Ferrosal®

An optimal source of **elemental iron**

amsal

Stages of Iron Deficiency

1. Iron depletion
The initial stage of reduced iron stores in the body's natural storage sites, including the liver, spleen and bone marrow. Laboratory findings indicate that iron (Fe) and haemoglobin (Hb) levels remain within normal ranges.

2. Anaemia
A condition in which serum iron levels fall below the normal range.

Reference values indicating anaemia according to sex:
- Men: Hb concentration ≤ 130 g/L or Hct ≤ 39%
- Women: Hb concentration ≤ 120 g/L or Hct ≤ 37%

In diagnosed anaemia, other laboratory parameters typically show decreased ferritin, MCV (mean corpuscular volume) and MCHC (mean corpuscular haemoglobin concentration), together with increased UIBC (unsaturated iron-binding capacity).

Elemental Iron

Elemental iron **contains more than 98% iron** and has a low molecular weight, allowing considerably lower doses to be used to meet daily iron requirements compared with iron salts.

- **High bioavailability of 69%** in the human body.
- **Slow absorption** from the gastrointestinal tract, as elemental iron is released gradually.
- **Reduced toxicity and fewer potential adverse effects**, such as constipation and tooth discolouration.
- **Better tolerated than iron salts.**
- **Safe to use** across a wide dosage range. Animal studies have shown that elemental iron is **30–150 times safer** than equivalent doses of soluble iron salts. This is due to the prolonged conversion of elemental iron into iron ions.

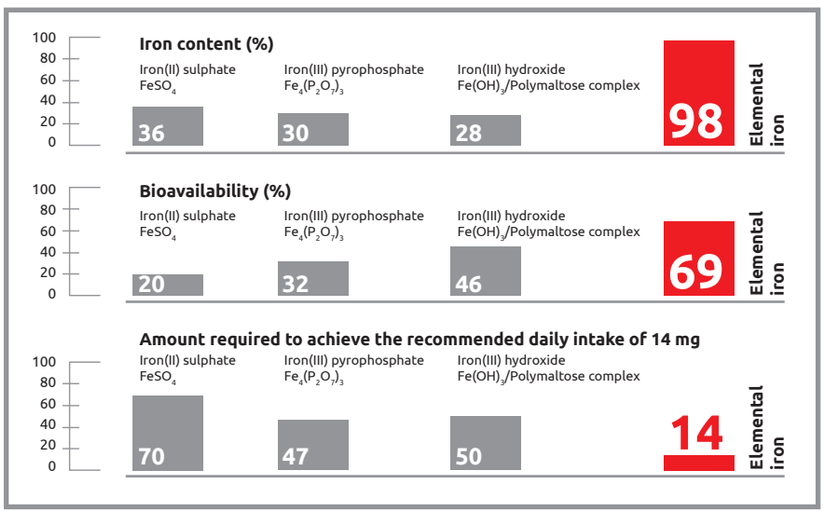


Table 1. **Comparative characteristics of iron preparations**

Brief Description of the Experiment

- Suspensions containing iron particles of different sizes were prepared in MCT oil.
- They were tested in 0.1 M HCl to simulate gastric conditions.
- FERROSAL, which contains optimally sized iron particles, demonstrated linear release kinetics, with the maximum concentration being reached as the preparation passed through the stomach.

