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## Characteristics of iron-containing dietary products on the Serbian market

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### Abstract

*Iron deficiency is one of the most common nutritional deficiencies that can lead to anemia. Children and adolescents, women in the reproductive period, pregnant women, regular blood donors, vegetarians and vegans, and people with gastrointestinal disorders have an increased risk of developing iron deficiency. For these population groups, regular monitoring of iron status and, if necessary, additional iron supplementation is important. The aim of the study was to make an overview of available iron-containing dietary products (food supplements and foods for special medical purposes) in the Serbian market. 44 iron-containing dietary products, 33 food supplements, and 11 foods for special medical purposes were selected for analysis. The com-*

*position, chemical sources, and content of iron and other vitamins/minerals, as well as the recommended dosage and dosage form, were evaluated based on the information from product labels. Capsules are the most predominant dosage form (41%). Iron(III)-pyrophosphate (34%) and iron(II)-bisglycinate (25%) are the most common chemical sources of iron. Most products (75%) provided between 50 and 150% nutritional reference value (NRV), while 91% of foods for special medical purposes contained more than 150% of the NRV for iron. Most of the analyzed products were multicomponent (91%), indicating the importance of other micronutrients in preventing anemia and improving iron status. Among them, vitamin C (71%), folic acid (61%), and vitamin B12 (59%) were predominant. Adequate selection of the type, as well as counseling on proper consumption of iron-containing products, is important to ensure the rational and safe use of these products.*

**Key words:** iron; deficiency; anemia; food supplement; food for special medical purposes; vitamins; minerals.

### INTRODUCTION

Iron is an essential mineral required for various vital functions in the human body, including deoxyribonucleic acid synthesis and repair, oxygen transport via hemoglobin, enzymatic reactions in energy metabolism, and immune functions [1]. The regulation of iron homeostasis is a complex process involving several nutritional and systemic factors, such as the absorption, transport, storage, and utilization of iron [2]. Iron balance is mainly regulated by the gastrointestinal absorption of dietary iron, which depends on the physiological circumstances and the type of iron entering the duodenum [3]. In the intestinal lumen, inorganic insoluble ferric iron ( $\text{Fe}^{3+}$ ) is reduced to absorbable ferrous iron ( $\text{Fe}^{2+}$ ) and absorbed by transporters for divalent metals in the epithelial cells of the duodenum [4].

Iron-rich foods are meat, fish, grains, beans, nuts, egg yolks, dark green vegetables, and potatoes. Dietary iron can occur in two forms: heme iron (from animal tissue) and non-heme iron (including ferritin). Opposite to heme iron which has a high bioavailability (15-35%) and dietary factors have little effect on its absorption, the absorption of non-heme iron is much lower (2-20%) [5]. Food components could influence iron absorption acting either as enhancer or inhibitor. Vitamin C, as well as prebiotics, probiotics, and symbiotics, enhance its absorption [6,7], while polyphenols, phytic acid, tannin, calcium, and peptides from partially digested proteins reduce the bioavailability and absorption of iron [8].

Population-specific and individual factors influence iron dietary requirements. The recommended daily al-

lowance for iron ranges from 0.27 mg in infancy to 27 mg in pregnancy [9]. Groups and individuals at greatest risk for iron deficiency are those with high iron demand due to growth (infants, children, adolescents, pregnant women), high losses (women of reproductive age), or those with impaired gastrointestinal absorption [10]. Since non-heme iron is less bioavailable than heme iron, vegans/vegetarians require a higher intake than individuals who consume animal products.

The World Health Organisation reported iron deficiency as the most common nutritional deficiency globally [11]. Inadequate dietary iron intake is responsible for most iron deficiency anemia worldwide. Although some functional changes may occur in the absence of anemia most functional deficits appear with the development of anemia. Folic acid, vitamin B12, and vitamin A deficiency can also lead to anemia due to their specific roles in haemoglobin synthesis and/or erythrocyte production [9].

