

# >your< iron line

why launch clinically supported iron supplements & why now?

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WHITE PAPER



# executive summary.

Iron deficiency is the most common nutritional disorder in the world. The market is projected to grow at a rate above the industry average.

Yet the majority of available supplements typically have a metallic taste, frequent side effects, low bioavailability, and weak iron stability.

An opportunity exists for effective, user-friendly supplements and case studies show they can also be a valid product launch option in times of economic crisis.



## >your< iron line

#1 iron supplements in several markets.

- Highly bioavailable and effective iron source
- Significantly diminished chance of side effects
- Awarded taste
- Great user reviews and success cases globally

## highly supported with scientific data.

Studies confirm superior bioavailability and beneficial effects on iron levels by Qfer.

Results of an ongoing gold standard clinical trial on our liquid product will further facilitate medical detailing.

**2,7x** improved absorption

of Qfer compared to iron sulfate over 12 hours



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# why launch now?

Currently, all new product launch decisions are evaluated in the perspective of the upcoming economic crisis. Consumer habits will be affected and therefore business activities should adapt. While there certainly is no uniform solution for all companies, our previous experience indicates that launching clinically supported iron supplements may be a valid course of action for certain brands.

In the post-2008 financial crisis some of our partners saw the opportunity to overtake market shares, taking advantage of the conservative stance and reduced activity of the majority of the industry. A certain partner launched >Your< Iron Syrup and >Your< Iron Capsules under their brand in a market in the European Union and achieved **120.000 units sold in the first year**.



To demonstrate the principle further, we look at a different iron product that also achieved outstanding growth - **from a 14% market share to a 50% market share** between 2008 and 2012 in one of the largest supplement markets in Europe.

The common denominators were:

- Both products successfully addressed iron deficiency - a serious health issue that consumers seem to continue to prioritize in times of reduced expenditure.
- Both products were premium and scientifically supported. This segment may have grown because consumers more clearly separate into those looking for the lowest price and those researching proof of quality and efficacy, making more educated investments of their available income.



# indication

Iron deficiency is defined as low body iron status due to increased iron loss or impaired iron absorption. It is the most common nutritional deficiency in the world, affecting particularly women of reproductive age and children. However, it often remains unnoticed and continues untreated for an extended period.

Iron deficiency can progress to iron deficiency anemia (IDA), which is a condition in which hemoglobin concentration in red blood cells is lower than normal and impairs the oxygen transport capacity of the blood. According to the last official report by the WHO, **anemia affected nearly 25% of the global population**. IDA is estimated to affect one-third of all women of reproductive age and over 40% of children under 5 years of age.

While the causes of anemia are variable, it is estimated that **up to 50% of cases are due to iron deficiency**. Vitamin deficiencies also

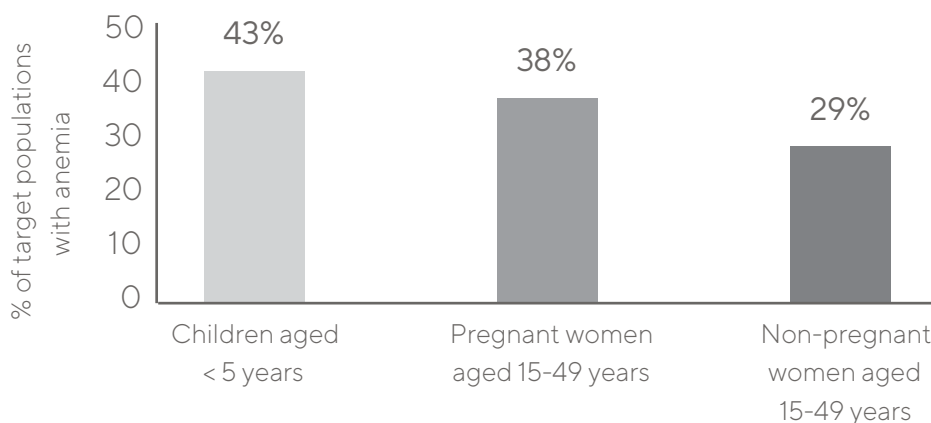
cause anemia, due to their specific roles in production of hemoglobin or red blood cells. Anemia has significant consequences for human health as well as social and economic development in countries worldwide. Vulnerable population groups include:

- children under 5 years of age
- adolescents and women of reproductive age (15–49 years)
- pregnant women

**Children are the most vulnerable population**, since the need for iron is increased during their growth and development, particularly during the first years of life. Especially at risk of developing iron deficiency are:

- preterm-born children
- children born with low birth weight
- children born to iron deficient mothers

## Global prevalence of anemia



Healthy, full-term infants usually have sufficient iron stores and need little if any iron from external sources until they are 4 to 6 months old. However, they are at risk of becoming iron deficient at 6 to 9 months, unless they obtain adequate amounts of food rich in bioavailable iron or iron-fortified formulas.

