National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Supplements for the elderly

An inventory of vitamins and minerals available for elderly in the Netherlands

RIVM Letter report 090143001/2013
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Colophon

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Rapport in het kort

Supplementen voor ouderen.
Inventarisatie van vitaminen en mineralen die in Nederland voor ouderen beschikbaar zijn

De industrie heeft een veelheid aan supplementen ontwikkeld die specifiek voor ouderen zijn. Sommige van deze supplementen bevatten hoge doseringen van bepaalde vitaminen en mineralen. Deze doseringen blijven onder de ‘maximaal aanvaardbare bovengrens’ (Upper Limit), en zijn meestal niet hoger dan drie keer de aanbevolen dagelijkse hoeveelheid (ADH). Uit onderzoek van het RIVM blijkt dat deze supplementen niet schadelijk zijn voor de gezondheid.

Verder zijn er in supplementen voor ouderen hoge doseringen gevonden van stoffen waarvoor geen UL bestaat: B-vitamines, vitamine C en ijzer. Daardoor kunnen voor deze stoffen geen conclusies worden getrokken over de veiligheid van de doseringen. In algemene zin is daarom voorzichtigheid geboden als deze producten langere tijd worden gebruikt.

Er zijn algemene supplementen op de markt, niet specifiek gericht op ouderen, die een dosering bevatten boven de Upper Limit. Ook ouderen kunnen deze producten gebruiken. Het gaat om bepaalde preparaten die hoge gehalten bevatten van de vitaminen foliumzuur, B6, D en E, en de mineralen zink en selenium. Het is niet uitgesloten dat een te hoge inname van de vitaminen B6 en E op de lange termijn schadelijk kan zijn voor de gezondheid en het welzijn van ouderen. Te hoge doseringen van vitamine B6 kan neurologische klachten veroorzaken, het gebruik van te veel vitamine E kan bloedstollingen veroorzaken.

Samenvattend, supplementen die specifiek voor ouderen ontwikkeld zijn, kunnen beschouwd worden als niet gevaarlijk. Er zijn echter een aantal producten verkrijgbaar die niet specifiek op ouderen gericht zijn maar die wel door ouderen gebruikt kunnen worden, die de Upper Limit van toxiciteit overschrijden. Dagelijks gebruik van deze producten gedurende langere perioden is mogelijk schadelijk voor de gezondheid van ouderen.

Voor dit onderzoek zijn alle supplementen die ouderen kunnen gebruiken geïnventariseerd.

Trefwoorden: supplementen, ouderen, vitaminen, mineralen, maximaal aanvaardbare bovengrens (UL), aanbevolen dagelijkse hoeveelheid (ADH)

Abstract

On the consumer market, supplements are available that are specifically designed and targeted for the elderly. Some of these supplements contain high doses of certain vitamins and minerals. These doses remain below the Upper Limit (UL), and do usually not rise above the Recommended Daily Allowance (RDA). RIVM research shows that these supplements can be considered as non-toxic.

Some supplements specifically targeted for the elderly contain high doses of vitamins and minerals for which no UL exists, namely, B vitamins, vitamin C, and iron. As a result, for these vitamins and minerals, no conclusions can be drawn about the safety of the doses. Therefore, caution should be exercised when these products are used long time .

There are supplements on the market that are targeted for the general population, that contain doses of vitamins and/or minerals above the UL. The elderly can use these products as well. Some of these supplements contain high levels of the vitamins folate , B6 , D and E , and/or the minerals zinc and selenium. It is not excluded that a high and long-term intake of vitamin B6 and E may be harmful to the elderly. High doses of vitamin B6 can cause neurological symptoms, the use of too much vitamin E increases the risk of blood clotting.

In conclusion, all available supplements advised for the elderly can be considered as non-toxic. There are, however, a number of products available, that or not specifically targeted to, but may be commonly used by the elderly, that exceed the UL. A daily consumption of these products during longer periods cannot exclude a possible occurrence of detrimental effects on health and well-being for elderly people.

For this research, an inventory was made of all supplements that can be used by the elderly.

Keywords: supplements, the elderly, vitamins, minerals, Upper Limit (UL), Recommended Daily Allowance (RDA)

Contents

1 Introduction

The Dutch population is aging due to an increased life expectancy and lower birth rate. Elderly are considered a high risk group with different dietary habits and needs and a different lifestyle (Gezondheidsraad, 2011). The normal biology of aging, from about middle age, has several biological mechanisms, such as oxidative damage, and DNA and tissue repair capacity. Different nutritional and consumer products are on the market that claim to limit oxidative damage thereby promising to decrease the aging process. Some of these products are advertised for the general population, some are specifically targeted at the elderly. The Netherlands Food and Consumer Product Safety Authority (NVWA) would like to know what type of products, substances and substance classes are available on the consumer market that suggest or claim to slowdown the biological aging process.

