

4/28/2014

Vitamins & Supplements - Consumer Reports Investigates

ConsumerReports.org

10 surprising dangers of vitamins and supplements

Don't assume they're safe because they're 'all natural'

Consumer Reports magazine: September 2012

More than half of American adults take vitamins, minerals, herbs, or other nutritional supplements. Some of those products aren't especially helpful, readers told us in a recent survey, but that aside, don't assume they're safe because they're "all natural." They may be neither. Here are 10 hazards that we've distilled from interviews with experts, published research, and our own analysis of reports of serious adverse events submitted to the Food and Drug Administration, which we obtained through a Freedom of Information Act request. Read and be warned.

1. Supplements are not risk-free

More than 6,300 reports of serious adverse events associated with dietary supplements, including vitamins and herbs, streamed into the FDA from supplement companies, consumers, health-care providers, and others between 2007 and mid-April of 2012. The reports by themselves don't prove the supplements caused the problems, but the raw numbers are cause for some concern. Symptoms included signs of heart, kidney, or liver problems, aches, allergic reactions, fatigue, nausea, pains, and vomiting.

The reports described more than 10,300 serious outcomes (some included more than one), including 115 deaths and more than 2,100 hospitalizations, 1,000 serious injuries or illnesses, 900 emergency-room visits, and some 4,000 other important medical events.

The FDA gets far more reports about serious problems with prescription medication than about supplements. But there's a big difference between the two, notes Pieter Cohen, M.D., an internist at Cambridge Health Alliance in Massachusetts with a special interest in supplements. "These powerful medications with powerful side effects are actually saving lives when used appropriately," he says of prescription drugs. "But when healthy consumers use supplements, there's rarely, if ever, a powerful lifesaving effect."

The FDA suspects most supplement problems never come to its attention, says Daniel Fabricant, Ph.D., director of the agency's Division of Dietary Supplement Programs. But those that do are still useful because they can raise red flags about a developing problem. For instance, last year the agency noted seven reports of serious health problems regarding consumers who took Soladek vitamin solution, marketed by Indo Pharma of the Dominican Republic. When the FDA learned that tested samples contained vitamins A and D at concentrations many times the recommended daily allowances, it issued a consumer warning.

Why not simply order a problem product off the market? Current laws make that so difficult for the FDA that to date it has banned only one ingredient, ephedrine alkaloids. That effort dragged on for a decade, during which ephedra weight-loss products were implicated in thousands of adverse events, including deaths.

Type the name of the supplement you're interested in into the search box at www.fda.gov to see whether it has been subject to warnings, alerts, or voluntary recalls. If you suspect you're having a bad reaction to a supplement, tell your doctor. You can also report your problem to the FDA at 800-332-1088 or www.fda.gov/medwatch.

2. Some supplements are really prescription drugs

Fabricant has said that dietary supplements spiked with prescription drugs are "the largest threat" to consumer safety. Since 2008 there have been recalls of more than 400 such products, mostly those marketed for bodybuilding, sexual enhancement, and weight loss, according to the FDA.

We've seen many recalled products that have contained the same or similar active ingredients as prescription drugs, such as sildenafil (Viagra), tadalafil (Cialis), and sibutramine (Meridia, a weight-loss drug that was withdrawn from the market in 2010 because of evidence that it increased the risk of heart attacks and strokes). Others contained synthetic steroids.

Those adulterated products can cause some of the same side effects and interactions that consumers may have been trying to avoid by choosing supplements over drugs. The FDA has received reports of strokes, acute liver injury, kidney failure, pulmonary embolism (blood clots in the lung), and death associated with drug-tainted supplements.

"A number of the spiked sexual enhancement products claim to work within 20 to 45 minutes," Fabricant said on the FDA's website. "When we see a product that makes claims above and beyond what a dietary supplement might do—above supporting health—and within a time frame of a few minutes, it tips us off that we might have a spiked product."

Slim down with diet and exercise. Build muscles by weight training. And consult a doctor if you need help in the bedroom, since it could indicate an underlying health problem. If you suspect you've purchased a product that is tainted with undeclared prescription drugs or steroids, send an e-mail about it to the FDA, at taintedproducts@fda.hhs.gov.

