

Dietary Supplements: Herbals and Botanicals

Fact Sheet 9.370

Food and Nutrition Series | Health

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Herbals and botanicals have been used medicinally for thousands of years. Once thought of as 'traditional medicine' used by native or ancient cultures, herbal medicine has emerged as a popular complementary and alternative medicine (CAM), or supplement to modern medicine. Herbal supplement sales have been increasing each year for the last decade and in 2020, for the first time, sales surpassed \$10 billion. Herbal and botanical supplements are the leading type of CAM for both adults and those under the age of 18. Despite the natural origin of many herbals and botanicals, these substances are considered dietary supplements and should be taken with caution, as their use may result in negative side-effects.

What are Dietary Supplements?

Dietary supplements include vitamins, minerals, herbs, amino acids, enzymes, and other substances that may be 'supplemented', or added to the diet, to complete dietary needs or to make up for a nutrition deficiency.

These substances are not intended to replace a healthy diet. Dietary supplements may be found in many forms including pills, capsules, powders, drinks, or energy bars. For more information on other forms of dietary supplements, see fact sheet <u>Dietary Supplements: Vitamins and Minerals.</u>

Herbal and botanical supplements are plants used for oral medicinal purposes, and include the flower, leaf, root, and/or seed of the plant. Herbs and botanicals are sold as dietary supplements, which are regulated differently than pharmaceutical drugs and are sold under the terms: 'herbals', 'herbal products', 'herbal medicines', and 'herbal remedies.' Supplements are not required to go through the same stringent testing as over the counter (OTC) and prescribed medicine and are not regulated as closely by the Food and Drug Administration (FDA).

Why Take Herbal and Botanical Supplements?

Many consider herbs and botanicals to be natural and therefore healthier and gentler than conventional drugs, even though 30% of all prescription drugs are of herbal origin.



Quick Facts

- Herbals and botanicals are sold as dietary supplements and regulated differently than pharmaceutical drugs.
- The Food and Drug Administration (FDA) does not test herbs for safety or efficacy.
- Some people choose herbs and botanicals to avoid side effects from conventional drugs.
- Products described as "natural" are not always safe.
- There is no data to suggest that herbs are more beneficial than conventional drugs for treating illnesses.
- The best prescription for disease prevention is a healthy lifestyle.

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Many use herbs and botanicals for a variety of medical conditions, as well as for overall health and well-being. For others, herbal use is grounded in traditions passed down from generation to generation or recommended by folk healers. Depending on the strength of the preparation, and the bioactivity (sometimes rated as "mild" to "powerful"), an herbal supplement may work immediately or after a few weeks. There are often a few different forms of herbal supplementations such as teas, tinctures, extracts, and pills, each with varying strengths. See Table 1 for the top ten most used herbal supplements.

Table 1. Top ten most commonly used herbs in 2020.

| Common name, source | Main uses and health claims | Possible side effects | What the research says |
|---|--|--|--|
| Elderberry (Sambucus nigra and S. canadensis) | Reduces cold and flu symptoms | If elderberries are undercooked, nausea and vomiting may occur. | Unripe (green) berries, and stems contain poisonous amounts of cyanide and must be cooked for at least 20 minutes to lose their toxicity. Small studies have shown significant reductions in flu like symptoms with elderberry, but to date, no large-scale studies have been done to confirm these findings. |
| Horehound (Marrubium vulgare) | Expectorant Hypoglycemic effect Reduce duration of colds | | Horehound has been used in traditional medicine in several cultures to treat diabetes. Animal studies show reductions in blood glucose after horehound administration, |



