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INDEPENDENT, OBJECTIVE AND EVIDENCE-BASED

## Fact sheet: Using dietary supplements and complementary medicines



Dietary supplements, complementary or "alternative" treatments like homeopathy and herbal remedies are very popular. Many people see them as gentle self-management options for treating illnesses and minor health complaints, and assume that they are all completely safe.

Some people swear by complementary medicines and never use any other kind. And other people dismiss all complementary therapies as pure quackery and a waste of money. Yet, as with all kinds of health care treatments, some work and some do not. Many complementary medicines can also have adverse effects. The assumption that "herbal" means "safe", and "chemical" means "dangerous", is wrong. Plants can be poisonous, for example.

Regardless of whether a treatment is conventional or complementary, the same scientific rules about how to assess claims of benefit or harm apply. There is no logical reason why a chemically produced drug should be assessed differently than, for instance, a herbal drug. And there are things to watch out for whenever you are thinking about using complementary medicines.

## What is complementary medicine?

There is not really a clear line that neatly divides complementary and conventional medicine. For example, some people see vitamins and all dietary supplements as complementary, but some of these are a standard part of conventional medicine too. Massage is seen by some as complementary medicine, but it is also a traditional part of physiotherapy and nursing care. Chinese herbal medicine is seen as "alternative" in Western countries, but not in Asian countries. Yoga is regarded as a complementary therapy by some people, and as a conventional form of exercise and relaxation by others.

Generally, though, those kinds of treatments that are based on different approaches and underlying theories than those taught in university medical schools are called complementary or "alternative" therapies. Such approaches could include something like stimulating the body's energy to heal itself, as with acupuncture. It could involve a different set of theories about what is causing illness, as for example theories about the influence of the spine on health in chiropractic medicine. Or it could involve a different theoretical approach to developing medications, as for example with homeopathy or anthroposophical medicine.

Treatments that are based on herbs or plants, also known as

phytotherapy, are generally considered to be "complementary" medicine. Herbal products are used in conventional medicine too. This fact sheet is about these and other forms of complementary medicines and dietary supplements.

Dietary supplements and complementary products are often used to try to strengthen the immune system and prevent illnesses. These kinds of treatments are often called "complementary" rather than "alternative" so that their role is understood as being alongside that of other treatments. That is, the treatments are an addition to conventional medicine rather than a replacement for it. This is important, because one of the main concerns about complementary medicine is not that the treatment itself will necessarily cause harm, but that people will be harmed if they fully rely on something that is less effective than a conventional treatment.

## What are dietary supplements?

Basically, a dietary supplement is a kind of nutritional product that you swallow: it could be a tablet, powder or a liquid. It has a substance in it that also occurs in things you could eat, like a vitamin or mineral. A dietary supplement is not necessarily made from plants: it could also be an animal product, like fish oil. So it is not a form of herbal medicine. And it is not necessarily "natural": it could be synthetically produced.

Here are some examples that are usually regarded as dietary supplements:

- Vitamins and pro-vitamins (such as vitamin C, vitamin E, folic acid and beta-carotene)
- Minerals and trace elements (such as calcium, magnesium, iron and zinc)
- Vitamin-like substances (such as coenzyme Q10)
- Essential fatty acids (such as omega-3 and omega-6 fatty acids)
- Protein components (such as amino acids like L-cysteine and L-carnitine)
- Carbohydrates (such as oligofructose)
- Substances like brewer's yeast, algae and probiotics

A dietary supplement usually has doses of the substance that are much higher than you could manage to eat or drink. Very high doses of vitamins or minerals can become toxic though. Very high doses are often treated as

medicines, and not as dietary supplements.

What is defined as a dietary supplement or a medicine can differ from country to country: plant extracts such as ginseng and ginkgo biloba are treated as dietary supplements in some countries and as herbal medicines in others.