Micronutrient interventions have been shown to prevent malnutrition in high-risk groups and protect against the progression of iron deficiency anemia [12,13]. In Serbia, there are two categories of iron-containing dietary products (DP): food supplements or food for special medical purposes, depending on the iron content in the recommended daily dose. Food supplements are concentrated sources of vitamins, minerals, and other substances intended to supplement the diet, designed for oral use, and regulated as food in the European Union [14], as well as in Serbia [15]. In the European Union, foods for special medical purposes are defined according to Regulation 609/2013 [16] as food specially processed or formulated for people with particular medical disorders and nutritional needs to be used under medical supervision. Foods for special medical purposes are defined similarly according to the national Regulation [17] in Serbia.

The aim of this research was to identify iron-containing DP available on the Serbian market and evaluate their characteristics (qualitative and quantitative content, daily doses, chemical sources, and dosage forms).

## MATERIALS AND METHODS

Iron-containing DP were selected based on the assortment available at pharmacy retailers and pharmacies, including online sales, in the Serbian market. Data on the active ingredients, their contents, and nutrient reference values (NRVs) per daily dose, as data on the chemical sources of active ingredients and dosage forms were collected from DP labels. Data collection was performed throughout April 2023. Only DP available for sale and had complete label information were included in further evaluation. The compliance of the chemical sources of vitamins/minerals and their con-

tents were checked against the abovementioned national Regulation [15,17].

## RESULTS AND DISCUSSION

44 DP with declared iron content were selected for analysis, purchased from pharmacies and wholesalers in the area of the city of Belgrade. Of these, 33 products were food supplements, and 11 were classified as food for special medical purposes (29 imported, 15 produced in Serbia). All products were registered as DP, which was confirmed by the presence of the notification number on the labels.

### Qualitative characteristics of the iron-containing DPs

Most of the analyzed iron-containing DP were multi-component (91%). Thirty DP were multi-ingredient products containing iron with other vitamins and bioactive ingredients; ten were multivitamin/mineral products. Nonetheless, only four DP were monocomponent products with only iron as the active ingredient.

The total number of active ingredients in multicomponent DP ranged from 2 to 16 active ingredients. The majority of multicomponent DP contained hydrosoluble vitamins: vitamin C (71%), folic acid (61%), vitamin B<sub>12</sub> (59%), vitamin B<sub>6</sub> (36%), riboflavin (18%), thiamine (14%), pantothenic acid (9%), niacin (7%), and biotin (2%). Only two DP contain vitamin D (cholecalciferol), and one DP contains beta carotene. Two food supplements contained either probiotics or lactoferrin. The most common minerals in DP were zinc and copper (both 21%), while manganese, iodine, and selenium together accounted for 13%.

Including synergistic nutrients in DP with iron, especially vitamin C and folic acid, might result in better efficacy even at a low dose. On the contrary, several minerals (copper, zinc, manganese) may share the intestinal absorption pathway of iron and reduce its absorption due to competition for the cellular transporter [18]. This interaction could be important since these minerals were present in over half of the DP analyzed.

Vitamin C enhances iron absorption due to its chelating and reducing properties. Lane *et al.* [19] pointed out that vitamin C transfers an electron to the luminal Fe<sup>3+</sup> via cytochrome b to obtain more soluble ferrous ions. This is the physiological basis for the intake of iron-containing DP in combination with vitamin C. Vitamin C also overcomes the negative effect of all inhibitors on iron absorption, which include phytates, polyphenols, and calcium [20-22]. Iron supplementation with probiotics could mitigate the iron-induced changes in the microbiota. Iron has many effects on the microbiota, leading to increased growth of pathogenic and decreased numbers of beneficial

bacterial species [23]. In addition to promoting commensal bacteria and lowering the intestine's pH, *Lactobacillus fermentum* could increase iron absorption via bivalent metal transporter-1 [24]. Lactoferrin is an iron-binding protein involved in nutritional immunity. Zimmermann *et al.* [25] have shown that iron supplementation with lactoferrin could reduce the impact of iron on the gut microbiota by increasing iron absorption.

