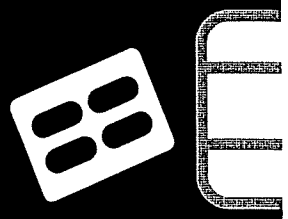
5 THINGS TO CONSIDER BEFORE TAKING A DIETARY SUPPLEMENT



Dietary supplements include ingredients such as vitamins, minerals, herbs, and amino acids. Dietary supplements can help you get the nutrients you need to maintain health.

Dietary supplements can be good for your health by helping you get the nutrients you need to maintain health. But there are some risks, especially if you take too many or use them in addition to, or in place of, prescription medications.

So how can you make an informed decision for yourself about using supplements?

CONSIDER THIS:

1. Ask your healthcare provider if the supplement you're considering would be safe and beneficial for you.
2. Remember that supplements are not permitted to be marketed for the purpose of treating, diagnosing, preventing, or curing diseases. Disease claims, such as "lowers high cholesterol" or "treats heart disease," cannot be legitimately made for dietary supplements.
3. When searching for information about supplements on the internet, use noncommercial sites (e.g., the National Institutes of Health, the Food and Drug Administration, the U.S. Department of Agriculture) rather than depending on information from sellers.
4. If claims sound too good to be true, they probably are. Be mindful of product claims such as "works better than [a prescription drug]," "totally safe," or has "no side effects."
5. Be aware that the term "natural" doesn't always means "safe."

If you decide to take a supplement and have a bad reaction, report the reaction to FDA through one of the following:

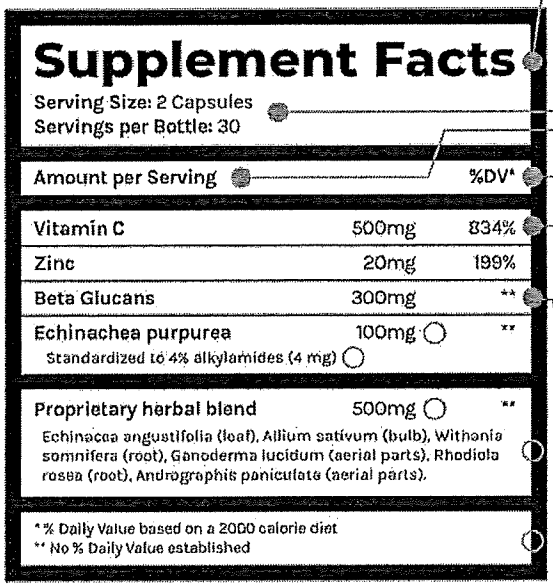
Contact the **Consumer Complaint Coordinator** in your area.

File a safety report only through the **Safety Reporting Portal.**

FDA U.S. FOOD & D
ADMINISTRATION

How to read a supplement label

Dietary supplements are regulated by the FDA, and all labels need to follow a consistent format to make it easier for consumers to understand supplements. There are some tricks to understanding dietary supplement labels well, so be sure to pay attention to the following points when you're evaluating your supplements.



Supplement Facts

Serving Size: 2 Capsules
Servings per Bottle: 30

Amount per Serving		%DV*
Vitamin C	500mg	834%
Zinc	20mg	199%
Beta Glucans	300mg	**
Echinachea purpurea	100mg	**
Standardized to 4% alkylamides (4 mg)		
Proprietary herbal blend	500mg	**
Echinacea angustifolia (leaf), Allium sativum (bulb), Withania somnifera (root), Ganoderma lucidum (aerial parts), Rhodiola rosea (root), Andrographis paniculata (aerial parts).		

* % Daily Value based on a 2000 calorie diet
** No % Daily Value established

The "Supplement Facts" title is an indicator that the product is marketed for sale in the USA and is an FDA standard.

The serving size, and sometimes the number of servings per bottle will be included to help you compare more easily between products

Make sure the serving sizes match when you're comparing supplements to get an accurate comparison between the products.

Vitamins and minerals will always show the dose in both weight and % daily value to help you understand how you're hitting your dietary requirements.

Many supplements will have doses that exceed the recommended daily amount. Always talk to your health care practitioner to make sure that you're taking the right dose of supplements.

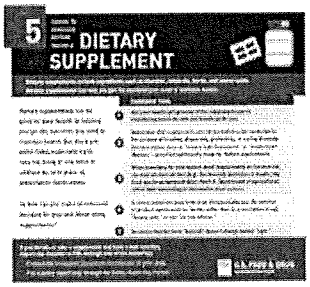
Dietary supplement ingredients that aren't vitamins or minerals won't have a % daily value because the values haven't been established as they are not essential ingredients in the diet.

