COMPARATIVE ANALYSIS OF CONSUMER INFORMATION: FOOD SUPPLEMENTS WITH GINKGO BILOBA

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ABSTRACT

Over the past 20 years, food supplements gained great popularity. A considerable part of nutritional supplements contain plant extracts with powerful pharmacological action and interact with many prescription and non-prescription medicines when taken concurrently. Worldwide, Ginkgo biloba is one of the commonly used most higher plants in the production of food supplements. The earliest evidence of use of leaves of Ginkgo biloba in clinical practice are found in the Chinese Materia Medica (Shen Nung Pen Tsao Ching), 2800 BC.

In the 50 years of last century western medicine began to study the clinical application of Ginkgo biloba, and interest in nutritional supplements with Ginkgo biloba intensively increased in the late 70's. Today, many medical professionals recommend Ginkgo-products in peripheral vascular disease, cerebral insufficiency, intermittent claudication and others. Adverse reactions related to the use of Ginkgo-products have frequency below 0.1% and are mostly mild gastrointestinal disturbances, headache and allergic skin reactions. Ginkgo-containing food supplements can influence human metabolism as well as the effectiveness of some prescription and non-prescription medicinal products (anticoagulants, anticonvulsants, thiazide diuretics, antihypertensives, antidepressants, etc.).

The aim of this publication is to make a comparative analysis of consumer information in leaflets and packaging of Ginkgo-containing food supplements, available in Bulgaria, with respect to its conformity with the applicable Bulgarian legislation and the completeness and correctness of the safety information (side effects, contraindications, interactions with medicinal products, etc.). Information is obtained from two wholesalers, 11 websites and 10 pharmacies.

The study included 38 food supplements containing Ginkgo biloba, from which 11 products are mono-preparations, containing dried leaves or standardized extract of Ginkgo biloba. The most common combination products include vit.C, vit.A, vit.E, magnesium, selenium, bamboo fiber, royal jelly and honey.

All food supplements included in the study have announced the composition of the product and the mandatory warning information for non-exceeding the daily dose, storage conditions and that food supplements are not substitute for rational nutrition. Only 7 Ginkgo-food supplements (18.42 %) contained contraindications for use in pregnant and lactating women. Only 5 products (13.16 %) announced restrictions for use in children and only one product was positioned as contraindicated for use before sleep (due to a combination with caffeine). Only one product contained information that it can not be combined with anticoagulants, and one product claimed that Ginkgo had no contraindications, did not interact with pharmaceutical products and had no side effects!

The results of the comparative analysis showed that 78.94 % of Ginkgo-containing food supplements available in Bulgaria did not provide information, essential for their safe intake (side effects, contraindications and interactions with medicinal products).

More active stance of consumer organizations and medical professionals to address this phenomenon is needed, in order achieve adequate realization of the benefits of the safe use of food supplements.

Key words: Ginkgo biloba, food supplements, side effects, rational use, consumers
INTRODUCTION

Over the past 20 years, food supplements gained great popularity and their importance in people's daily life has significantly increased. [17,18, 33, 36, 37] This has led to growing concerns about efficacy and safety of food supplements. [7, 27, 29]

A considerable part of nutritional supplements contain plant extracts with powerful pharmacological action and interact with many prescription and non prescription medicines when taken concurrently. [1, 4, 6, 8, 9, 11, 15, 20, 38]

Worldwide, Ginkgo biloba is one of the commonly used most higher plants in the production of food supplements.[5, 26, 25, 31, 32]

Ginkgo biloba is one of the oldest of living plants. Fossil records clearly demonstrate that the group of trees known as Ginkgoales, of which today Ginkgo biloba is the sole living member, date back over 200 million years. [28, 30]

The earliest evidence of use of leaves of Ginkgo biloba in clinical practice are found in the Chinese Materia Medica (Shen Nung Pen Tsao Ching), 2800 BC. [10,12,16,21]

In the 50 years of last century western medicine began to study the clinical application of Ginkgo biloba, and interest in nutritional supplements with Ginkgo biloba intensively increased in the late 70's. Today, many medical professionals recommend Ginkgo-products in peripheral vascular disease, cerebral insufficiency, intermittent claudication and others. Adverse reactions related to the use of Ginkgo-products have frequency below 0.1% and are mostly mild gastrointestinal disturbances, headache and allergic skin reactions. Ginkgo-containing food supplements can influence human metabolism as well as the effectiveness of some prescription and non-prescription medicinal products (anticoagulants, anticonvulsants, thiazide diuretics, antihypertensives, antidepressants, etc.).[1-3, 10, 13, 14, 19, 22-24, 34, 35]

The aim of this publication is to make a comparative analysis of consumer information in leaflets and packaging of Ginkgo-containing food supplements, available in Bulgaria, with respect to its conformity with the applicable Bulgarian legislation and the completeness and correctness of the safety information (side effects, contraindications, interactions with medicinal products, etc.).

MATERIALS AND METHODS

The information regarding available on the market Ginkgo-food supplements was obtained from two wholesalers, 11 websites and 10 pharmacies.

