

Dietary Supplements and Adverse Events

What is an adverse event?

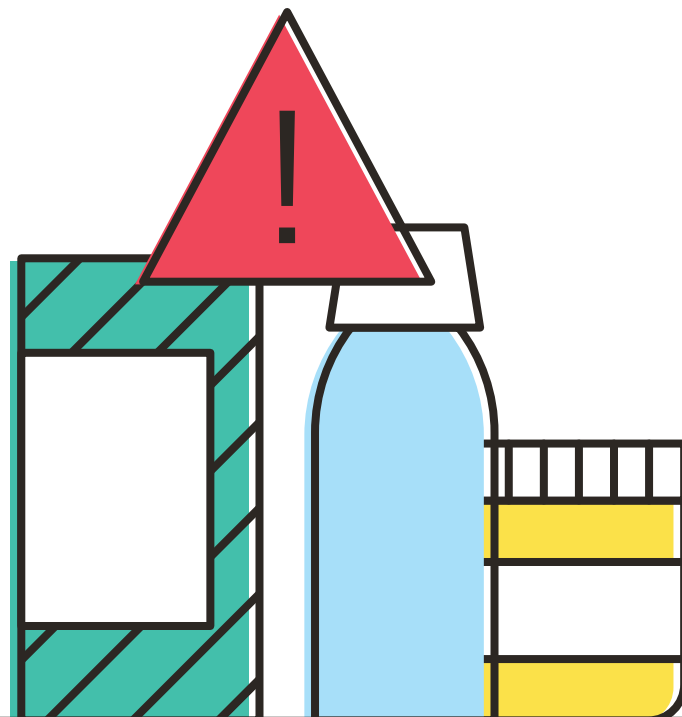
It is possible to experience an adverse event, also known as a side effect or bad reaction, while using dietary supplements. Sometimes these reactions can be life-threatening.

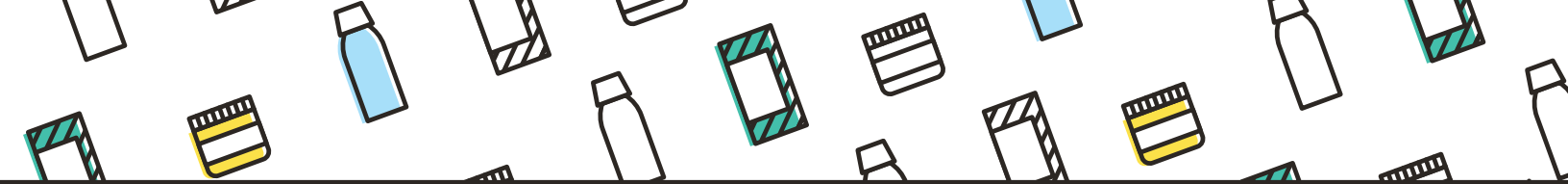
Examples include:

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

What should I do if I experience an adverse event?

If you are taking a dietary supplement and experience an adverse event, you should immediately stop using the product and seek immediate medical care or advice. You should also submit a report to FDA through the Safety Reporting Portal at <https://www.safetyreporting.hhs.gov> or by calling a Consumer Complaint Coordinator.





The phone number for the Consumer Complaint Coordinator assigned to your state can be found at <https://www.fda.gov/safety/report-problem-fda/consumer-complaint-coordinators>. Please provide as much information as you can. Complete reports are the most helpful, but even pieces of information can help to protect the public from potentially unsafe products.

Even if you aren't sure the supplement caused the adverse event, it's always better to report it.

Why should I report an adverse event?

By law, FDA does not have the authority to approve dietary supplements before they are sold to the public; in fact, in most cases, FDA isn't even notified of a new dietary supplement. When you report an adverse event or make a complaint, FDA is able to identify potentially dangerous products and possibly remove them from the market. To see the latest actions FDA has taken to protect the public health, visit <https://www.fda.gov/food/dietary-supplements/whats-new-dietary-supplements>.





Dietary Supplements: Know the Risks

Supplements can be beneficial to your health, but they can also involve health risks, especially when you take them with or instead of prescription medicines.