3. You can overdose on vitamins and minerals

Unless your health-care provider tells you that you need more than 100 percent of the recommended daily intake of a particular nutrient, you probably don't.

"It doesn't make sense to me to take huge doses of vitamins and minerals unless there's a diagnosed problem, because there is so little evidence that they do good and sometimes a possibility that they might do harm," says Marion Nestle, M.P.H., Ph.D., a professor of nutrition, food studies, and public health at New York University.

Megadoses of the fat-soluble vitamins A, D, E, and K can cause problems, and even some standard doses may interfere with certain prescription medicine. Some people may experience adverse effects from too much calcium or iron.

The table below shows the maximum daily intake of key nutrients that the Institute of Medicine has determined is unlikely to pose a risk of adverse health effects. (The numbers apply to the general population, not to those who may need supplementation because of a medical condition.)

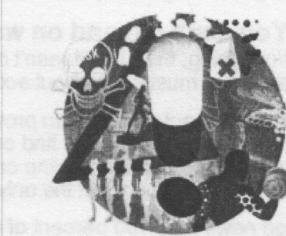
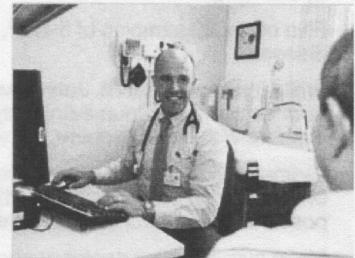


Illustration: Andy Potts



Pieter Cohen, M.D., with a patient who had a heart attack while on supplements.

It's surprisingly easy to overdo it. For instance, a 50-something woman who's worried about her bones might eat a breakfast of Whole Grain Total cereal, which contains around 1,000 milligrams of calcium per serving, with a half-cup of skim milk (150 milligrams of calcium), and take a calcium supplement (500 milligrams) on top of her One-A-Day Menopause Formula multivitamin, which includes 300 milligrams of calcium. She'd already be coming close to the upper tolerable daily calcium limit of 2,000 milligrams.

Using information from the labels on the supplements and food you routinely consume, add up your total daily exposure to everything, and then check the related table to see whether you're overdoing it. If your doctor says you need more of a specific nutrient than you can get from food (or sun exposure, in the case of vitamin D), a single-ingredient pill may be sufficient.

4. You can't depend on warning labels

For one thing, the FDA doesn't require them on supplements. There is an exception: Supplements that contain iron must warn about accidental overdosing and fatal poisoning in children.

But supplement makers can provide warning labels if they want to. We went shopping to see what warnings, if any, we would find on labels from 14 varieties of supplements. After looking at 233 products, all purchased online or in stores in the New York City metropolitan area in the spring of 2012, we can report that the only thing consistent about the labels is their lack of consistency.

Good news first: 100 percent of the 15 brands we bought that contained iron had the required warning.

Of the 233 labels we examined, most included only general warnings, such as those about not using the product during pregnancy or nursing, or about possible unspecified drug interactions. But specific warnings were rarer. Forty percent of labels warned people against taking the supplement if they had a medical condition, but only some cited an ailment, such as a bleeding disorder; 36 percent warned of possible adverse reactions; but only 13 percent warned of possible interactions with a specific drug or type of drug.

Five of our 20 samples of 5-HTP, a mood and sleep supplement, carried warnings about a possible interaction with drugs for Parkinson's disease.

While it's known that St. John's wort can reduce the effectiveness of certain prescription drugs, including birth-control pills and blood thinners such as warfarin (Coumadin), only two of the 17 samples of it we purchased warned explicitly about those hazards. Ginkgo biloba can also interfere with blood thinners, but we saw a warning about that possible interaction on just one bottle of ginkgo.

"Some companies go with an overabundance of caution, and that's certainly their right to do that," says Steve Mister, president and CEO of the Council for Responsible Nutrition, a leading industry trade group. "Other companies say, you know what, I'm not going to warn for possible things that I don't believe are a serious concern to my consumers."

Make sure that your doctor or pharmacist knows what supplements and prescription drugs you are taking or thinking of taking. You can also learn about interactions in our free "Guide: 100+ Commonly Used Supplements" (funded by a grant from the Airborne Cy Pres Fund).