| | | | unfortunately, a human clinical trial showed only a tiny reduction in glucose in a small percentage of participants. More studies are needed. |
|--------------------------------------|--|---|--|
| Cranberry (Vaccinium macrocarpon) | Prevention of urinary tract infections (UTI's) | High doses cause stomach upset and diarrhea. May interfere with anti-coagulant medications, warfarin, but studies are conflicting. | In 2020, the FDA announced cranberry supplements could make claims stating there was "limited" evidence showing reduction in UTI's in women taking daily specified amounts of cranberry supplements. Cranberry has not been shown to be effective in treating active UTI's. |
| Turmeric (Curcuma longa) | Reduce symptoms of arthritis Reduce Inflammation | Mild GI distress has been reported, but rarely. | Studies show curcumin is as effective as pain relievers for the treatment of arthritis. However, larger and more rigorous studies are needed to confirm these findings. Not only is turmeric unstable in supplement form, it also is not very bioavailable; both of these attributes may be why the effects of turmeric are varied and hard to study. |



| | | | Novel delivery systems of turmeric improve bioavailability and show improved pain outcomes in studies |
|------------------------------------|---|---|--|
| Apple Cider Vinegar (ACV) | Weight Loss Blood glucose control Cancer prevention | Damage to tooth enamel can occur if liquid ACV is sipped regularly. Can decrease potassium levels, so people with low potassium should take caution. | Apple cider vinegar diets are popular recommendations on the internet, but weight loss studies are inconclusive. A systematic review does show a favorable effect for ACV in lowering blood lipids. |
| Echinacea (Echinacea angustifolia) | Reduce duration of colds Boost immune system Heal wounds | Gl symptoms including nausea, abdominal pain, diarrhea, and vomiting. Allergic reactions (especially those allergic to the daisy/aster family). | Evidence shows echinacea can lower your chance of catching a cold but has not been shown to shorten the duration of a cold. Wound repair is not supported in the literature. Echinacea products are frequently mislabeled or may contain no Echinacea, or contaminated with selenium, arsenic, and lead. Do not consume if you have reduced immunity (HIV, lupus tuberculosis), or take medications that may be toxic to the liver (anabolic steroids). |



Garlic (Allium sativum)

- Reduce the risk of heart disease
- Lower high blood cholesterol
- Lower high blood pressure
- · Prevent cancer
- Treat athlete's foot
- Safe for most individuals.
- Increase in bleeding.
- Breath or skin odor.
- Possible nausea, heartburn, or diarrhea at high doses.
- Topical garlic can cause skin irritation, blistering and burns.
- Asthma and other allergic reactions are possible.
- Taking garlic can lower blood cholesterol (total and LDL cholesterol), but most results are after at least 8 weeks of consumption.
- Epidemiological studies show that people who consume garlic and other vegetables in the same family are less likely to develop gastric cancer. However, clinical studies do not support this claim, so evidence is limited.
- Garlic has been shown to lower blood pressure in some people, but more studies are needed.
- Fresh garlic is the best form and contains allicin.
- If consuming high doses of garlic, do not take bloodthinning, anticoagulant drugs, ginko, ginger, Panax ginseng, or highdose vitamin E.
- High doses of garlic may decrease the effectiveness of oral contraceptives and other drugs.
- Avoid taking 7 days prior to surgery.



| Fenugreek (Trigonella foenum-graecum) | Lower blood sugar Increase milk supply in breastfeeding women | Fenugreek should not be taken by pregnant women, it is linked to birth defects. Possible side effects are Gl upset, and, rarely, headache and dizziness. | Small studies and two meta-analysis (2014 & 2016) show that Fenugreek supplementation decreases in fasting blood glucose and HbA1c in people with pre-diabetes and T2D. However, larger and higher quality randomized studies need to be conducted before this correlation can be confirmed. Studies show conflicting results on the effect Fenugreek has on breastmilk production. |
|---------------------------------------|--|---|--|
| Wheatgrass (Triticum aestivum) | Mitigate chemotherapy effects Prevents cancer | Nausea, especially if taken after meals. Wheat grass is high in Vit K, so care should be taken in those on anticoagulant medication. Headaches Pregnant women may avoid raw wheat grass juice because of possible bacterial or mold contamination. | Small studies have shown wheatgrass reduces vascular damage during chemotherapy, another study showed a reduced risk of leukemia in rats fed wheat grass. Wheat grass has been shown to be antioxidative, but larger studies are needed before use is recommended for cancer prevention. |
| Ginger (Zingiber officinale) | Prevent motion sickness Reduce morning sickness Reduce mild nausea | Well tolerated when used in small doses. High doses may cause abdominal discomfort, heartburn, diarrhea | Ginger can reduce nausea but the effect seems to be limited to very mild cases, and not to motion sickness. |



| • | Used as digestive |
|---|-------------------|
| | aid |
| • | Treatment for |
| | |

