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STATEMENT OF THE COMMITTEE OF HUMAN NUTRITION SCIENCE OF THE POLISH ACADEMY OF SCIENCES ON THE USE OF DIETARY SUPPLEMENTS CONTAINING VITAMINS AND MINERALS BY ADULTS*

http://wydawnictwa.pzh.gov.pl/roczniki_pzh/

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ABSTRACT

The use of dietary supplements (supplementation) is the individual enrichment of the diet with ingredients naturally occurring in food. As a rule, dietary supplements should be used periodically. In nutritional practice, there are many indications for dietary supplementation, but the decision to take dietary supplements should be made by consumers wisely and only in justified situations, when there is a risk that the usual diet does not provide vitamins and minerals in an amount adequate to meet dietary recommendations. However, we should remember about the real dangers of taking too large doses of vitamins and minerals. Many people using dietary supplements, especially several types at the same time, may experience undesirable side effects and deterioration of health, and in addition, people taking medicines may seriously disrupt or weaken the effect of the drug, or even lack the therapeutic effect of the drug. The document presents 10 steps and rules for the use of dietary supplements available on the market, which are addressed to the general population.

Key words: diet, minerals, vitamins, supplements, shortages, nutrition, food, adults

STRESZCZENIE

Stosowanie suplementów diety (suplementacja) to indywidualne uzupełnianie diety w składniki naturalnie występujące w żywności. Z założenia suplementy diety powinny być przyjmowane okresowo. W praktyce żywieniowej istnieje wiele wskazań do suplementacji, ale decyzja o przyjmowaniu suplementów diety powinna być podejmowana przez konsumentów z rozsądkiem i tylko w uzasadnionych sytuacjach, gdy istnieje ryzyko, że zwyczajowa dieta nie dostarcza witamin i składników mineralnych w ilości odpowiedniej do pokrycia zapotrzebowania organizmu. Należy jednak pamiętać o realnym niebezpieczeństwie wynikającym z przyjmowania zbyt dużych dawek witamin i składników mineralnych. U wielu osób stosujących suplementy diety, zwłaszcza kilka rodzajów jednocześnie, mogą wystąpić niepożądane skutki uboczne i pogorszenie stanu zdrowia, a u osób przyjmujących leki – może dodatkowo dojść do poważnego zakłócenia lub osłabienia działania leku, a nawet braku efektu leczniczego. W dokumencie przedstawiono 10 kroków i zasad korzystania z dostępnych na rynku suplementów diety, które skierowano do populacji generalnej.

Słowa kluczowe: dieta, składniki mineralne, witaminy, suplementy, niedobory, żywienie, żywność, osoby dorosłe

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The use of dietary supplements (supplementation) is the individual enrichment of the diet with ingredients naturally occurring in food. As a rule, dietary supplements should be taken periodically [1]. In nutritional practice, there are many indications for supplementation, but the decision to take dietary supplements should be made by consumers wisely and only in justified situations, when there is a risk that a regular diet will not provide vitamins and minerals in an amount adequate to comply with dietary recommendations. Dietary supplements that have been introduced to the Polish market are safe and should not pose a threat to the health and life of consumers, but their improper use may pose a threat. Taking dietary supplements should be consulted with doctor, nutritionist or pharmacist as there is a risk of overdosing or interactions with food, medicines or other supplements. Eating a varied diet based on available food should always be considered as the first step in improving the nutritional status and health.

LEGAL REGULATIONS AND DIETARY SUPPLEMENTS

The Act of Food Safety and Nutrition of 25 August 2006 [10], defines a **dietary supplement** as a **food**, **supplementing a normal diet**, being a concentrated source of vitamins or minerals or other substances with a nutritional or other physiological effect, single or complex, marketed in dosage form, in the form of: capsules, tablets, dragees and other similar forms, powder sachets, liquid ampoules, dropper bottles and other similar forms of liquids and powders intended for consumption in small, measured unit amounts, excluding products with the properties of a medicinal product within the meaning of pharmaceutical law.