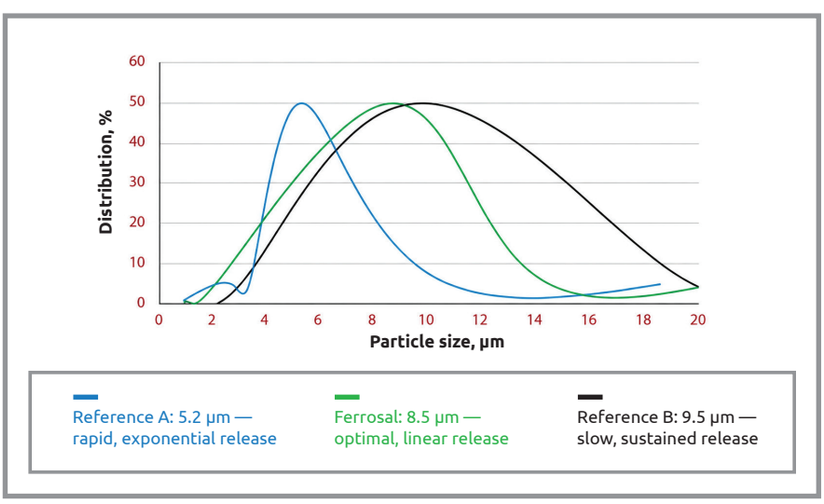
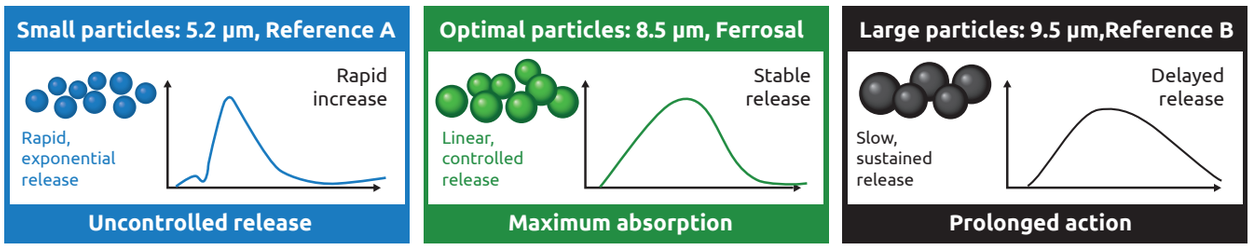


Figure 1.
Iron Release – Ferrosal

Figure 2.
Comparison of Iron Ion Release According to Particle Size



Optimal particle size enables controlled release and maximum absorption.

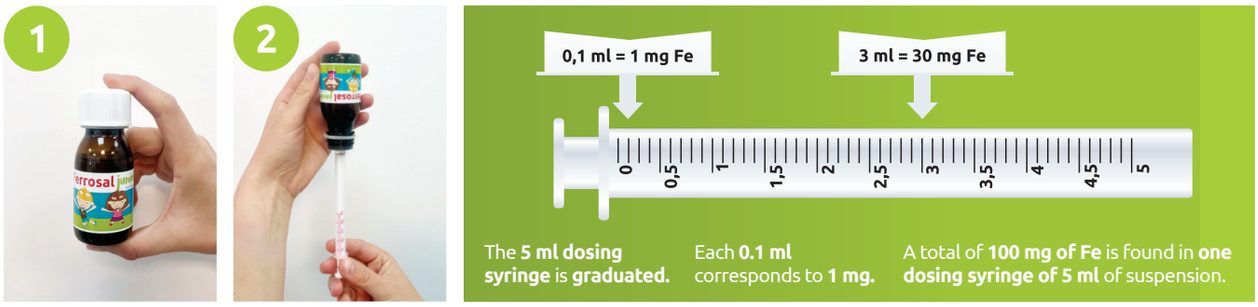
RESULTS			
SAMPLE	PARTICLE SIZE	RELEASE PROFILE	CHARACTERISTICS
Reference A	5.2µm	Exponential	Rapid, uncontrolled
Ferrosal	8.5µm	Linear	Optimal, controlled
Reference B	9.5µm	Sustained	Slow, prolonged

CONCLUSION

Smaller particles ▶ rapid but uncontrolled release
Larger particles ▶ slow, prolonged action
Optimal particle size (Ferrosal) ▶ best absorption and stability

Directions for Use of Ferrosal junior Oral Suspension

- Shake the oral suspension vigorously before use.
  (Shake the bottle for approximately 30 seconds, until the liquid becomes dark in colour)
- Administer each dose within 3 minutes. If necessary, shake the bottle again.
- Administer the dose directly into the mouth and rinse the syringe under running water after use.