**Even mild iron deficiency in infancy, especially if prolonged, can lead to adverse cognitive and psychological effects**, including delayed attention, social withdrawal and aggressiveness; some of these effects might be irreversible. To prevent neurologic and developmental issues resulting from deficiency, iron supplementation is recommended from infancy on. In fact, a beneficial effect of early supplementation on child's behavior later in life has been shown in a recent clinical trial.

Women are another group at risk of iron deficiency from early adolescent years on. Insufficient iron levels may occur due to menstrual blood loss, infections, gynecological, urological and digestive disorders, or general unhealthy lifestyle. Deficiency can display in several symptoms such as fa-

tigue, impaired physical work capacity, shortness of breath, reduced mood and cognitive function, which can significantly influence the quality of life.

Iron deficiency may not have significant consequences for women alone but also for their offspring. **Deficiency is very common among expectant mothers**, affecting almost half of pregnant women worldwide. Maternal iron deficiency has been associated with a higher risk of preterm delivery, low birth weight and infant iron deficiency, which in turn, can permanently affect intelligence, cognitive, psychomotor and behavioral development of the child.

Other groups at risk of iron inadequacy include vegetarians, frequent blood donors, elderly and patients with chronic or inflammatory diseases. Due to unbalanced diet and stressful lifestyle, iron supplementation may be the most convenient way to ensure sufficient levels of body iron in the wider population.



# market status.

Several factors impacting iron levels are projected to remain: lack of a balanced nutritional diet, environmental factors, various health problems, and smoking.

Consumer interest in iron supplementation has grown significantly and is reflected in a **92% growth of web searches for “iron supplement”** in the past 8 years.

In 2019, the category was projected to grow with an above industry average growth rate - a **CAGR of 9,3%** for the period of 2019 - 2025.

Considering the frequency of iron deficiency, the consumer interest, and the projections for the future, most available products still poorly address several reoccurring issues:

- unpleasant metallic taste of typical iron sources, such as ferrous fumarate and ferrous sulfate
- low bioavailability and absorption
- frequent side effects, such as irritation of the digestive tract and sickness
- weak iron stability through the product's shelf life
- interactions between different ingredients, often resulting in oxidation

The majority of available iron supplement products for children are drugs that doctors prescribe for iron deficiency. They are often based on water-insoluble iron compounds or low-cost elemental iron salts in high dosages, to compensate for low bioavailability. This causes bad organoleptic properties, frequent side effects and metallic taste. Additionally, existing iron supplements usually come in inconvenient solid forms that often trigger reluctance to supplementation in children or adults with swallowing difficulties.



Collectively, these factors create a market need for products with **high bioavailability, pleasant taste, low chance of side effects and convenient form.**



# >your< iron line

>Your< Iron Line is a globally present line of products with several market-leading cases and an ongoing clinical trial. Both doctors and users notice the positive change and absence of typical side effects. The line is based on Qfer - a highly bioavailable, clinically supported iron source. Its unique delivery system conceals metallic flavors and protects the intestinal lining. Through an extensive R&D process, we developed several convenient liquid formulations with proven stability and awarded taste. The line has been successfully launched by trusted pharmaceutical and supplement brands and is consistently achieving stable growth.