5. None are proved to cure major diseases

If you're surfing the Internet for dietary supplements and find a site that claims its products can diagnose, cure, mitigate, treat, or prevent a disease, surf right off to another site. Such claims are off-limits to supplements, according to the FDA. "We'd like to see those things go away," Fabricant says. "Those are a direct threat to public health." Since 2007, the agency has sent dozens of warning letters to companies telling them to stop making those types of claims about their supplement products.

Earlier this year, for instance, the FDA sent a warning letter to BioAnue Laboratories of Rochelle, Ga., when these statements and others were spotted on websites: "Formula CX will reverse wasting disease," and "Bovine cartilage stops tumor growth." (The FDA said it's still reviewing the company's response. The president of BioAnue Laboratories told us it "complies with all U.S. laws.")

Over the past decade, the FDA's regulatory partner, the Federal Trade Commission, which monitors dietary-supplement advertising, has brought more than 100 legal challenges to claims about the effectiveness of supplements.

Research supplements at reliable government sites such as the Food and Drug Administration, the National Institutes of Health's Office of Dietary Supplements, and the National Center for Complementary and Alternative Medicine.

6. Buy with caution from botánicas

These stores, which sell traditional medicinal plants and other artifacts for physical and spiritual healing, are a valued presence in Hispanic neighborhoods in many American cities. But when Consumer Reports sent a Spanish-speaking reporter on a shopping trip to several New York-area botánicas in 2011, he came away with incomplete information and bags of mystery herbs.

Our reporter asked for advice on how to treat type 2 diabetes, high blood pressure, and impotence, conditions that have effective conventional drug treatments. Healers offered a variety of instructions and herbs, but none volunteered relevant facts about possible side effects or the risky interactions that can occur when an herb is taken with a medication. And when we brought the herbs back to the office and checked the scientific evidence, we found that conclusive research on efficacy and safety was lacking for all of them.

Our investigation left us concerned about product quality and identity at the shops. And experts we consulted suggested that the supply chain used by some of the stores might not follow the best industry standards.

"These markets should not be singled out, but they also should not be exempt from meeting the same standards required by other purveyors of herbal and dietary supplements," says Tieraona Low Dog, M.D., a clinical associate professor of medicine at the University of Arizona College of Medicine and fellowship director of the Arizona Center for Integrative Medicine.

Check with your doctor before taking traditional herbs, and make sure you know what they are and where they come from. If your culture's health practices are important to you, consider seeking out an integrative physician, such as Low Dog, who combines conventional medical care with holistic and traditional methods.

7. Heart and cancer protection are not proved

Omega-3 pills and antioxidants are widely thought to reduce the risk of heart disease and cancer, respectively, and millions of women take calcium to protect their bones. But recent evidence casts doubt on whether those supplements are as safe or effective as assumed.

Calcium. The latest blow against calcium supplements was a report by German and Swiss researchers who followed almost 24,000 adults for an average of 11 years. They found that regular



Illustration: Andy Potts

users of calcium supplements had an 86 percent increased heart-attack risk compared with those who didn't use supplements, as reported in the June 2012 issue of the journal Heart. On the other hand, there was a statistically significant 30 percent reduction of heart-attack risk among adults with a moderately high intake of calcium from food itself.

Why the disparity? The researchers theorized that the supplements may cause quick spikes in blood calcium levels that have been linked to risky lipid levels, whereas calcium in food is likely to be absorbed more slowly. Get calcium from dairy products, green leafy vegetables, and fish with edible bones, such as sardines.

Omega-3 fish oil. The widely held view that fish-oil pills help prevent cardiovascular disease hit a snag when a study of 12,500 people with diabetes or prediabetes and a high risk of heart attack or stroke found no difference in the death rate from cardiovascular disease or other outcomes between those given a 1-gram fish-oil pill every day and those given a placebo, according to a June 11, 2012, New England Journal of Medicine online report. But the results may be clouded by the fact that participants were already taking other heart medication.

Most people can get enough omega-3s by eating fatty fish at least twice a week. The American Heart Association says that people who have coronary artery disease may want to talk to their doctor about omega-3 supplementation.

Antioxidants. Far from reducing cancer risk, as a lot of people believe, high doses of some antioxidant supplements may actually increase it, evidence suggests.