**Do all herbal products and dietary supplements have the same level of quality and safety regulation as prescription medicines?**

There are differences in the ways that quality and safety issues are regulated for pharmaceutical medicines and dietary supplements for example. If a product is not regarded as a pharmaceutical, then it will not have to go through all the strict testing and quality assurance processes that prescription medicines have to. This means that you cannot be as sure that all the products you can buy in a drugstore, pharmacy, supermarket or on the internet are standardised either: what is inside the bottle, for example, may not be exactly what it says on the label. The contents might vary slightly from bottle to bottle.

Dietary supplements are regulated like food products rather than like medicines. They are not allowed to be advertised as substances which cure, relieve or prevent illnesses. That is why dietary supplements will often make claims such as "boosts your immune system", "balances your hormones" or "strengthens your joints".

Although there is protection against very dangerous substances being on the market, this does not mean that herbal medicines or even vitamins cannot do harm. For example, very high doses of some antioxidants and vitamins have been linked to increased risk of cancer or even deaths. And some people can have serious allergic reactions to medicines based on particular plants. In Germany, for instance, the Federal Institute for Risk Assessment (BfR) has placed limits on the amount of carotenes that vitamin supplement manufacturers are allowed to have in their products.

The German Federal Institute for Drugs and Medical Devices (BfArM) is the agency responsible for authorising medicines in accordance with German drug legislation. For full licensing, for example, a prescription medicine needs to prove efficacy on the basis of controlled trials. However there is a special simpler registration that can be used for particular traditional and presumed-to-be "harmless" medicinal products. Instead of proof of efficacy in the usual

way, under certain circumstances traditional use and plausible efficacy can be enough.

It is not always easy to clearly classify herbal products as conventional or complementary medicines. The manufacturers of herbal medicines can, but do not have to, apply for drug approval. Herbal products can be bought directly in a wide range of shops and from the Internet. But some herbal products are listed as being potentially more risky and can only be bought in pharmacies. Some herbal products or high-dose supplements are fully licensed as medicines for certain uses. These are only available from pharmacies with a doctor's prescription.

However, just because a complementary or conventional medicine is available to buy, it does not mean that all questions about its effectiveness or safety have been answered. It often takes many years before the full impact of a treatment can be known. Research and monitoring continues after medicines are on the market and being used. In fact, research that is fully independent of the manufacturer often only begins once a medicine is on the market and therefore accessible to independent researchers.

**What are the main questions to think about when considering or using complementary medicines or dietary supplements?**

As with all medicines, there are some central questions to consider:

- Is this product suitable for my condition or health goal? Treating symptoms without being sure what is causing them can sometimes mean that the real problem is being neglected and could get worse.
- What benefits and harms have been observed in other people with similar conditions using the product? You can read more about why trials are needed and how this research is analysed and interpreted here.
- What dose is necessary to get any benefits that have been proven in research, and is the complementary medicine or supplement that I can buy similar to the one that researchers studied?
- What are the other ingredients in the product, and is there anything in it that I have been allergic to in the past? Does the product have alcohol in it?
- What will happen if I do not use the medicine or

supplement at all? Is the condition likely to get better quickly by itself, or will doing nothing mean I am at risk of serious problems?

- How much will it cost and what do I have to do to use it properly?
- Can this medicine interact or interfere in some way with some other medication that I am taking or might soon need?

## **What are my other options, and might any of them be preferable for me?**

Some complementary medicines could reduce the effectiveness of other drugs like anaesthetics and painkillers, or increase the risk of losing too much blood. This may be important if you are going to have an operation or start a new treatment. For these and many other reasons, it is important that your doctors know what it is that you are taking. If you are pregnant or breastfeeding, everything you take might have an effect on your baby or the pregnancy.

We include research-based information on dietary supplements, complementary and pharmaceutical products on our website, and you can keep up-to-date with new research by subscribing to our newsletter here (URL: <http://www.gesundheitsinformation.de/newsletter.255.69.en.html>)

## Glossary

### beta-carotene

Beta-carotene (or  $\beta$ -carotene) is the colouring that makes some fruit and vegetables yellow or orange (like carrots). It is an early chemical stage of vitamin A, and this is why it is sometimes called pro-vitamin A. The food industry uses beta-carotene as a food colouring agent. It is also an ingredient in many multi-vitamin preparations.