The above conditions should be met cumulatively. The ingredients of dietary supplements can be:

- vitamins: A, D, E, K, B vitamins (B₁, B₂, B₆, B₁₂, niacin, pantothenic acid, folic acid, biotin), vitamin C;
- minerals: calcium, phosphorus, magnesium, iron, zinc, copper, iodine, selenium, fluorine, manganese, sodium, potassium, chlorine (chlorides) and others, e.g. boron, chromium, silicon, molybdenum;
- other substances, e.g. amino acids, fatty acids, dietary fiber, pro and prebiotics, substances of plant origin and others having a potential biological effect on the body.

Dietary supplements are labeled with the following information on the packaging:

• the term "dietary supplement";

- the name of the category of nutrients or substances characterizing the product or an indication of their properties;
- the portion of the product recommended for consumption during the day;
- a warning about not exceeding the recommended daily dose;
- a statement that dietary supplements cannot be used as a substitute (replacement) for a varied diet;
- a statement that dietary supplements should be stored out of reach of small children;
- information on the content of vitamins and minerals;
- the content of vitamins and minerals as a percentage of the recommended daily intake.

The labeling of dietary supplements must not attribute to them the property of preventing, treating, or cure human diseases or suggest such properties. This policy also applies to advertising.

DIETARY SUPPLEMENTS AND MEDICINES

A medical claim that states, suggests, or implies that a product or ingredient(s) has properties for treating or preventing disease(s) are proprietary to medicaments.

Dietary supplements, like medicines and medical devices, are in the form of tablets, dragees, capsules, drops, powders, but the differences between these products are fundamental (Table 1). This applies not only to the method of operation, but also to the principles of marketing authorization, intended use, and the possibility of advertising the preparation and placing it on the market. A drug differs from a medical device, among other, mode of action. Medicinal products (medicines) have a pharmacological effect, i.e. they cure or prevent a disease, and medical devices only have a physical and mechanical effect. Thus, the effect of the medical devices is limited compared to the medicines. Diet supplements, on the other hand, are used to enrich the usual diet (based on typically consumed food). They do not have any healing properties, but they can support the functioning of the body, improving its nutritional status.

In the light of legal regulations [2, 3, 5, 7, 8, 9], the maximum content of vitamins and minerals in a daily portion of a dietary supplement should be determined taking into account:

 the upper level of safe intakes (UL) for vitamins and minerals based on scientific risk assessment and generally accepted scientific data, taking into account the varying degrees of sensitivity of different groups of consumers;

Differences	Food supplement	Medicines
Intended use	A food supplement is used to supplement the nutritional value of a regular diet. It is intended for healthy individuals who do not have an adequate supply of certain ingredients in their diet.	A medicine is used to treat or prevent diseases. It is intended for people who are ill or at increased risk of developing the disease.
Safety	Food supplements satisfy the requirements applying to foodstuffs. The content of an ingredient in the product may differ from the amount declared on the label by -20% to +50% for vitamins and -20% to +45% for minerals.	Each medicine is subject to detailed testing of its composition. Only small, strictly defined differences in the content of a given component resulting from the test method used are permitted.
Placing on the market in Poland	A food supplement is a food item and therefore does not require a marketing authorisation. The decision to market it is taken by the entrepreneur, who notifies the Chief Sanitary Inspector (GIS). In case of any doubt, the Chief Sanitary Inspector may initiate a clarification procedure.	A medicine, before it can be marketed, must be approved by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL, WMiPB). The product label shows the marketing authorisation number of the medicines.
Inclusion in a relevant list	Products that have been approved as food supplements are listed in the special Register of Products www.rejestrzp.gis.gov.pl	Medicines that have been authorised for marketing in Poland are included in the Official List of Medicinal Products www.urpl.gov.pl

able 1. The main differences between food supplements and medicines

Source: https://gis.gov.pl/wp-content/uploads/2020/01/suplementy-diety_A5.pdf

- intake of vitamins and minerals from food and drinking water, including fortified foods;
- recommended intakes of vitamins and minerals for the population, taking into account different groups of consumers.