Despite the differences in solubility and absorption of various organic/inorganic iron salts, the guidelines for treating iron deficiency do not recommend specific chemical sources that successfully improve iron status while minimizing gastrointestinal side effects.

**Table 1** shows that the chemical forms of iron varied among DP; 57% of DPs contained ferrous salt, 46% ferric salt and 5% contained elemental iron as an iron source. The majority of analyzed DP contained iron in the form of ferric pyrophosphate (34%). Two products have more than one chemical source of iron. Iron salts (bisglycinate, fumarate, sulfate, gluconate) are preferred for oral use due to their low cost and high bioavailability. However, these salts often lead to gastrointestinal side effects such as vomiting, nausea, and epigastric discomfort [26], and further result in low patients' compliance. Iron absorption from soluble iron compounds (such as ferrous sulfate and ferrous gluconate) is upregulated more efficiently at low iron status than absorption from more insoluble compounds, such as ferric pyrophosphate [27]. Therefore, ferric pyrophosphate absorption is lower in individuals with iron deficiency than in individuals with adequate iron status.

**Table 1.** Chemical sources of iron in DPs.

Iron	Chemical sources	[%]
ferrous	bisglycinate	25
	fumarate	16
	sulfate	9
	gluconate	7
ferric	ferric pyrophosphate	34
	ferric ammonium citrate	5
	L-pidolate	5
	ferric saccharate	2
elemental	heme iron	5

Vitamin C and folic acid are the most common vitamins in multi-ingredient iron-containing DP. All chemical sources of vitamins and minerals in the analyzed DP were compliant with the national Regulation [15,17] (**Table 2**). Sodium L-ascorbate used as a source of vitamin C in some DP has a similar bioavailability to

L-ascorbic acid but is less irritating to the gastrointestinal mucosa, making it more suitable for individuals experiencing gastrointestinal adverse effects of ascorbic acid. Pteroylmonoglutamic acid is the most common chemical source of folic acid (52%). However, other forms of folic acid, calcium L-methyl folate, and 5-MTHF glucosamine salt, do not require reduction via dihydrofolate reductase and can enter the circulation directly.

**Table 2.** Chemical sources of vitamin/mineral in analyzed DPs.

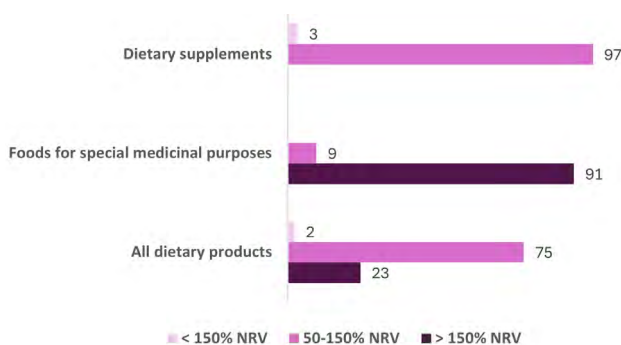
Vitamin/Mineral	Chemical sources	[%]
Vitamin C	L-ascorbic acid	66
	Sodium L-ascorbate	7
Folic acid	Pteroylmonoglutamic acid	52
	Calcium L-methylfolate	5
	(6S) 5-methyltetrahydrofolic acid, glucosamine salt	2
Vitamin B <sub>12</sub>	Cyanocobalamin	54
	Methylcobalamin	5
Vitamin B <sub>6</sub>	Pyridoxine hydrochloride	36
Vitamin B <sub>2</sub>	Riboflavin	18
Vitamin B <sub>1</sub>	Thiamine hydrochloride	9
	Thiamine mononitrate	5
	Calcium-D-pantothenate	5
Pantothenic acid	D-panthenol	2
	Pantothenic acid	2
Niacin	Nicotinamide	7
Vitamin D	Cholecalciferol	5
Biotin	D-biotin	2
	Zinc sulphate	7
Zinc	Zinc gluconate	7
	Zinc oxide	7
Copper	Copper sulphate	14
	Copper gluconate	5
	Copper bisglycinate	2
Manganese	Manganese sulphate	9
Selenium	Sodium selenate	2
Iodine	Potassium iodide	2