This study is dedicated to vitamins and minerals that are specifically targeted to or commonly used by the elderly and intend to intervene in the biological aging process. The aim of this study is to provide information on the safety of these products for the elderly. Therefore, the daily dose as prescribed by the manufacturer was compared to the Recommended Dietary Allowance (RDA) as established by the Health Council of the Netherlands and the Tolerable Upper Intake Levels (UL) as established by the European Food and Safety Authority (EFSA).

2 Methods

Due to the wealth of products, substances and substance classes available on the market and specifically targeted (with indications 50+, 55+, 60+ or 65+) or commonly used by the elderly, this study was dedicated to vitamins and minerals only. Vitamin and mineral content was compared to RDA's of males aged between 51 and 70 years. This study is therefore specifically targeted at elderly males in this age category but representative for elderly in general, since RDA values do not differ significantly between males and females. The information on the composition of specific supplements is obtained mainly from the website of Vitamineshoppen [2]. For more detailed information, several other websites were consulted (see reference list). In addition, the following stores were visited for an inventory of supplements marketed for the elderly: Kruidvat, ETOS and HEMA. These inventories were made between August and October 2013. In Table 1 the vitamins and minerals which were considered for this study are listed.

Table 1. Vitamins and minerals considered from the inventory.

vitamin/mineral (unit)	RDA[1]	UL (EFSA)	highest dose (µg or mg/day)	highest dose (% RDA)	highest dose (% UL)
vitamin A (ug RE/day)	1000	3000	1557	156	52
vitamin B1 (mg/day)	1.1	ND	60	5455	-
vitamin B2 (mg/day)	1.5	ND	100	6667	-
vitamin B3 (mg/day)	17	900	648	3812	72
vitamin B5 (mg/day)	5	ND	252	5040	-
vitamin B6 (mg/day)	1.8	25	100	5556	400
vitamin B11 (ug/day)	300	1000	5000	1667	500
vitamin B12 (ug/day)	2.8	ND	1000	35714	-
vitamin C (mg/day)	70	ND	1500	2143	-
vitamin D (ug/day)	10	50	100	1000	200
vitamin E (mg/day)	10.7	300	335	3131	112
Iron (mg/day)	9	30[2]	100	1111	333
Zinc (mg/day)	10	25	100	1000	400
Selenium (ug/day)	150	300	400	267	133

[1] RDA of males (51-70 y) as established by the Dutch Health Council

[2] for iron no UL was established by EFSA, but a daily dose of 30 mg or more can result in high iron stores

The composition of a product was compared with the recommended dietary allowance (RDA) as established by the Health Council of the Netherlands. This information is extracted from the website of the Vitamine Informatie Bureau [3]. The recommended daily dosage (recommended by the manufacturer) is calculated as a percentage of the RDA. The comparison with the Tolerable Upper Intake Levels (UL) was made with data from the European Food Safety Authority (EFSA) [4]. Also information was used of the United States Department of Agriculture (USDA) and Food and Nutrition Board (FNB) [1].

3 Inventory

The inventory includes supplements marketed specifically for the elderly as well as supplements that contain high levels of one or more vitamins or minerals that can be used by the elderly. Table 2 lists the supplements that contain vitamins or minerals in dose levels exceeding the UL. It was shown that supplements targeted specifically for the elderly (as indicated by 50+, 55+, etcetera) are all within the safe range concerning the doses of the (individual) components. There are some supplements available, however, that contain vitamins or minerals that exceed the RDA substantially and sometimes are close to or even exceed the UL. These components are vitamin B with special attention for vitamin B11 (folic acid) and vitamin B6 (pyridoxine), the fat-soluble vitamins, vitamin D and vitamin E and for the minerals iron and zinc.

Table 2. Supplements with vitamins or minerals in dose levels exceeding the UL.

Suppl#	Vitamin B6	Vitamin B6
	mg/day	% of UL
1	25	100
2	25	100
3	25	100
4	25	100
5	25	100
6	41	164
7	50	200
8	50	200
9	50	200
10	50	200
11	60	240
12	60	240
13	80	320
14	100	400
15	100	400
16	100	400
17	100	400
	Folic acid	Folic acid
	ug/day	% of UL
18	1000	100
19	5000	500

Suppl#	Vitamin D	Vitamin D
	ug/day	% of UL
20	100	200
	Vitamin E	Vitamin E
	mg/day	% of UL
21	300	100
22	335	112
23	671	224
	Iron*	Iron*
	mg/day	% of 30mg
24	30	100
25	30	100
26	100	333
	Zinc	Zinc
	mg/day	% of UL
27	25	100
28	25	100
29	25	100
30	27	108
31	30	120
32	50	200
33	60	240
34	100	400

*for iron no UL was established by EFSA, but a daily dose of 30 mg or more can result in high iron stores.