In Poland, the Team for Diet Supplements, which functions within the Sanitary and Epidemiological Council, as an advisory body to the Chief Sanitary Inspector (GIS), has been entrusted with determining the maximum content of vitamins and minerals in dietary supplements. The Team for Diet Supplements develops opinions in the form of resolutions on the maximum daily amounts of vitamins and minerals in dietary supplements (in the recommended daily dose) intended for adults, with additional guidelines (Table 2).

Additional guidelines of the Team for Diet Supplements regarding the maximum content of vitamins and minerals in dietary supplements [4]:

- vitamin D before use, it is advisable to test the concentration of 25(OH)D in the blood and consult the result of the test with a doctor or pharmacist;
- vitamin C in the labeling of dietary supplements with a high content of vitamin C, it is recommended to include a warning: "Do not use in people with a predisposition to the formation of kidney stones or suffering from kidney stones";
- vitamin A 800 µg in the form of retinol equivalent (retinol and retinyl esters) and 7 mg in the form of β-carotene;
- **folic acid** 800 µg if the supplement is marked as intended for pregnant women; in addition, it is

recommended to include a warning: "In pregnant women, use after consulting a doctor";

- **niacin** 830 mg in the form of nicotinic acid amide or 16 mg in the form of nicotinic acid;
- **pantothenic acid** 10 mg in the form of pantethine or 200 mg in the other chemical forms, expressed as pantothenic acid;
- **iodine** 200 µg if the supplement is designated as intended for pregnant and lactating women;
- iron 30 mg if the supplement is marked as intended for pregnant women; in addition, it is recommended to include a warning: "Supplement for pregnant women, use after consulting a doctor";
- vitamin K in the labeling of dietary supplements with a high content of vitamin K, it is recommended to include a warning: "The supplement should not be consumed by people taking anticoagulants containing vitamin K antagonists (eg. warfarin and acenocoumarol)";
- **boron** 3 mg;
- chromium 200 μg.

THE INTAKE OF FOOD SUPPLEMENTS AND CONSUMER SAFETY

The use of food supplements containing vitamins and minerals may, for some people, improve compliance with dietary recommendations and more fully meet the body's requirements for these nutrients. However, it should be remembered that **taking excessive doses of vitamins and minerals involves a real risk** (Table 2 and 3). For many individuals, taking food supplements, especially several types of supplements at the same time, undesirable side effects and deterioration of health may occur and, in those taking medicines, the effect of their medicines may additionally be seriously affected or impaired or the therapeutic effect may even be completely absent. For these reasons, food supplements need to be appropriately labelled by the manufacturer, i.e. to include reliable information on contraindications to the use of these preparations, to indicate possible interactions with medicines, food components or components of other food supplements and to recommend that consumers consult their doctor before using them, especially if they are ill or taking medicines.

TEN STEPS AND RULES FOR USING FOOD SUPPLEMENTS

Based on current scientific knowledge and existing legislation, ten steps and rules have been formulated for using food supplements available on the market:

- 1. Ongoing education of the public concerning the principles of proper nutrition and a well-balanced diet through the consumption of a wide variety of foods.
- 2. Before using a food supplement, a qualitative and quantitative assessment of the diet should be conducted by a dietician or another professional, taking into account the individual needs of the consumer according to gender, age, physical activity and physiological state (pregnancy, breastfeeding).

Table 2. Recommended daily allowances (RDA) of vitamins and minerals in Poland in relation to the upper safe level of intake (UL) from food, drinking water and food supplements jointly, as well as their maximum daily amounts in food supplements (according to the values provided by the Team for Diet Supplements)[4]