|                                 | >your<<br>iron<br>syrup | >your<<br>iron only<br>drops | >your<<br>iron<br>spray | >your<<br>iron forte<br>spray | >your<<br>iron<br>capsules | >your<<br>iron forte<br>capsules | >your<<br>iron<br>liquid<br>sachets | >your<<br>iron forte<br>liquid |
|---------------------------------|-------------------------|------------------------------|-------------------------|-------------------------------|----------------------------|----------------------------------|-------------------------------------|--------------------------------|
| Based on Qfer                   | ●●●●●                   | ●●●●●                        | ●●●●●                   | ●●●●●                         | ●●●●●                      | ●●●●●                            | ●●●●●                               | ●●●●●                          |
| Clinical substantiation         | ●●●●●                   | ●●●●●                        | ●●●●●                   | ●●●●●                         | ●●●●●                      | ●●●●●                            | ●●●●●                               | ●●●●●                          |
| Absence of typical side effects | ●●●●●                   | ●●●●●                        | ●●●●●                   | ●●●●●                         | ●●●●●                      | ●●●●●                            | ●●●●●                               | ●●●●●                          |
| Digestive tract-friendly        | ●●●●●                   | ●●●●●                        | ●●●●●                   | ●●●●●                         | ●●●●●                      | ●●●●●                            | ●●●●●                               | ●●●●●                          |
| Preservative-free               |                         | ●●●●●                        |                         |                               | ●●●●●                      | ●●●●●                            |                                     |                                |
| Children approve the taste      | ●●●●●                   | ●●●●●                        | ●●●●●                   | ●●●●●                         |                            |                                  |                                     |                                |
| Leader in several markets       | ●●●●●                   |                              |                         |                               | ●●●●●                      |                                  |                                     |                                |



**>your< iron capsules**  
Market-leader in several markets.

**>your< iron forte capsules**  
New product with higher iron content.

**>your< iron syrup**  
Market-leading solution for children.

**>your< iron forte liquid**  
Adult liquid product with awarded taste.

**>your< iron spray**  
Convenient solution in spray form for children.

**>your< iron forte spray**  
New product for adults.

**>your< iron liquid sachets**  
High iron content in on-the-go liquid form.

**>your< iron only drops**  
Preservative-free drops for the most delicate young users.

## COMPOSITION PER DOSAGE (mg):

| Main ingredients | >your< iron syrup | >your< iron only drops | >your< iron spray | >your< iron forte spray | >your< iron capsules | >your< iron forte capsules | >your< iron liquid sachets | >your< iron forte liquid |
|------------------|-------------------|------------------------|-------------------|-------------------------|----------------------|----------------------------|----------------------------|--------------------------|
| Qfer             | 14 mg Iron        | 14 mg Iron             | 7 mg Iron         | 14 mg Iron              | 15 mg Iron           | 30 mg Iron                 | 30 mg Iron                 | 35 mg Iron               |
| Vitamin B6       | 0,7               | -                      | -                 | -                       | -                    | -                          | -                          | 0,7                      |
| Vitamin B12      | 0,00125           | -                      | -                 | -                       | -                    | -                          | -                          | 0,00125                  |
| Vitamin C        | -                 | -                      | -                 | -                       | 60                   | 60                         | -                          | -                        |
| Dosage           | 5 ml/day          | 28 drops/day           | 1 ml/day          | 2 ml/day                | 1 capsule/day        | 1 capsule/day              | 1 sachet/day               | 5 ml/day                 |
| Total dosages    | 24                | 33                     | 30                | 30                      | 30                   | 30                         | 30                         | 24                       |
| Target group     | children          | children               | children          | adults                  | adults               | adults                     | adults                     | adults                   |



# ingredients.

## Qfer

Iron is the most challenging micronutrient to add to foods, because iron compounds with the best bioavailability tend to interact most strongly with food constituents, producing undesirable organoleptic changes.

Qfer is a micronized and microencapsulated iron source with **high bioavailability** and without the unpleasant taste. Microencapsulation results not only in **concealing metallic taste** of the iron, but also in **avoiding many** of the **common side effects** of iron supplementation. It prevents constipation and nausea, as well as protects mucosal layers in the gastrointestinal tract against irritation.

Traditional iron salts - the most commonly used sources of iron - are changed into the free form in the stomach and can therefore irritate the mucus tissue and cause unpleasant side effects. Iron salts get absorbed mainly with the help of membrane transporters on enterocytes. Iron must compete with other similar nutrients for a place on the transporter and usually only 10-15% of the administered iron is absorbed.

**2,7x** improved  
absorption  
of Qfer compared to iron sulfate over 12 hours

Qfer has been compared with other iron sources available in the market and has shown higher bioavailability than iron sulfate, iron pyrophosphate, as well as iron fumarate:

- **2,7 x higher** absorption compared to iron sulfate
- **3,5 x higher** absorption compared to iron pyrophosphate
- **4,7 x higher** absorption compared to iron fumarate

Besides several studies confirming the bioavailability of this micronized and microencapsulated iron, Qfer has been the subject of several published clinical trials, showing significant increases in both hemoglobin and ferritin level in various demographic groups.