### Daily doses of vitamins and minerals in the analyzed DP

The labeled content of iron in the recommended daily dosages of the DP ranged from 4.2 mg to 47 mg. As expected, the mean dose of iron in foods for special med-

ical purposes (30.1 mg) was higher than the iron content in food supplements (15.3 mg). Namely, labeled iron content in food supplements ranged from 4.2 mg to 20 mg, the maximum iron content established by national Regulation. The iron content ranged from 21 mg to 47 mg in recommended daily doses in foods for special medical purposes. The European Food Safety Authority does not define a tolerable upper intake level (UL), while the Institute of Medicine specifies 45 mg/day of iron as UL, based on gastrointestinal distress as an adverse effect [28]. Only one of the analyzed DP had iron content greater than 45 mg. This product is intended for the partial feeding of individuals whose nutritional requirements cannot be met by normal foods and is used under medical supervision.

The NRV values for vitamins and minerals are specified in the European Union Regulation No 1169/2011 [29] and in Serbia [30]. For vitamins and minerals, a "significant" quantity is defined as "at least 15% of the NRV" per daily dose of DP. All analyzed DP had more than 15% NRV per recommended daily dose and ranged from 30-143% NRV for food supplements and 150-336% NRV for foods for special medical purposes. Figure 1 shows the percentage of dietary products according to iron content expressed as % NRV. The 75% of DP contained 50-150% NRV of iron.



**Figure 1.** The percentage of DP according to iron content expressed as a percentage of the nutrient reference value (NRV).

Most DPs were multi-ingredient iron products containing, often, other vitamins and minerals. Vitamins exceeded 150% of the NRV for all vitamins except biotin, pantothenic acid, and vitamin B1 (Table 3). Copper is the only mineral where 150% of the NRV has been exceeded.

**Pharmaceutical forms of the analyzed DP**

The majority of DPs were in solid pharmaceutical forms (81%) (Table 4). The evaluated iron-containing DPs were in 12 different pharmaceutical forms. Capsules are the most common dosage form (41%). Since vegans and vegetarians are among the groups eligible for iron supplementation, in addition to gelatine cap-

**Table 3.** Labeled vitamin/mineral content per daily dose in analyzed DP.

Vitamin/Mineral	Labeled content per daily dose Mean (min-max)	% Nutrient Reference Value
Vitamin C (mg)	74 (12-180)	93 (15-225)
Folic acid (µg)	337 (30-600)	169 (15-300)
Vitamin B <sub>12</sub> (µg)	7.8 (0.4-100)	312 (16-4000)
Vitamin B <sub>6</sub> (mg)	2.8 (0.4-9.3)	200 (29-664)
Vitamin B <sub>2</sub> (mg)	2 (1.4-4.7)	143 (100-336)
Vitamin B <sub>1</sub> (mg)	1.4 (1.1-1.6)	127 (100-145)
Pantothenic acid (mg)	5.2 (4-6)	87 (67-100)
Niacin (mg)	27 (16.0-44.9)	169 (100-281)
Vitamin D (µg)	30 (10-50)	600 (200-1000)
Biotin (µg)	50	100
Zinc (mg)	8.5 (3-15)	85 (30-150)
Copper (mg)	1.3 (0.4-2.5)	130 (40-250)
Manganese (mg)	1.5 (0.6-2.5)	75 (30-125)
Selenium (µg)	46	84
Iodine (µg)	100	67

**Table 4.** Dosage forms of the analyzed DP.

Dosage forms	[%]
Capsules	41
Powder for direct oral use	14
Tablets	7
Effervescent tablets	5
Granules for direct oral use	5
Sustained-release capsules	5
Controlled-release tablets	2
Film-coated tablets	2
Syrup	11
Oral suspension	4
Oral gel	2
Oral drops	2

sules, there are also capsules with ingredients of plant origin such as hydroxypropyl methylcellulose, which is often highlighted on the product label. There are also liquid forms (19%), mainly intended for children and adults with swallowing difficulties.