The discouraging news appeared in the May 16, 2012, issue of the Journal of the National Cancer Institute. Based on current evidence, vitamins C and E haven't been found to shield people from cancer; vitamin E, beta-carotene, and vitamin C don't seem to protect against getting or dying from cancer; selenium doesn't prevent prostate cancer; and there's no convincing evidence that beta-carotene or vitamin A, C, or E supplements prevent gastrointestinal cancers. Still worse, the researchers wrote, "Some clinical trials show that some of these antioxidant nutrients may increase cancer risk."

And there's more bad news, from a study of 35,000 men reported in the Oct. 12, 2011, issue of the Journal of the American Medical Association: Daily vitamin E supplementation may increase the risk of prostate cancer among healthy men.

The investigators warned that the implications of their findings were worrisome given that more than half of people 60 or older take supplements containing vitamin E. Moreover, 23 percent of them take at least 400 IU per day despite a recommended daily dietary allowance of only 22 IU for adult men.

Lay off the antioxidant supplements and reduce your cancer risk safely by quitting smoking, avoiding excessive drinking, and eating a healthy diet that includes plenty of fruit, vegetables, nuts, legumes, and whole grains.

8. Pills can irritate the esophagus

Choking as a serious symptom showed up surprisingly often in the database we analyzed of problem reports to the FDA in the last five years, with more than 900 mentions. But true cases of choking, in which a pill actually goes down the windpipe instead of the esophagus, probably happen infrequently, says Joel Blumin, M.D., incoming chairman of the Airway and Swallowing Committee of the American Academy of Otolaryngology—Head and Neck Surgery. That's a medical emergency that requires immediate intervention, such as the Heimlich maneuver.

More typically, Blumin says, pills irritate the esophagus, causing a muscle spasm, or get physically stuck or slowed. "That sensation feels like choking," he says, but it isn't. Sometimes all you need is a second swallow or extra water to get the pill down.

To get a pill down easily, first take a swig of water to moisten your mouth and throat. Place the pill on the front of your tongue, take a sip of water, tilt your head back slightly, and swallow. Then drink the rest of the water to help propel the pill down your esophagus. People with persistent swallowing problems can switch to liquid or chewable formulations and should probably seek evaluation by an otolaryngologist.

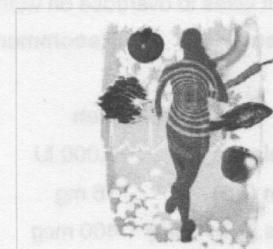


Illustration: Andy Potts

9. Some 'natural' products are anything but

Vitamin pills can be synthetically, and legally, produced in a lab. Synthetic ingredients are even allowed in multivitamins that bear the Department of Agriculture's "Organic" seal. But the FDA has said that synthetic copies of botanicals don't qualify as dietary-supplement ingredients at all.

"Vitamins can be synthetic because, by definition, a vitamin doesn't have to come from nature," says Fabricant at the FDA. They just have to perform the biological activity of vitamins, he added, whereas a "botanical" means that it was alive at some point. In other words, botanicals and their extracts must come from actual living plants, not a test tube.

In April 2012, the agency sent warning letters to 10 manufacturers and distributors of products containing dimethylamylamine (DMAA), often touted as a natural stimulant. It said the ingredient lacked safety evidence and warned that synthetically produced DMAA was not a dietary ingredient at all. (The FDA said it is studying the companies' responses.)

The FDA doesn't require supplements to go through rigorous testing for safety and efficacy the way that drugs are tested. If you choose to take vitamins, botanicals, or other supplements, look for those with the "USP Verified" mark, which means they meet standards of quality, purity, and potency set by the nonprofit U.S. Pharmacopeia.

10. You may not need supplements at all

If you are already getting the recommended amount of nutrients by eating a variety of fruit, vegetables, cereals, dairy, and protein, there's little if any additional benefit from ingesting nutritional supplements. Here's our take on five top-selling vitamins, plus multis:

Vitamin A. Few people in the U.S. are outright deficient in vitamin A. The retinol form—which comes from animal sources such as eggs, liver, and whole milk—is more readily absorbed than beta-carotene, but even strict vegetarians can usually meet their needs by eating five servings a day of produce, including dark green leafy vegetables and orange and yellow fruit. Too much retinol can cause birth defects and liver abnormalities, and might harm bones.