## Vitamin B6

Vitamin B6 in its active form in the body is known as pyridoxal-5-phosphate or P5P. It is a nutrient that participates in at least 100 essential biochemical processes in the body, including iron metabolism. P5P is a cofactor in the synthesis of aminolevulinate, which represents the first step in heme (iron-containing part of hemoglobin) biosynthesis. Vitamin B6 deficiency can decrease the levels of hemoglobin, leading to microcytic anemia.

## Vitamin B12

Vitamin B12 plays an integral part as a cofactor in the production of red blood cells, which carry oxygen throughout the body. B12 deficiency can result in megaloblastic anemia due to inadequate dietary intake or impaired absorption of the vitamin from the small intestine. Untreated deficiency can cause neuro-cognitive dysfunction and blood disorders, therefore vitamin B12 supplementation is recommended.

## Vitamin C

Vitamin C (ascorbic acid) acts as a ligand for the common non-heme iron and thus has a physiological role in the enhancement of iron absorption and mobilization of iron from stores. Additionally, ascorbic acid reverses the strong inhibitory effect of known inhibitors of iron absorption such as calcium, phosphates, phytates or certain polyphenols. Vitamin C deficiency can result in oxidative damage of red blood cells.

### EFSA HEALTH CLAIMS:

Iron contributes to normal formation of red blood cells and hemoglobin.

Iron contributes to normal oxygen transport in the body.

Iron contributes to normal cognitive function and normal cognitive development of children.

Vitamins B6 and B12 contribute to normal red blood cell formation.

Iron, vitamins B6, B12 and C contribute to normal energy-yielding metabolism.

Iron, vitamins B6, B12 and C contribute to the normal function of the immune system.

Iron, vitamins B6, B12 and C contribute to the reduction of tiredness and fatigue.

Vitamins B6, B12 and C contribute to normal functioning of the nervous system.

Vitamins B6, B12 and C contribute to normal psychological function.

Vitamin C contributes to the protection of cells from oxidative stress.

Vitamin C increases iron absorption.



# clinical trial.

As is the case with all categories in food supplements, there is a great lack of high quality clinical trials conducted on finished products in the iron supplement segment. While trials conducted on ingredients, along with proven stability of those ingredients within the finished product, already presents a level of clinical substantiation far above the average, it is effects proven on the finished product itself that the industry should strive for every time.

This is why we have undertaken the project of proving the efficacy of our liquid iron through a clinical trial of the highest possible standard, conducted on children.

The trial is run by an independent CRO and under the supervision of the most recognized experts in hematology of a national university medical center.

## Clinical trial gold standards:

- double-blind
- placebo-controlled
- randomized
- multi-centric
- strict inclusion criteria - not performed on anemic subjects
- relevant number of subjects
- supervised by leading independent experts

Importantly, the trial is not only double-blind, randomized, and placebo-controlled, but also multi-centric, avoiding the potential bias of conducting the trial in a single testing center.

Trials on iron supplements or ingredients are often conducted on subjects with anemic levels of iron because this makes it easier to show an effect as a result of supplementation. However, our trial design avoids such compromises and includes only subjects in the stage of iron deficiency - still without, or with mild anemia, as is recommended for food supplements by EFSA. Determined effects will thus carry a greater value and will be more applicable to the actual final users of our liquid iron products.

The trial is in its final stages with over 60 children having already completed testing. The stringent inclusion criteria have extended the process of recruitment to nearly 3 years which is a testament of our determination to maintain gold standards. Too often food supplement clinical trials are pressured into cutting corners to speed up returns of investment.