On the market, sustained-release capsules (5%) and controlled-release tablets (2%) are presented that ensure optimal iron levels without the risk of unwanted gastrointestinal discomfort. Although iron is widely taken orally, the mechanisms by which gastrointestinal side effects are mediated are poorly understood. Various explanations for iron-induced side effects have been proposed, including hydroxyl radicals action, lipid peroxidation, cell damage, and microbiota changes [26]. There is also a liposomal iron, in which a phospholipid bilayer protects ferric iron ( $\text{Fe}^{3+}$ ) until it reaches the intestine. This ensures better iron bioavailability and good tolerability without nausea, stomach problems, constipation, and a metallic taste in the mouth. Pre-clinical data suggest that it may be better tolerated than other oral iron formulations while having similar efficacy in restoring iron levels [31].

## CONCLUSION

Most of the analyzed iron-containing DPs on the Serbian market are multivitamin/mineral products. Educating consumers on the proper use of DPs is in the public health interest in resolving nonanemic iron deficiency and preventing the progression of anemia. Individualized strategies and nutritional counseling should be sought to achieve greater success in iron supplementation of this common malnutrition. Making the right choice is often complicated by the frequency of side effects and lack of patient compliance. Individuals may benefit from innovative supplements that meet iron requirements without side effects.

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## Karakteristike sastava dijetetskih proizvoda koji sadrže gvožđe na tržištu Srbije

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### Kratak sadržaj

*Nedostatak gvožđa predstavlja jedan od najčešćih nutritivnih deficita koji može dovesti do nastanka manifestne anemije. Deca i adolescenti, žene u reproduktivnom periodu, trudnice, redovni davaoci krvi, vegetarijanci i vegani, kao i osobe sa gastrointestinalnim poremećajima predstavljaju rizične grupe za razvoj nedostatka gvožđa. U ovim popula-*

*cionim grupama značajna je redovna kontrola statusa gvožđa i ukoliko je potrebno i dodatna suplementacija gvožđem. Cilj ovog istraživanja bio je da se napravi pregled dostupnih dijetetskih proizvoda (dodaci ishrani i hrana za posebne medicinske namene) namenjenih za nadoknadu gvožđa na tržištu Srbije. Podaci o sastavu, hemijskim izvorima i sadržaju gvožđa, kao i drugih vitamina/minerala, preporučenom načinu upotrebe i farmaceutskim oblicima prikupljeni su sa deklaracija 44 dijetetska proizvoda, od čega 33 iz kategorije dodataka ishrani (dijetetskih suplemenata) i 11 iz kategorije hrane za posebne medicinske namene. Većina proizvoda je bila u obliku kapsula (41%). Od hemijskih izvora gvožđa, najzastupljeniji su gvožđe(III)-pirofosfat (34%) i gvožđe(II)-bisglicinat (25%). Većina proizvoda (75%) sadrži gvožđe u količini između 50% i 150% nutritivne referentne vrednosti (NRV) za gvožđe, a 91% proizvoda iz kategorije hrane za posebne medicinske namene sadrži gvožđe u količini većoj od 150% NRV. Od ukupnog broja, 91% dijetetskih proizvoda su višekomponentni, što ukazuje na značaj drugih mikronutrijenata u prevenciji anemije i regulaciji statusa gvožđa. Među ostalim aktivnim sastojcima, najzastupljeniji su vitamin C (71%), folna kiselina (61%) i vitamin B12 (59%). Adekvatan odabir vrste dijetetskog proizvoda, kao i savetovanje o pravilnoj primeni je neophodno u cilju obezbeđenja racionalne i bezbedne upotrebe dijetetskih proizvoda sa gvožđem.*

**Ključne reči:** gvožđe; deficit; anemije; dijetetski suplementi; hrana za posebne medicinske namene; vitamini; minerali.