Tips for Dietary Supplement Users

Making Informed Decisions and Evaluating Information

FDA, as well as health professionals and their organizations, receive many inquiries each year from consumers seeking health-related information, especially about dietary supplements. Clearly, people choosing to supplement their diets with herbals, vitamins, minerals, or other substances want to know more about the products they choose so that they can make informed decisions about them. The choice to use a dietary supplement can be a wise decision that provides health benefits. However, under certain circumstances, these products may be unnecessary for good health or they may even create unexpected risks.

Before taking a dietary supplement...



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Given the abundance and conflicting nature of information now available about dietary supplements, you may need help to sort the reliable information from the questionable. Below are tips and resources that we hope will help you be a savvy dietary supplement user. The principles underlying these tips are similar to those principles a savvy consumer would use for any product.

- **Basic Points to Consider**
- **Tips on Searching the Web for Information on Dietary Supplements**
- **More Tips and To-Do's**

Note: *Links to non-Federal government organizations found on this site are provided solely as a service to consumers and do not represent an FDA endorsement of these organizations or their products. (For resources see Selected References.)*

Basic Points to Consider

- **Do I need to think about my total diet?**
  Yes. Dietary supplements are intended to supplement the diets of some people, but not to replace the balance of the variety of foods important to a healthy diet. While you need enough nutrients, too much of some nutrients can cause problems. You can find information on the functions and potential benefits of vitamins and minerals, as well as upper safe limits for nutrients at the National Academy of Sciences Web site (http://www.iom.edu/iom/iomhome.nsf/Pages/FNB+Reports) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) disclaimer icon (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm).

- **Should I check with my doctor or healthcare provider before using a supplement?**
  This is a good idea, especially for certain population groups. Dietary supplements may not be risk-free under certain circumstances. 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 doctor or pharmacist before purchasing or taking any supplement. While vitamin and mineral supplements are widely used and generally considered safe for children, you may wish to check with your doctor or pharmacist before giving these or any other dietary supplements to your child. If you plan to use a dietary supplement in place of drugs or in combination with any drug, tell your health care provider first. Many supplements contain active ingredients that have strong biological effects 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.

- **Some supplements may interact with prescription and over-the-counter medicines.**
  Taking a combination of supplements or using these products together with medications (whether prescription or OTC drugs) could under certain circumstances produce adverse effects, some of which could be life-threatening. Be alert to advisories about these products, whether taken alone or in combination. For example: Coumadin (a prescription medicine), ginkgo biloba (an herbal supplement), aspirin (an OTC drug) and vitamin E (a vitamin supplement) can each thin the blood, and taking any of these products together can increase the potential for internal bleeding. Combining St. John's Wort with certain HIV drugs significantly 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.

- **Some supplements can have unwanted effects during surgery:**
  It is important to fully inform your doctor 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 2-3 weeks ahead of the procedure to avoid potentially dangerous supplement/drug interactions -- such as changes in heart rate, blood pressure and increased bleeding - that could adversely affect the outcome of your surgery.

- **Adverse effects from the use of dietary supplements should be reported to MedWatch:**
  You, your health care provider, or anyone may directly to FDA if you believe it is related to the use of any dietary supplement product, by calling FDA at 1-800-FDA-1088, by fax at 1-800-FDA-0178 or reporting report a serious adverse event or illness on-line (/safety/reporting-serious-problems-fda/how-consumers-can-report-adverse-event-or-serious-problem-fda). FDA would like to know whenever you think a product caused you a serious problem, even if you are not sure that the product was the cause, and even if you do not visit a doctor or clinic. In addition to communicating with FDA on-line or by phone, you may use the MedWatch form available from the FDA Web site.

- **Who is responsible for ensuring the safety and efficacy of dietary 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 determining that the claims on their labels are accurate and truthful. Dietary supplement products are not reviewed by the government before they are marketed, but FDA has the responsibility to take action against any unsafe dietary supplement product that reaches the market. If FDA can prove that claims on marketed dietary supplement products are false and misleading, the agency may take action also against products with such claims.

back to top

Tips on Searching the Web for Information on Dietary Supplements

When searching on the Web, try using directory sites of respected organizations, rather than doing blind searches with a search engine. Ask yourself the following questions:

- **Who operates the site?**
  Is the site run by the government, a university, or a reputable medical or health-related association (e.g., American Medical Association, American Diabetes Association, American Heart Association, National Institutes of Health,

National Academies of Science, or U.S. Food and Drug Administration)? Is the information written or reviewed by qualified health professionals, experts in the field, academia, government or the medical community?