 Treatment for rheumatoid arthritis, joint, and muscle pain (most often may cause abdominal associated with powdered ginger). More studies are needed to determine whether ginger is effective at alleviating arthritic joint pain.

 May increase the risk of bleeding – ask pharmacist/doctor before taking with anticoagulant/antipl atelet drugs, garlic, ginko, taking with anticoagulant/or Panax ginseng.

Disclaimer: Information concerning herbals and botanicals is constantly changing; therefore take all herbs with caution and consult a physician. Some herbs are not recommended for people suffering from autoimmune disorders or liver disease, those undergoing surgery or other invasive medical procedure, pregnant or lactating women, or infants and small children. Use herbs only for minor conditions and only for the short-term. Discontinue if you experience any adverse side effects.

How are Herbs Regulated

Herbal products, similar to vitamin and mineral supplements, are classified by the FDA as dietary supplements, not drugs. As a result, they are not tested for safety or efficacy, and can be marketed at any time without scientific research and without approval from the FDA. The FDA can take regulatory action on an herbal product only after it has received a sufficient number of reports of ill effects, and can demonstrate that the product is unsafe. The FDA can then recommend that the product be withdrawn from the market and/or labeled to reflect potential side effects.

Summary of Herbal Regulation

- Herbs are not standardized, and doses differ between herb capsules and from product to product.
- The active ingredients vary depending on the plant part (flower, root, seeds, nuts, bark, branch), plant form (dried, extract, tincture, tea) and plant species.
 Some herbal products may contain impure ingredients (such as lead), and less active ingredients than claimed on the label.
- If a manufacturer follows certain protocols for extracting or drying herbs, they can include United States Pharmacopeia (USP) or Natural Formulary (NF) on their label. This label does not ensure that doses are similar or that the product is safe, it only provides assurance that the product was properly manufactured and contains the ingredients listed on the label.
- The most rigorous stamp of approval is from Consumer Lab (CL). CL conducts independent tests of products for identity and potency (proper labeling), purity (any contaminants), and consistency (the same identity, potency, and purity from one batch to the next). Products that pass their tests contain a CL stamp of approval.



- Dietary supplement manufacturers are required by the FDA to follow 'good manufacturing practices' (GMP's) which are designed to confirm a product's purity, strength and composition. However, the FDA does not regularly inspect companies to ensure these GMP's are being followed. Look for companies that advertise that they batch test their products with a third party testing facility and post the results on their websites. Good third-party testing will include things like microbial testing, bioactive levels, and heavy metals.
- For information on how to identify nutrition fraud, see fact sheet <u>Nutrition Misinformation: How to</u> <u>Identify Fraud and Misleading Claims</u>.

Are Herbals and Botanicals Effective?

Current research shows limited health benefits from taking herbal and botanical supplements, and no conclusive evidence that herbals should be used to treat or prevent any type of medical condition. However, there is enough evidence to support the limited use of herbs and botanicals under the guidance of a medical professional. The body of well-controlled research is growing, but the short-term and long-term benefits and risks, as well as active or beneficial ingredients are still largely unknown.

To address this uncertainty, federal law states that herbs cannot claim to prevent, diagnose, treat or cure a condition or disease. Herbs may carry health-related claims about effects on the "structure or function of the body" or "general well-being" that may result from the product. This definition is very loose and gives rise to misleading health claims. The consumer is ultimately responsible for checking their validity and avoiding products with fraudulent claims.