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Component	RDA for an adult	UL values for an adult	Maximum daily amount in the recommended daily portion of the supplement
Vitamin A (µg)	700 ¹⁾ / 900 ²⁾	3000	800
Vitamin D (µg)	15 (600 IU)	100 (4000 IU)	50 (2000 IU) ^{6)/} 100 (4000 IU) ⁷⁾
Vitamin E (mg)	8 ¹⁾ /10 ²⁾	300	250
Vitamin K (µg)	55 ¹⁾ / 65 ²⁾	no data	200
Vitamin C (mg)	75 ¹)/ 90 ²)	no data	1000
Thiamine (mg)	1.1 ¹)/ 1.3 ²)	no data	100
Riboflavin (mg)	$1.1 \ {}^{1)}/ \ 1.3 \ {}^{2)}$	no data	40
Niacin (mg)	14 ¹ / 16 ²)	nicotinic acid – 10 mg nicotinamide – 900 mg	16
Vitamin B_6 (mg)	$1.5^{1}/1.7^{2}$	25	18
Folacin (µg)	400	1000 as folic acid	600 as folic acid
Vitamin B ₁₂ (µg)	2.4	no data	100
Biotin (µg)	30	no data	not established
Pantothenic acid (mg)	5	no data	10
Calcium (mg)	1000 ³⁾ / 1200 ⁴⁾	2500	not established
Phosphorus (mg)	700	no data	450
Magnesium (mg)	320 ¹⁾ / 420 ²⁾	250 5)	400
Iron (mg)	$18^{1}/10^{2}$	no data	20
Zinc (mg)	8 ¹⁾ / 11 ²⁾	25	15
Copper (mg)	0.9	5	2
Iodine (µg)	150	600	150
Selenium (µg)	55	300	not established
Fluoride (mg)	3 1)/ 4 2)	7	3.5
Manganese (mg)	1.8 ¹⁾ / 2.3 ²⁾	no data	1.8

¹⁾ women; ²⁾ men; ³⁾ for women under 50 and men under 65; ⁴⁾ for women 50 or over, and men 65 or over; ⁵⁾ value for the intake of magnesium from food supplements and magnesium added to food (excluding magnesium naturally occurring in products); ⁶⁾ for the healthy adult population under 75; ⁷⁾ for the healthy adult population 75 or over

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Group	Health risk	Component
А		thiamine (vitamin B_1), riboflavin (vitamin B_2),
	levels of consumption	biotin, vitamin B_{12} , pantothenic acid, vitamin K,
	(from all sources in total)	chromium (III)
В	The risk of exceeding UL [*] is low	vitamins: B ₆ , C, D, E, folic acid, nicotinamide,
		phosphorus, magnesium, molybdenum, selenium,
		potassium
C	There is a risk of excessive intake when using	vitamin A, beta-carotene, calcium, copper, iodine,
	supplements	iron, manganese, zinc

Table 3. The presence of risks related to excessive intake of vitamins or minerals with food supplements in adults [6]

* UL (Upper Level) – upper safe level of the component intake with food, drinking water and food supplements

- 3. If a diet is found to be poorly balanced in relation to the dietary recommendations, making changes to food intake and ensuring the consumption of food enriched with vitamins and minerals.
- 4. Carrying out medical and biochemical tests on nutritional status to assess health condition and confirm vitamin and mineral deficiencies in the body.
- 5. Choosing an appropriate food supplement, while eliminating the risk of potential interactions associated with the simultaneous intake of several food supplements or interactions between a food supplement and medicines.
- 6. Using food supplements only from verified sources.
- 7. Educating patients on the use of the food supplement to minimize the risk of adverse reactions resulting from excessive intake, i.e. exceeding the upper safe intake level (UL) for vitamins and minerals (including diet, drinking water and food supplements).
- 8. Seeking follow-up advice from a doctor and a dietician to monitor the effectiveness of the food supplement and, if necessary, to change the type or dose of the food supplement.
- 9. After periodic dietary supplementation and confirming the elimination of vitamin and mineral deficiencies in the body, discontinuing the intake of the food supplement and following a well-balanced diet.
- 10. For population groups at higher risk of deficiencies, e.g. children, adolescents, the elderly and pregnant [11] or lactating women, following the recommendations addressed to those groups by the relevant expert panels and, in the case of sick persons, following individual medical advice.

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