- **What is the purpose of the site?**
  Is the purpose of the site to objectively educate the public or just to sell a product? Be aware of practitioners or organizations whose main interest is in marketing products, either directly or through sites with which they are linked. Commercial sites should clearly distinguish scientific information from advertisements. Most nonprofit and government sites contain no advertising; and access to the site and materials offered are usually free.
- **What is the source of the information and does it have any references?**
  Has the study been reviewed by recognized scientific experts and published in reputable peer-reviewed scientific journals, like the New England Journal of Medicine? Does the information say "some studies show..." or does it state where the study is listed so that you can check the authenticity of the references? For example, can the study be found in the National Library of Medicine's database of literature citations (PubMed (http://www.ncbi.nlm.nih.gov/PubMed/)).
- **Is the information current?**
  Check the date when the material was posted or updated. Often new research or other findings are not reflected in old material, e.g., side effects or interactions with other products or new evidence that might have changed earlier thinking. Ideally, health and medical sites should be updated frequently.
- **How reliable is the Internet or e-mail solicitations?**
  While the Internet is a rich source of health information, it is also an easy vehicle for spreading myths, hoaxes and rumors about alleged news, studies, products or findings. To avoid falling prey to such hoaxes, be skeptical and watch out for overly emphatic language with UPPERCASE LETTERS and lots of exclamation points!!!! Beware of such phrases such as: "This is not a hoax" or "Send this to everyone you know."

back to top

More Tips and To-Do's

- **Ask yourself: Does it sound too good to be true?**
  Do the claims for the product seem exaggerated or unrealistic? Are there simplistic conclusions being drawn from a complex study to sell a product? While the Web can be a valuable source of accurate, reliable information, it also has a wealth of misinformation that may not be obvious. Learn to distinguish hype from evidence-based science. Nonsensical lingo can sound very convincing. Also, be skeptical about anecdotal information from persons who have no formal training in nutrition or botanicals, or from personal testimonials (e.g. from store employees, friends, or online chat rooms and message boards) about incredible benefits or results obtained from using a product. Question these people on their training and knowledge in nutrition or medicine.
- **Think twice about chasing the latest headline.**
  Sound health advice is generally based on a body of research, not a single study. Be wary of results claiming a "quick fix" that depart from previous research and scientific beliefs. Keep in mind science does not proceed by dramatic breakthroughs, but by taking many small steps, slowly building towards a consensus. Furthermore, news stories, about the latest scientific study, especially those on TV or radio, are often too brief to include important details that may apply to you or allow you to make an informed decision.
- **Check your assumptions about the following:**
  - #1 Questionable Assumption --
    "Even if a product may not help me, it at least won't hurt me." It's best not to assume that this will always be true. When consumed in high enough amounts, for a long enough time, or in combination with certain other substances, all chemicals can be toxic, including nutrients, plant components, and other biologically active ingredients.
  - #2 Questionable Assumption --
    "*When I see the term 'natural,' it means that a product is healthful and safe.*" Consumers can be misled if they

assume this term assures wholesomeness, or that these food-like substances necessarily have milder effects, which makes them safer to use than drugs. The term "natural" on labels is not well defined and is sometimes used ambiguously to imply unsubstantiated benefits or safety. For example, many weight-loss products claim to be "natural" or "herbal" but this doesn't necessarily make them safe. Their ingredients may interact with drugs or may be dangerous for people with certain medical conditions.

- #3 Questionable Assumption --
  "*A product is safe when there is no cautionary information on the product label.*" Dietary supplement manufacturers may not necessarily include warnings about potential adverse effects on the labels of their products. If consumers want to know about the safety of a specific dietary supplement, they should contact the manufacturer of that brand directly. It is the manufacturer's responsibility to determine that the supplement it produces or distributes is safe and that there is substantiated evidence that the label claims are truthful and not misleading.
- #4 Questionable Assumption --
  "*A recall of a harmful product guarantees that all such harmful products will be immediately and completely removed from the marketplace.*" A product recall of a dietary supplement is voluntary and while many manufacturers do their best, a recall does not necessarily remove all harmful products from the marketplace.

- **Contact the manufacturer for more information about the specific product that you are purchasing.** 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 address your questions, some of which 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 evidence-based 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 events reports from consumers using their products?

back to top

Selected References

THE FOLLOWING ARE SELECTED REFERENCES THAT MAY HELP USERS UNDERSTAND AND EVALUATE INFORMATION ENCOUNTERED ON THE INTERNET OR IN THE MARKETPLACE. *(Links to non-Federal government organizations found on this site are provided as a service to our users and do not represent FDA endorsement of these organizations or their materials. FDA cannot monitor other sites to ensure that the information is the most current available.)*

Evaluating Research

10 Things to Know About Evaluating Medical Resources on the Web (http://nccam.nih.gov/health/webresources/) disclaimer icon (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
A short guide developed by the National Cancer Institute, NIH, to help you evaluate medical Web sites. (July, 1999)

How to Understand and Interpret Food and Health-Related Scientific Studies (http://www.ific.org/publications/reviews/scientificir.cfm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) disclaimer icon

(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
This article provides an overview for understanding and interpreting food and health-related scientific studies (from the International Food Information Council, May 2000).