### folic acid

Folic acid is a water-soluble vitamin. Green and leafy vegetables (eg lettuce, spinach and broccoli), liver, egg yolk, and particularly wheatgerm are rich sources of folic acid. Having too little of this vitamin can lead to anaemia. In pregnancy, low levels of folic acid can increase the risk of a fetal abnormality called spina bifida. This is why women who are pregnant, or trying to get pregnant, are encouraged to increase their intake of folic acid.

### calcium

Calcium is an important mineral for human health. It is one of the building blocks for bones and teeth, and it is necessary for blood clotting, the muscles and the nerves. Calcium occurs in milk and milk products, as well as in green leafy vegetables. People can get a calcium deficiency if they have a chronic inflammatory bowel disease, as well as in pregnancy or during breastfeeding.

### vitamin C

Vitamin C is water-soluble. It is also called ascorbic acid. It is the vitamin that people need to have the most of every day. It occurs primarily in fresh fruit and vegetables. Vitamin C is one of the antioxidants. This means it protects cells from damage caused by particular aggressive atoms and molecules called free radicals. The food industry uses it frequently as a conservative. A major vitamin C deficiency leads to tiredness, irritability, and symptoms in bones, cartilage and teeth.

### vitamin E

Vitamin E describes a group of 8 different fat-soluble vitamins. They are antioxidants, which mean they protect cells from damage caused by aggressive types of atom or molecule called free radicals. Vitamin E occurs particularly in nuts and cold-pressed plant oils, like sunflower oil. The

food industry uses it as a conservative. Because it is not water-soluble, the body only absorbs vitamin E if it comes in fats in the diet.

### hormones

“Hormones” is the collective term for different types of messenger substances in the body. They are produced in different organs or tissues and released into the blood or the lymphatic system to be distributed throughout the body. Hormones only have an effect on those parts of the organism that have a corresponding docking site. This is how hormones can have such specific effects. Insulin, estrogens, vasopressin and thyroxine are some well-known hormones. Many medical ingredients imitate the effect of hormones.

### acupuncture

Acupuncture is a complementary form of therapy used in traditional Chinese medicine. A doctor inserts thin needles at precisely defined points on the body. This is supposed to loosen what are thought to be blockages in the body or to stimulate or calm different organs.

### immune system

The immune system is the body's defense system and its task is to protect the body against germs or degenerated cells (like cancer cells). The immune system is very complex and has not been understood in every detail yet. There are two components: the cellular immune defense (for example “scavenger cells” and “killer cells”) and the complement system (“antibodies”, for example).

### dietary supplement

Dietary supplements (also known as food supplements or nutritional supplements) are concentrated vitamins, minerals, trace elements, fibers and/or other substances that are intended to supplement the diet. Advocates of dietary supplements claim that they have a certain, often preventive or strengthening effect on the body. They are available as capsules, pills, powder or ampules, for example. From a legal point of view, dietary supplements rank among foods and therefore – as opposed to medications – do not need official approval. More information is available on the website of the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR): To the BfR website (in English)

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## **The German Institute for Quality and Efficiency in Health Care (IQWiG)**

The German Institute for Quality and Efficiency in Health Care (IQWiG) was established by legislation to provide evaluations of the effectiveness, quality and efficiency of healthcare services. This includes the assessment of medicines as well as the publication of health information for consumers and patients.

## **Evidence basis of our health information**

Our information is based primarily on systematic reviews of the effects of health care. Systematic reviews are necessary to gain an objective picture of health care. In order to do this, a clear question is formulated. Researchers then find all the relevant studies that could answer this question. They then evaluate those studies.

You can find a list of the evidence and other scientific literature on which this information is based at [\*\*www.informedhealthonline.org\*\*](http://www.informedhealthonline.org)

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