Risks of Taking Dietary Supplements

Dietary supplements can help improve or maintain your health, but they can also be ineffective or have unexpected consequences. That's because many supplements contain ingredients that can have strong effects in the body. Problems can occur if you:

- Take too much of some supplements
- Combine supplements
- Use supplements with medicines (whether prescription or over-the-counter)
- Substitute supplements for prescription medicines

If you experience any side effects or bad reactions, known as adverse events, immediately stop using the product, seek medical care or advice, and submit a report to FDA. You can submit a report by visiting the Safety Reporting Portal at <https://www.safetyreporting.hhs.gov>. You can also submit a report by calling a Consumer Complaint Coordinator in your

state. The phone number can be found at <https://www.fda.gov/safety/report-problemfda/consumer-complaint-coordinators>. Adverse events can include itching, dizziness, severe and persistent vomiting or diarrhea, abdominal pain, blood in your urine, severe joint or muscle pain, and more.

Drugs vs. Dietary Supplements

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





Using Dietary Supplements with Prescription Medications

It is important to know that supplements can interact with some medicines and cause problems. Here are some examples:

- Vitamin K can reduce the ability of the blood thinner warfarin to prevent blood from clotting.¹
- Coumadin (a prescription medicine), ginkgo biloba (an herbal supplement), aspirin (an over-the-counter drug), and vitamin E (a vitamin supplement) can each thin the blood. Taking any of these products alone or together can increase the potential for internal bleeding or stroke.²
- St. John's wort can reduce the effectiveness of many medicines prescribed for heart disease, depression, seizures, certain cancers, and HIV.²
- Antioxidant supplements, such as vitamins C and E, might reduce the effectiveness of some types of cancer chemotherapy.¹

Talk with Your Healthcare Professional

Talk with a healthcare professional, such as your primary care provider or pharmacist, if you are taking or thinking about taking a dietary supplement—and especially if you have a chronic health condition. They can help you decide how much to take, offer advice on how long you should take it, and let you know

whether if it is safe to use in combination with any over-the-counter or prescription medicines you are taking. They can also help you determine if your dietary supplement is meeting your needs.

It's helpful to keep a complete record of any dietary supplements and medicines you take. For each product, note the name, the dose you take, how often you take it, and the reason for use. Bring it with you to any appointments with healthcare professionals. A sample can be found at <https://ods.od.nih.gov/pubs/DietarySupplementandMedicineRecord.pdf>.

What to Ask Your Healthcare Professional

- Is taking a dietary supplement an important part of my overall health?
- Are there any precautions or warnings I should know about (e.g., is there an amount or "upper limit" I should not go above)?
- Are there any known side effects (e.g., loss of appetite, nausea, headaches, etc.)? Do they apply to me?
- Are there any foods, medicines (prescription or over-the-counter), or other supplements I should avoid while taking this product?
- If I am scheduled for surgery or lab work, should I be concerned about the dietary supplements I am taking?

¹ <https://ods.od.nih.gov/factsheets/WYNTK-Consumer/>

² <https://www.fda.gov/food/information-consumers-using-dietary-supplements/tips-older-dietary-supplement-users>



Understanding Dietary Supplements

Dietary supplements offer some benefits, but they also come with risks. Unlike drugs, supplements are not intended to treat, diagnose, prevent, or cure diseases. That means supplements cannot take the place of medications, and they are not permitted to make claims such as “lowers cholesterol” or “treats heart disease.” These types of claims can only be made for drugs. Consumers should be cautious of a product that claims to be “totally safe” or “has no side effects.” If a claim sounds too good to be true, it probably is. Here is what you should know about dietary supplements and how to use them safely.