Are Herbs and Botanicals Safe?

Though many herbs are considered safe, some have hazardous side effects especially in children, pregnant women, or those with underlying medical conditions and diseases. Herbals and botanicals have the potential to interact with prescription medications, over-the-counter drugs, vitamins and minerals. For example, ginkgo taken with ibuprofen may lead to spontaneous and/or excessive bleeding. High doses of garlic may enhance the effects and adverse effects of anticoagulant and antiplatelet drugs, including aspirin, clopidogrel (Plavix), enoxaparin (Lovenox), and others. Herbs are not as closely regulated as drugs and other medications, though they are often used for similar purposes. Herbs are not recommended in place of medical treatment or conventional medicine for chronic conditions or diseases, such as severe depression, diabetes, hypertension, and heart disease. Herbs may not be recommended for those who are immuno-compromised, those with kidney damage or liver disease, anyone who may be undergoing surgery or other invasive procedures, pregnant or lactating women, or children under the age of six. Because the elderly may be taking multiple medications, it is suggested that they check with their doctors before starting an herbal supplement.

For a time, the FDA maintained a "Poisonous Plant Database" that listed toxic botanicals sometimes found in supplements. The FDA decommissioned this page in response to criticisms that the list included plant compounds that were studied in isolation and not as they would naturally occur in a food or supplement, and because some of the listed botanicals were only toxic to grazing animals. In March of 2023, the FDA released a more relevant website, Dietary Supplement Ingredient Directory, for consumers to view ingredients that are found in dietary supplements that have been reviewed by the FDA for safety concerns.



When considering an herbal supplement, cross reference your supplement label with this FDA list to identify any potential harm:

https://www.fda.gov/food/dietarysupplements/dietary-supplement-ingredient-directory

Summary

Consumers should be informed in order to protect themselves from questionable health products and services. The following are tips intended to help one become more aware of the risks associated with taking herbal and botanical supplements:

- Determine whether an herbal supplement is truly needed.
- Stay informed by researching the product to determine safety, validity of claims, dosage, most effective form, plant part, species, time frame of use, side effects, counter indications with other supplements or medications, and reasonable price.
- Inform a doctor, pharmacist and other health care professionals of any herbs being considered or routinely used. Consult them with any questions.
- Choose brands that have been tested for consistency in dosage by looking for the United States Pharmaceopia (USP), National Formulary (NF), or Consumer Lab (CL) symbols.
- Read the product label and follow the instructions closely.
- Use herbal products only for minor conditions and only on a short-term basis. If a condition is serious or chronic, consult a medical professional.
- Discontinue use if adverse side effects are experienced.
- Avoid herbal therapies if you suffer from certain conditions or under certain circumstances. (See the section located above: 'Are Herbs and Botanicals Safe?')

- Do not take herbal products known to be toxic. The list in this fact sheet may not include all potentially toxic herbs, so check the resources listed in this fact sheet regularly, for additional toxic herbs.
- The best prescription for disease prevention is a healthy lifestyle that includes a diet high rich in whole foods such as fruits, vegetable, whole grains, lean proteins, and unsaturated fats. Physical activity also plays an important role in reducing one's risk for disease.

Additional Resources

For more information and advice for choosing herbal and botanical products, see The National Institute of Health's (NIH) Office of Dietary Supplements website-Botanical Supplement Fact Sheet: http://ods.od.nih.gov/factsheets/list-Botanicals/

For in depth information regarding supplement regulation see the NIH Office of Dietary Supplements website:

http://ods.od.nih.gov/factsheets/BotanicalBackground-HealthProfessional/

For more information on how to spot a false health claim, see the Federal Trade Commission (FTC) website:

 $\underline{www.ftc.gov/bcp/edu/pubs/consumer/health/hea07.sht} \\ \underline{m}$

For information on recent supplement alerts and safety information, see the Food and Drug Administration (FDA) website:

https://www.fda.gov/consumers/consumer-updates

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Consumer Lab: www.Consumerlab.com



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