3.1 Vitamin B

Several multi-vitamin supplements contain a mixture of B-vitamins with rather high doses. The highest doses which were found have been listed in Table 1, expressed as percentage of the RDA and the UL. In several supplements the B-vitamins are present in high dose levels which exceed the RDA by 16-70 times. Highest dose level that were found are 55 (vitamin B1), 67 (vitamin B2), 38 (vitamin B3), 50 (vitamin B5), 56 (vitamin B6), 16 (vitamin B11, folic acid) and even 357 (vitamin B12) times higher than the corresponding RDAs. The UL for

the B-vitamins is exceeded only for vitamin B6 and folic acid with 400% and 500%, respectively. The highest doses for the other B-vitamins remain below the ULs, 12% for vitamin B1, 72% for vitamin B3. For vitamins B2, B5 and B12 no UL was derived by EFSA.

3.1.1 Vitamin B11 (folic acid)

Only one supplement with folic acid contained a high dose of 5000 µg/day which exceeded the UL with a factor 5. Several supplements contained doses between 800 and 1000 µg, which is just below or at the UL of 1000 µg/day. The UL is based on masking the hematological signs and the potential of progression of neurological symptoms in pernicious anemia patients caused by vitamin B12 deficiency.

3.1.2 Vitamin B6 (pyridoxine)

In a few supplements high doses of vitamin B6 are present of 25-100 mg/day, which is 100-400% of the UL. The same supplement can be found on different internet sites. These sites gave different information on the dose level of vitamin B6, ranging from 25 to 100 mg/day [5,6,7,8]. Recently the EFSA has established an UL of 25 mg/day which is 4 times lower than the previously defined UL (100 mg/day) of the USDA/FNB and other authorities. A possible explanation may therefore be that the manufacturer has changed the dose recently according the new UL derived by EFSA and that this information was not (yet) adopted by the websites selling the products. According to EFSA, the main toxicity with pyridoxine is neurotoxicity, which has been demonstrated clearly in animal and human studies. EFSA derived an UL of 25 mg/day, which is mainly based on a study in which some individuals reported neurological complaints taking 50 mg op pyridoxine per day.

3.1.3 Vitamin B12

For vitamin B12 supplements are available with a relatively high dose up to 1000 µg/day, which corresponds to 357 times the RDA. EFSA and other authorities could not establish an UL for vitamin B12. In the EFSA study, human studies were reported in which doses of 1000-5000 µg/day did not cause adverse effects.

3.2 Vitamin D

The highest dose of vitamin D3, which was found in only one supplement, is 100 µg, which is 200% the UL. A few other supplements for the elderly suggest a dose of 20-25 µg vitamin D3 per day. EFSA proposed an UL of 50 µg/day based on the protection against a risk for hypercalciuria or hypercalcemia.

3.3 Vitamin E

Besides the incorporation of vitamin E in multivitamin supplements, also single supplements of vitamin E are available. They are sometimes added in high dose levels. Several preparations contain 268-671 mg/day with vitamin E as a single component, which is about 25-63 times the RDA for males aged 51-70 y. One of the supplements advertises with the slogan: "gaat veroudering van al je lichaamscellen tegen" (prevent aging of all cells in your body). The highest dose is 224% of the UL which is set at 300 mg/day. EFSA an UL was derived of 270 mg/day for adults, mainly based on the risk of blood clotting, and rounded to 300 mg/day. This UL is mainly based on the risk on blood clotting.
More recently, two meta-analyses of randomized trials [10,11] have linked supplementation of vitamin E to small but statistically significant increases in all-

cause mortality, even at doses higher than 150 IU [10]. In this study the risk on all-cause mortality was higher when supplements were used contained vitamin E only. The adverse effects of high-dose vitamin E supplements, however, were questioned [12] because the participants were also older people and had chronic diseases. Results from another recently study show that vitamin E supplements which equals the UL increases the risk of prostate cancer [13].

3.4 Vitamin C

Vitamin C was found in high doses in a number of supplements, with the highest dose of 1500 mg/day. The EFSA could not establish an UL because of insufficient data, but even a dose level of 1500 mg/day did not cause an increased risk in humans for the formation of kidney stones.