Making Sense of Health and Nutrition News (http://www.ific.org/foodinsight/2001/jf/makingsensefi101.cfm)
(http://www.fda.gov/about-fda/website-policies/website-disclaimer) disclaimer icon
(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
Provides tips for evaluating science. (IFIC, *Food Insight*. Jan/Feb 2001)

Navigating the Internet

Medical products and the Internet. A guide to finding reliable information
(http://www.who.int/medicinedocs/en/d/Js2277e/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) disclaimer icon
(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm).
This document provides advice from the World Health Organization to help internet users obtain reliable, independent, and comparable information on the internet.

"Navigating for Health: Finding Accurate Information on the Internet"
(http://www.ific.org/foodinsight/2000/nd/navigatingfi600.cfm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) disclaimer icon
(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm).
(IFIC *Food Insight* article, November-December, 2000)

Quality of Health Information (http://www.healthfinder.gov/scripts/SearchContext.asp?topic=14310&section=5)
disclaimer icon (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm).
Several links to other government and private sector web sites compiled by the Department of Health and Human Services' Healthfinder web site to help you evaluate online health information.

Product Claims and Labeling

"Claims That Can Be Made for Conventional Foods and Dietary Supplements" (/food/labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements)
An FDA explanation of the various kinds of claims that can be made for foods and supplements. (Updated April, 2001.)

Questions You Can Ask About Health Claims. "Improving Public Understanding: Guidelines for Communicating Emerging Science on Nutrition, Food Safety and Health." (http://www.ific.org/publications/brochures/guidelinesbroch.cfm)
(http://www.fda.gov/about-fda/website-policies/website-disclaimer) disclaimer icon
(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
These questions were developed to help journalists and scientists accurately convey health information. You can ask yourself these questions to help judge whether the information you are reading is fairly presented (the International Food Information Council, 1998)

"Miracle" Health Claims: Add a Dose of Skepticism (http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea07.shtm)
disclaimer icon (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
This FDA/FTC joint agency information piece focuses on how to assess claims and seek advice, and avoid becoming a victim of health fraud. The information discusses how to minimize being cheated out of money, time, and health. (September 2001)

Advertising Dietary Supplements

"Dietary Supplements: An Advertising Guide for Industry" (http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm)
disclaimer icon (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm).
This document describes the factors that FTC takes into account in deciding whether an ad is truthful and not misleading.

You can use them to judge the advertisements you see.
Other Sources

MedWatch (/medwatch-fda-safety-information-and-adverse-event-reporting-program).
FDA Safety Information and Adverse Event Reporting Program.

The Food and Nutrition Board (http://www.iom.edu/iom/iomhome.nsf/Pages/FNB+Reports)
(http://www.fda.gov/about-fda/website-policies/website-disclaimer) disclaimer icon
(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
The Food and Nutrition Board (FNB), National Academy of Sciences, as part of its mission, establishes principles and guidelines of adequate dietary intake. The FNB issues reports such as "Dietary Reference Intakes: Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline."

NUTRITION.GOV (https://www.nutrition.gov/) disclaimer icon
(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
NUTRITION.GOV, a new federal resource, provides easy access to all online federal government information on nutrition, including dietary supplements.

MEDLINE Plus Health Information: Vitamin and Mineral Supplements
(http://www.nlm.nih.gov/medlineplus/vitaminandmineralsupplements.html) disclaimer icon
(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
MEDLINE Plus Health Information is a service of the National Library of Medicine, National Institutes of Health, that provides information on health topics, including vitamin and mineral supplements.

International Bibliographic Information on Dietary Supplements (IBIDS) (http://ods.od.nih.gov/databases/ibids.html)
disclaimer icon (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
The International Bibliographic Information on Dietary Supplements (IBIDS) NIH, Office of Dietary Supplements is a database of published, international, scientific literature on dietary supplements, including vitamins, minerals, and botanicals.

National Center for Complementary and Alternative Medicine (http://nccam.nih.gov/) disclaimer icon
(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm), NIH.
The National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health
(http://www.nih.gov/) disclaimer icon
(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)(NIH) is dedicated to exploring complementary and alternative healing practices in the context of rigorous science; training CAM researchers; and disseminating authoritative information.

back to top