are marketed. In fact, companies can often introduce new dietary supplements to the market without even notifying FDA.



Understand the Risks

Dietary supplements may contain ingredients that can have strong effects in the body. **Consumers may experience adverse events (such as bad reactions, side effects, unexpected symptoms, or illnesses), especially if they:**

- Use dietary supplements with prescription or over-the-counter (OTC) medications
- Substitute supplements for medications
- Combine supplements
- Consume supplements in high doses



Did You Know?

Products falsely marketed as dietary supplements can sometimes contain hidden pharmaceutical ingredients. These are among the most concerning products sold as dietary supplements. Common hidden drug ingredients include sibutramine, sildenafil, tadalafil, and phenolphthalein.

Dietary Supplement-Drug Interactions

Some dietary supplements can interact with prescription and OTC medications by altering their absorption, metabolism, or excretion—which can have dangerous and even life-threatening consequences. For example:

- Vitamin K can reduce the ability of warfarin (Coumadin) to prevent blood from clotting.
- Ginkgo biloba, high-dose vitamin E, warfarin (Coumadin), and aspirin can each thin the blood. Taking any of these products alone or together can increase the potential for internal bleeding or stroke.
- St. John's wort can reduce the efficacy of some medications for heart disease, cancer, HIV, depression, seizures, and birth control.
- Vitamins C and E might reduce the effectiveness of some types of cancer chemotherapy.

Share Your Knowledge

FDA encourages you to talk to consumers about the benefits and risks of taking dietary supplements. It is important to remind them to let you know what supplements they are taking, to consult a healthcare professional before taking any supplement especially if they take prescription medication, and to always be alert to the possibility of an adverse event.

Adverse events may occur immediately or can happen sometime later and can range from less serious reactions to life-threatening illnesses such as:

- Itching, rash, hives, throat/lip/tongue swelling, or wheezing
- Low blood pressure, fainting, chest pain, shortness of breath, palpitations, or irregular heartbeat
- Severe, persistent nausea, vomiting, diarrhea, or abdominal pain
- Difficulty urinating, decreased urination, or dark urine
- Blood in urine, stool, vomit, or sputum
- Abnormal bleeding from nose or gums
- Fatigue or appetite loss
- Yellowing of the skin or eyes
- Severe joint or muscle pain
- Marked mood, cognitive, or behavioral changes, thoughts of suicide
- Stroke (slurred speech, one-sided weakness of face, arm, leg, or blurry/loss of vision)

Bad reactions can even result in Emergency Room visits or hospitalization.

Also, let consumers know that if they believe that a dietary supplement may have caused an adverse reaction or illness, they should immediately stop taking the product, seek medical care, and notify FDA.

Report Adverse Events to FDA

You play a crucial public health role by reporting adverse events to FDA. By reporting a reaction to a dietary supplement, or even the suspicion of a problem, you can help FDA protect the public from potentially unsafe products.

You can notify FDA of an adverse event by submitting a report through the Safety Reporting Portal at www.safetyreporting.hhs.gov.

FDA uses this information to evaluate the safety of marketed products, identify potentially dangerous products, and possibly remove them from the market. In some cases, a single adverse event report can be very helpful to FDA in investigating and taking action to protect public health.