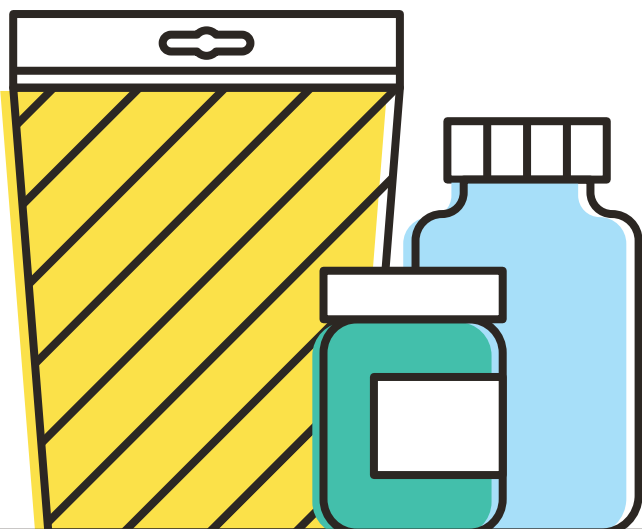
Dietary Supplements at a Glance

Dietary supplements are products intended to add to, or “supplement,” your diet.

Common dietary supplements include:

- Vitamins, either as individual or multivitamins, such as vitamin D and vitamin B12
- Minerals, such as calcium, iron, or magnesium
- Botanicals or herbals, like chamomile or ginger, as well as extracts and compounds from botanicals, like caffeine or curcumin
- Amino acids, such as tryptophan and glutamine
- Probiotics

Dietary supplements come in many forms such as pills, tablets, powders, liquids, and energy bars. Sometimes it can be tricky to determine whether a product is a food or a dietary supplement. Packaged foods have a “Nutrition Facts” panel on their labels, while dietary supplements have a “Supplement Facts” panel. Reading the panel can help you recognize the product type and understand what nutrients it contains.





Benefits of Dietary Supplements

Dietary supplements can help maintain or improve overall health and can help you meet the daily requirements of essential nutrients that your body needs to function. For example, calcium and vitamin D can help keep bones strong and omega-3 fatty acids from fish oils can help reduce the risk of heart disease.

Even though dietary supplements can be helpful and beneficial, they should not take the place of the variety of foods that are important for a healthy diet. They also should not be taken in place of prescription medication. To get the most out of dietary supplements and make sure they are working for you, talk to your healthcare professional.

Risks and Adverse Events

Many supplements contain ingredients that can have strong effects in the body. You are most likely to have side effects, bad reactions, or even illness if you take too much of one supplement, combine supplements, or use supplements with prescription or over-the-counter medicines. And, if you take dietary supplements instead of prescribed medicines, the results could not only be harmful, but life-threatening.

Always be alert to the possibility of a reaction, especially when taking a new product. These bad reactions are known as adverse events and can include:

- Itching
- Fatigue
- Slurred speech
- Blood in urine
- Diarrhea
- Severe joint and muscle pain
- Heart palpitations
- Hospitalization

For a full list of reactions please see <https://www.fda.gov/food/dietary-supplements/how-report-problem-dietary-supplements>.

If you think that a dietary supplement may have caused an adverse event, you should immediately stop using the product and seek medical care or advice. You should also submit a report to FDA through the Safety Reporting Portal at <https://www.safetyreporting.hhs.gov> or by calling a Consumer Complaint Coordinator. The phone number for the Consumer Complaint Coordinator assigned to your state can be found at <https://www.fda.gov/safety/report-problem-fda/consumer-complaint-coordinators>. Any information a consumer can provide will help FDA identify problematic products on the market and enable the agency to take action, which will protect you and others from unsafe products.



Talk to Your Healthcare Professional

Tell your healthcare professionals, including doctors, dentists, pharmacists, and dietitians, about any dietary supplements you're taking. They can help you determine which supplements, if any, might be right for you. It's also helpful to keep a complete record of any dietary supplements and medications you take. For each product, note the name, how much you take, how often you take it, and the reason for use. You can share this record with your healthcare professionals to discuss what's best for your overall health.



Did You Know?

Under the Dietary Supplement Health and Education Act (DSHEA), FDA does not have the authority to approve dietary supplements. In fact, companies can often introduce a dietary supplement to the market without even notifying the FDA. The companies are responsible for ensuring that their dietary supplement products are safe and lawful before they go to market. If they are not safe or lawful, FDA can take action after they reach the market. That's why reporting adverse events and side effects through the Safety Reporting Portal is important.