B vitamins. Most people get plenty through their diet. Exceptions include vegetarians, who might need extra B12, which is found in animal-derived foods; the estimated 10 to 30 percent of people over 50 who don't have enough stomach acid to extract B12 from food; and women who are pregnant or trying to get pregnant, who should take 400 micrograms a day of extra folic acid to help prevent birth defects.

Vitamin C. There's some evidence that 200 milligrams or more of vitamin C a day might improve cold symptoms in smokers and seniors,

though it won't prevent colds. Vitamin C can enhance iron absorption, so avoid high doses if you have hemochromatosis, a condition in which the body absorbs and stores too much iron.

Vitamin D. If you get some midday sun exposure during the warmer months and regularly consume vitamin D-rich foods, such as fatty fish, eggs, and fortified dairy products, you probably don't need to take a supplement. People who are middle-aged or older, are overweight, or have darker skin might need supplements. If you're unsure about your vitamin D status, ask your doctor about having a blood test.

Vitamin E. Two analyses have linked as little as 400 IU a day to a small but statistically significant increase in mortality. Moreover, vitamin E may inhibit blood clotting, so it shouldn't be taken with blood thinners.

Multivitamins. Large clinical trials have repeatedly found that multivitamins don't improve the health of the average person. People who might need a multivitamin include women who are pregnant, breast-feeding, or trying to conceive; dieters consuming fewer than 1,200 calories a day or cutting out an entire food group (carbs, for example); and those with medical conditions that affect digestion and food absorption.

Warnings we like to see

Makers of nutritional supplements have no legal obligation to put warnings about possible drug interactions on their products, but nothing's stopping them if they want to. St. John's wort is especially prone to drug interactions, and most of the 17 St. John's wort product labels we reviewed did contain a general warning or named specific drugs or drug classes. One of the most complete set of warnings we saw was on a Vitamin Shoppe bottle. The warning (shown) does a good job of alerting users to the herb's important interactions with anti-HIV medication, blood thinners, oral contraceptives, prescription antidepressants, and transplant drugs.

DIRECTIONS: As a dietary supplement, take one (1) to three (3) vegicaps daily, preferably with meals.

WARNING: Do not use St. John's Wort if you are pregnant, nursing, or taking anti-depressants, HIV protease inhibitors [such as Indinavir] or drugs to prevent organ transplant rejection [such as Cyclosporine]. Consult your physician before use if you are taking oral contraceptives, anticoagulant medication [such as Warfarin], selective serotonin reuptake inhibitors, or any other medication. Limit exposure to sun and other sources of ultraviolet light. Stop use and ask a doctor if you develop a rash.

NO Yeast, Wheat, Sugar, Salt, Dairy, Citrus, Fish, Animal Derivatives, Artificial Colors or Flavors Added.

How much is too much?

What it takes to overdose on vitamins and minerals.

Nutrient	Recommended daily intake		Safe upper limit (all sources)
	Men	Women	
Vitamin A	3,000 IU	2,300 IU	10,000 IU
Niacin (B3)	16 mg	14 mg	35 mg
Folate (folic acid)	400 mcg	400 mcg	1,000 mcg
Vitamin C	90 mg	75 mg	2,000 mg
Vitamin D	600 IU ages 19 to 70; 800 IU ages 71 and up	600 IU ages 19 to 70; 800 IU ages 71 and up	
Vitamin E	22 IU (natural) 33 IU (synthetic)	22 IU (natural) 33 IU (synthetic)	1,500 IU (natural) 1,100 IU (synthetic)
Vitamin K	120 mcg	90 mcg	Not established
MINERALS			
Calcium	1,000 mg ages 19 to 70; 1,200 mg ages 70 and up	1,000 mg ages 19 to 50; 1,200 mg ages 51 and up	2,500 mg through age 50; 2,000 mg ages 51 and up
Magnesium	420 mg	320 mg	350 mg (from supplements only)
Potassium	4,700 mg	4,700 mg	Not established
Selenium	55 mcg	55 mcg	400 mcg
Zinc	11 mg	8 mg	40 mg

Source: Institute of Medicine and the Office of Dietary Supplements, National Institutes of Health.

Copyright © 2006-2014 Consumer Reports. No reproduction, in whole or in part, without written permission.