



THE SAFETY OF VITAMIN E SUPPLEMENTS

The Issue

While vitamin E from dietary sources is needed to maintain good health, people often take vitamin E supplements in the belief that they may prevent disease. Recent studies, however, have suggested that the use of high doses of vitamin E may actually increase the risk of heart disease and cancer in people who are at high risk for these diseases.

Background

Vitamin E is the term used for a group of fat-soluble antioxidants, which act in the body to protect against cell damage. Vitamin E exists in eight different forms. Each form has its own biological activity, which is the measure of potency in the body. Alpha-tocopherol is the name of the most active form of vitamin E in humans. It is also a powerful biological antioxidant. Vitamin E is also thought to play a role in maintaining the body's immune system and other body processes.

Vitamin E supplements are usually sold in a form that protects the ability of the supplement to act as an antioxidant. The synthetic form of vitamin E is only half as active as the natural form. The synthetic form is labelled "dl" or "all rac," while the natural form is labelled "d" or "RRR."

The recommended dietary allowance (RDA) of vitamin E for people aged 14 years and over, including pregnant women, is 15 mg /d of alpha-tocopherol. This is equivalent to 22 IU (International Units) of natural source vitamin E per day, or 33 IU from synthetic sources. The RDA for breastfeeding women is 28 IU

natural/42 IU synthetic vitamin E. The tolerable upper intake level for adults is 1,000 mg per day of any form of vitamin E supplements.

Vitamin E is found naturally in such foods as:

- vegetable oils such as sunflower, safflower, canola, and olive
- seeds and nuts such as sunflower seeds, almonds, hazelnuts, and peanuts
- wheat germ
- some green leafy vegetables, although it is present in small amounts.

Vitamin E is also added to some foods as an antioxidant, but only in small amounts.

Vitamin E deficiency is rare in humans. Since vitamin E is a fat-soluble vitamin, deficiency usually occurs only in people with syndromes where fat is poorly absorbed. However, because most dietary vitamin E is found in oils, very low-fat diets can result in low intakes of vitamin E if food choices are not made carefully. To maintain vitamin E levels, it is important to eat a variety of antioxidant-rich foods such as fruits, vegetables, whole grains, and moderate amounts of healthy unsaturated fats, (such as those found in fish, olive oil, canola oil, some vegetable oils, nuts, and flaxseed), as part of a healthy diet.



Vitamin E Supplements

In general, an intake of vitamin E (for example as part of multivitamin supplementation) of up to

40 IU is considered to be a "normal" dose. Supplements are available that provide from 1.5 IU to 1,500 IU per day. Those providing 400 IU per day or more are considered to be "high dose" or "megadose."

Currently, vitamin E is not authorized for sale in Canada for the purpose of preventing any particular disease, including heart disease and cancer. Health Canada is developing guidelines for vitamin E that will recommend precautionary measures for people aged 55 years or older who have heart disease or diabetes, and for people who have, or have previously had, cancer. These people are advised to consult their doctor before taking doses of vitamin E of 400 IU or more. Also, people who are taking blood thinners, or have been diagnosed with a bleeding disorder and/or a vitamin K deficiency should consult their doctor before taking vitamin E.

Potential Benefits of Vitamin E Supplements

Some types of cell damage and disease are thought to be caused by the "oxidant" action of free radicals, which are by-products normally generated by the body. Although it is recognized that vitamin E is an antioxidant and prevents free-radical reactions, the theory that vitamin E

removes the free radicals and protects against a variety of diseases – such as heart disease, cancer, Alzheimer's disease, Parkinson's disease and age-related macular degeneration, to name a few – has yet to be demonstrated with any certainty.

While most studies have found that people who consume diets rich in vitamin E are at a lower risk of developing heart disease or cancer, studies that looked at supplementation with high doses of vitamin E gave conflicting results.

A recent study involving healthy women found that 600 IU of natural vitamin E taken every second day did not prevent heart disease or cancer. The currently available scientific studies seem to indicate that there is no compelling evidence of benefits from high doses of vitamin E supplements against these diseases. However, more research is needed in this area.

The Potential Health Risks of High-Dose Vitamin E Supplement Use

Recently published studies have suggested that vitamin E supplements not only fail to prevent heart disease and cancer, but may actually harm people who take high doses over a long term. However, these studies are limited by the fact that they involved:

- people 55 years or older who already had heart disease or diabetes
- people with cancer or who previously had cancer

- people who may be at higher risk of developing these diseases.

One study found that patients with heart disease or diabetes who took 400 IU of vitamin E daily for an average of seven years were at a significantly increased risk of heart failure compared to patients who were not taking vitamin E supplements. This study concluded that high-dose vitamin E supplements (400 IU or greater) should not be taken by patients with heart disease or diabetes.

In another study, daily doses of 400 IU of vitamin E were given to patients receiving radiation therapy for cancers of the head and neck. The theory was that the antioxidant treatment might reduce the incidence of additional cancers of the same type among these patients. However, it was found that those who received vitamin E supplements were significantly more likely to develop other similar cancers during the supplementation period than those receiving a placebo.

All these studies have limitations. It is difficult to interpret how the results might apply to healthy people taking high doses of vitamin E. Although there are justifiable concerns over certain at-risk groups of consumers, more research is needed, especially focusing on the long-term use of high-dose vitamin E supplements.

Minimizing Your Risk

You should tell your doctor about all the medications and natural



health products you use, including drugs, minerals, herbal products and high doses of vitamins, especially if you take a high-dose vitamin E supplement on a daily basis.

As well, you should take the following steps:

- Use products that are authorised by Health Canada. Look for the 8-digit Drug Identification Number (DIN) or a Natural Product Number (NPN) on the label.
- Follow all directions and warnings given on product labels.
- If you have cancer or previously had cancer, or are 55 years of age or older and have been diagnosed with heart disease or diabetes, talk to your doctor before taking high-dose vitamin E supplements. This also applies to people being cared for who have these diseases.
- If you suspect that you have had an adverse reaction to any product containing vitamin E, or any other health product, talk to your doctor or pharmacist.

Health Canada's Role

As a result of the recently published studies suggesting that high-dose vitamin E supplements may pose a health risk to certain groups of consumers, Health Canada is conducting an in-depth review of the scientific literature on the benefits and risks of high-doses of vitamin E. Should this review show that the potential

risks outweigh the benefits, appropriate measures will be taken to maintain the health and safety of Canadians.

In the meantime, the Natural Health Products Directorate of Health Canada is drafting guidelines on vitamin E to ensure that manufacturers provide appropriate information on product labels. Such information would include recommended dosages, the length of time products should be taken, and information on potential risk.

Need More Info?

For more information on the recommended intake of nutrients, including vitamin E, as well as information on healthy eating, go to:

http://www.hc-sc.gc.ca/fn-an/nutrition/index_e.html

Reporting Adverse Reactions:
Report any adverse reactions to vitamin E supplements or any other product by calling the toll-free number (866) 234-2345 or faxing toll-free to (866) 678-6789.

Or write to the Canadian Adverse Drug Reaction Monitoring Program (CADRMP) of Health Canada:

CADRMP, Marketed Health Products Directorate
Health Protection Building,
Tunney's Pasture, AL 0701C
Ottawa, Ontario, K1A 0K9
Email: cadrmp@hc-sc.gc.ca
Or visit our Web site at:
http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_adverse_e.html

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You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245*