We have reviewed 38 publications focused on Ginkgo biloba safety, interactions with pharmaceutical products and contraindications. The search was done through MEDLINE/PubMed, Scopus database as well as Internet. The most important information derived from the reviewed publications, concerning the safe use was compared with the information provided by the cartons and consumer leaflets.

RESULTS AND DISCUSSION

The study included 38 food supplements containing Ginkgo biloba, from which 11 products are mono-preparations, containing dried leaves or standardized extract of Ginkgo biloba (Table 1). The most common combination products include vit.C, vit.A, vit.E, magnesium, selenium, bamboo fiber, royal jelly and honey.

All food supplements included in the study have announced the composition of the product and the mandatory warning information for non-exceeding the daily dose, storage conditions and that food supplements are not substitute for rational nutrition. The content of Ginkgo biloba varied from 10 mg extract to 500 mg dried leaves. Preferred range of products are 20-120 mg extract.

The review of product information available to consumers revealed that important information was not present. This information concerns contraindications and interaction with pharmaceutical products which may lead to adverse events. The side effects information was also omitted.
Only 7 Ginkgo-food supplements (18.42%) contained contraindications for use in pregnant and lactating women.

Only 5 products (13.16%) announced restrictions for use in children and only one product was positioned as contraindicated for use before sleep (due to a combination with caffeine).

Only one product contained information that it cannot be combined with anticoagulants, and one product claimed that Ginkgo had no contraindications, did not interact with pharmaceutical products and had no side effects.

The results of the comparative analysis showed that 78.94% of Ginkgo-containing food supplements available in Bulgaria did not provide information, essential for their safe intake (side effects, contraindications and interactions with medicinal products).

<table>
<thead>
<tr>
<th>Product content</th>
<th>Side effects information</th>
<th>Interactions</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mg Ginkgo extract, 100 mg Mg, 30 mg caffeine, 2 mg vit.B6, 100 mg phosphatidylcholine</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>Avoid consumption before bed time.</td>
</tr>
<tr>
<td>10 mg Ginkgo extract, 50 mg vit.C, 11.5 mg propolis, 30 mg Echinacea</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>No contraindications.</td>
</tr>
<tr>
<td>15 mg Ginkgo extract, 191.16 mg soy lecithin, 133.78 mg fish oil, 5 mg vit.E, 2 mg beta-carotene</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>No contraindications.</td>
</tr>
<tr>
<td>20 mg Ginkgo extract, 20 mg vit.C,</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>Children under 12 years old, pregnant and lactating women.</td>
</tr>
<tr>
<td>20 mg Ginkgo extract, ginseng, honey</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>For adults only.</td>
</tr>
<tr>
<td>20 mg Ginkgo extract, honey, royal jelly</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>No contraindications.</td>
</tr>
<tr>
<td>25 mg Ginkgo extract</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>No contraindications.</td>
</tr>
<tr>
<td>26.5 mg Ginkgo extract</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>Pregnant and lactating women.</td>
</tr>
<tr>
<td>30 mg Ginkgo extract, 4.13 mg vit.E, 10 mg hawthorn</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>No contraindications.</td>
</tr>
<tr>
<td>30 mg Ginkgo extract, 210 mg Reishi, 130 mg Schisandra 110 mg Polygonum multiflorum</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>Children under 6 years old, pregnant and lactating women.</td>
</tr>
<tr>
<td>30 mg Ginkgo extract, 20 mg bamboo fibers</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>Children under 14 years old, pregnant and lactating women.</td>
</tr>
<tr>
<td>39 mg Ginkgo extract, 5 mg vit.E, 20 mg vit.C, 20 mg bamboo fibers</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>Children under 14 years old, pregnant and lactating women.</td>
</tr>
<tr>
<td>40 mg Ginkgo</td>
<td>gastrointestinal disturbance and headache</td>
<td>No interactions.</td>
<td>Pregnant and lactating women.</td>
</tr>
<tr>
<td>2 products with 40 mg Ginkgo extract and 10 mg vit.E</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>No contraindications.</td>
</tr>
<tr>
<td>40 mg Ginkgo extract, 2 mg vit.A, 10 mg vit.E,40 mg vit.C</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>No contraindications.</td>
</tr>
<tr>
<td>2 products with 40 mg Ginkgo extract</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>No contraindications.</td>
</tr>
<tr>
<td>50 mg Ginkgo extract, 30 mg troxerutin and vit.C</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>No contraindications.</td>
</tr>
<tr>
<td>2 products with 60 mg Ginkgo extract</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>No contraindications.</td>
</tr>
<tr>
<td>60 mg Ginkgo extract, Mg</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>No contraindications.</td>
</tr>
<tr>
<td>63 mg Ginkgo extract</td>
<td>No side effects.</td>
<td>No interactions.</td>
<td>No contraindications.</td>
</tr>
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</table>
**CONCLUSIONS**

Health care professionals (medical doctors and pharmacists) should take a proactive role in patient counseling when pharmaceutical products are taken concomitantly with Ginkgo-food supplements as essential information regarding the possible effects of such interaction as well as contraindications are missing in product information available to consumers. Moreover, public health policies should disseminate evidence-based information regarding consumption of herbal food supplements.

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