3.5 Iron

Some supplements for elderly contain no iron at all, whereas other supplements doses of iron were found closed to the RDA. Iron was also found in relatively high doses in a few supplements, with the highest dose being 50 mg or 100 mg/day. For this product a discrepancy was found on different internet sites regarding the recommended dose [8,9]. The recommendation ranged from 1 pill/day (25 mg) to 2 pills (50 mg), and even 4 pills/day (100 mg) for sportsmen. Other supplements contain 14, 15, 18, 20, 28 or 30 mg iron/day as highest dose level. The EFSA could not establish an UL because of insufficient data, but data indicate that supplemental intakes of non-heme iron at levels of 30 mg/day or more can be associated with indicators of high iron stores (e.g., elevated serum ferritin) in older adults which is a risk factor for several chronic diseases.

3.6 Zinc

Zinc was found in a number of supplements to exceed the UL. In a supplement with an advised dose of 100 mg zinc/day, the UL of 25 mg/day was exceeded with even 400%. The UL for zinc is based on adverse effects on the copper status and the lipoprotein metabolism.

Selenium

Selenium has a very narrow range between the RDA (150 µg) and UL (300 µg). Only one supplement was found with a recommended dose (2 pills) of 400 µg which exceeds the UL. The UL was based on a study with clinical selenosis. A safety factor of 3 was applied to derive the UL.

Vitamin A

Vitamin A has a very narrow range between the RDA (1000 µg) and UL (3000 µg). Only a few supplements are available with vitamin, with a highest dose of 1557 ug/day. However, b-carotene, the precursor of vitamin A can be found in higher dose level up to 15 mg/day,

4 Conclusions

In this inventory, supplements specifically advertised for the elderly (with indications 50+, 55+, 60+ or 65+) have been considered for safety concerning their vitamin and mineral content in relation to the Recommended Dietary Allowance (RDA) and established Upper Limit (UL) for this age group. The general situation is that the products specifically marketed for the elderly contain mainly multivitamins and –minerals with doses that usually do not exceed 3 times the RDA.

In addition, for other vitamin and mineral supplements commonly consumed by elderly but marketed for the general population, it was analyzed whether vitamin and mineral contents exceeded the UL as set for elderly. In these products sometimes high doses of vitamins and also high doses of minerals were found that exceeded the UL. Especially for vitamin B a number of supplements was found that contains doses that are 50-70 times the RDA. For vitamin B11 or folic acid, only one product was found with a dose that equals the UL of 1000 µg. For vitamin B6 or pyridoxine, doses were found that exceed the UL with a factor 4. For this vitamin, discrepancies were found on several internet sites; for an exact similar product, information on dose levels ranged from 25 to 100 mg/day. One explanation may be that the manufacturer has changed the dose level from 100 to 25 mg/day, due to a reduction in the UL as defined by EFSA (from 100 to 25 mg/day). These internet sites may not have adopted this information yet or may still sell the old product.

For vitamin D, one product was found that exceeds the UL with a factor 2. For the vitamins B12 and C also high doses were found, but the EFSA could not establish an UL for these vitamins. If the effects in humans are considered, no adverse effects can be expected with these doses.
For the fat-soluble vitamin E a few products were found to be close to or even exceed the UL. These products are all single-component supplements, which contain only vitamin E. These products advertise to prevent or slow down the aging process.

It is wise to use supplements in the form of a multivitamin complex, and not as a single anti-oxidant component. When used for over a long period of time, a high dose of a single anti-oxidant may have an inverted, adverse effect as a prooxidant.

Considering the minerals, iron and zinc need some attention. Since iron is an initiator of oxidative stress processes, literature states that a high iron status is of concern. Especially elderly people and women after menopause have higher iron stores. Although the EFSA could not establish an UL, they warned for high iron stores and iron overload in the body, especially for the elderly who take doses exceeding 30 mg/day. Iron doses exceeding 30 mg iron/day were found in two products. Several other products contained iron in a dose close to this level. On the contrary, some of the multi-vitamin and –mineral products advised for elderly (50+/65+) contain very low doses or even no iron at all. For iron a discrepancy was found on different internet sites regarding the advised dose ranging from 25 to 100 mg/day. Also for zinc the UL was exceed in a number of products to even 4 times of the UL.

In conclusion, all available supplements advised for the elderly can be considered as non-toxic. There are, however, a number of products available that exceed the UL, that or not specifically targeted to, but may be commonly used by the elderly. A daily consumption of these products during longer periods cannot exclude a possible occurrence of detrimental effects on health and well-being for elderly people.

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