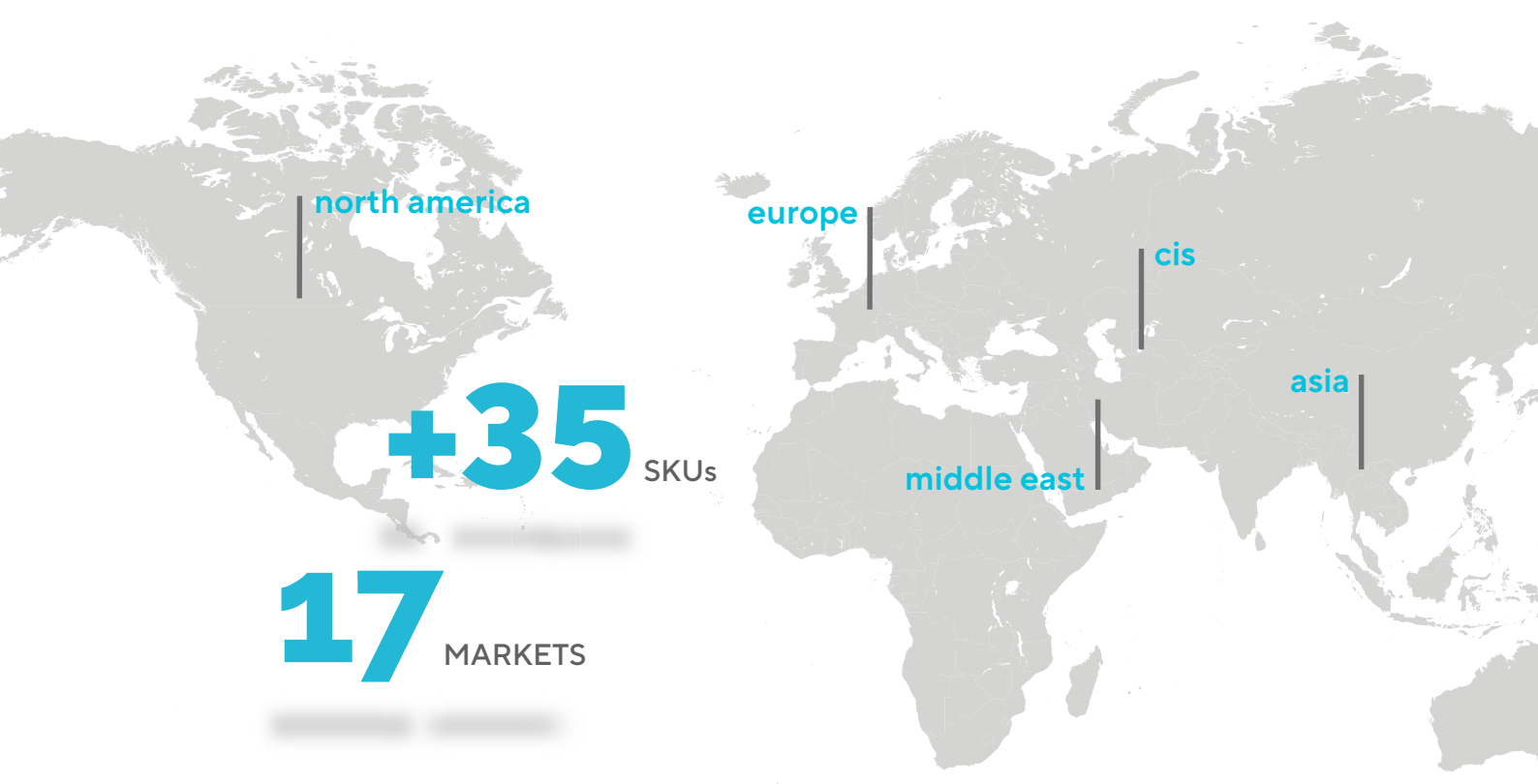
Important outcomes of the trial include the product's effect on ferritin levels, hemoglobin levels and compliance - a crucial factor and best demonstrated by children.



# global presence.

Through successful launches in what is now already 17 countries worldwide, >Your< Iron Line products have shown to solve consumer needs in markets as different as Western Europe and Southeast Asia.

Both recognized brands and challengers in the market are consistently achieving stable growth and, in certain cases, market-leading positions.



## CASE STUDY #1

Product: >Your< Iron Capsules

Territory: Southeast Europe

Result: the product has achieved and maintained the #1 position in Southeast Europe.

## CASE STUDY #2

Product: >Your< Iron Syrup

Territory: a market in Southeast Asia

Result: exponential growth in sales, with demand more than tripling each year in the market.



## awarded taste.

Several times already, industry professionals at Vitafoods - the largest nutraceutical industry event - recognized our expertise in the development of liquid supplements with great taste and user experience.

One of the awards we received in the category of best functional beverage was for **>Your< Iron Forte Liquid**. This achievement

is especially noteworthy because iron supplements are a product category where taste is widely known to be one of the key challenges in development and main obstacles for user compliance. Having our product awarded when compared to supplements from all categories is an important confirmation of the potential the line has to improve compliance.



# contact.

For more information on >Your< Iron Line or any of our other products, you are welcome to contact us using the information below.

We will be happy to provide you with details on each individual product, in-depth case studies, clinical studies, product specifications, and more, as we move forward.

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