RECOMMENDED DAILY DOSE OF FERROSAL JUNIOR			
AGE	DOSE (ML)	FREQUENCY	TOTAL DAILY DOSE
0-6 months	0.6 mL Ferrosal Junior	1x/daily	0.6 mL
7-36 months	1.0 mL Ferrosal Junior	1x/daily	1.0 mL
4-6 years	0.7 mL Ferrosal Junior	2x/daily	1.4 mL
7-11 years	1.0 mL Ferrosal Junior	2x/daily	2.0 mL

NOTE:
Store the bottle containing the suspension in its original packaging, in a dry and dark place at a temperature of up to 25°C. Use within 90 days after opening. Shelf life: 3 years.

Ferrosal®

Contains elemental iron.
For adults, children over 12 years of age and pregnant women.

Ferrosal is a food supplement containing elemental iron. It is recommended for adults and children over 12 years of age. One capsule contains 20 mg of iron.

Read the entire leaflet carefully before taking Ferrosal capsules.

1. Keep this leaflet. You may need to read it again.
2. Contact your doctor or pharmacist for any additional information.
3. If you notice any adverse effects, inform your doctor.

What Ferrosal capsules are and what they are used for

Ferrosal 20 mg capsules are a food supplement containing a unique form of elemental iron. In the gastrointestinal tract, under the influence of gastric juices, the iron in Ferrosal capsules is converted into its ionic form. The particle size enables optimal absorption of iron, while its gradual release over time helps reduce the risk of gastrointestinal adverse effects.

Iron is an essential micronutrient required for the proper development and functioning of the body at all stages of life :
- contributes to normal cognitive function
- contributes to normal energy-yielding metabolism
- contributes to the normal formation of red blood cells and haemoglobin
- plays a role in the process of cell division
- contributes to normal oxygen transport in the body
- contributes to the normal function of the immune system
- contributes to the reduction of tiredness and fatigue

A healthy lifestyle and a varied, balanced diet are essential for maintaining good health.

Elemental iron in Ferrosal capsules is an optimal source of iron because it:
1. Contains a high proportion of pure elemental iron, approximately 98%.
2. Has high bioavailability, approximately 69%.
3. Is considered a well-tolerated form of iron and causes fewer adverse effects than soluble iron salts, such as ferrous sulphate.
4. Does not cause tooth discolouration or a metallic taste in the mouth.
5. Is generally recognised as safe (GRAS – Generally Recognized as Safe).

Ingredients: MCT oil (medium-chain triglycerides of fatty acids); gelatine; elemental iron; emulsifier: glycerol monostearate; humectant: sorbitol 70% (E420); colour: beta-carotene (E160a).

The product is gluten-free and contains no milk proteins or lactose. It is suitable for people who are intolerant to these ingredients.

Ferrosal capsules contain no artificial colours or preservatives.

Ferrosal capsules are sugar-free.

Recommended daily dose
Children over 12 years of age and adults should take one capsule daily.
One capsule contains 20 mg of iron (142.86% NRV*).
**NRV – Nutrient Reference Value*

Directions for use: Swallow the capsule whole with water.

Precautions and warnings: Do not exceed the recommended daily dose. The product is not recommended for individuals who are sensitive to any of its ingredients. Food supplements should not be used as a substitute for a varied and balanced diet and a healthy lifestyle.
Do not use after the expiry date.

Note: Children under 12 years of age should not take the capsules.

Storage conditions: Store below 25°C in the original packaging, protected from light and moisture. Keep out of the reach of children. Refrigeration is not required.

Pack size: 30 capsules (1 blister containing 30 capsules).

Best before: See the date indicated on the packaging (month, year).

Ferrosal junior

Contains elemental iron.
For newborns, infants and children.

1. What is Ferrosal Junior?
Ferrosal Junior is an oral suspension recommended in cases of iron deficiency. It contains elemental iron. Iron is essential for good health and is an important nutrient for the human body, particularly in children, as it may help prevent various health problems, especially during the development of the nervous system. Iron contributes to normal cognitive development in children, the reduction of tiredness and fatigue, the normal formation of red blood cells and haemoglobin, improved resistance to infections and a healthy appetite.
In Ferrosal oral suspension, iron is present in the form of elemental particles which, once absorbed, are converted into the ionic form (Fe^{2}) and enter the bloodstream. Therefore, concomitant use with vitamin C is not required.

2. Elemental iron – an optimal source of iron
- Contains a high proportion of iron, over 98%.
- Has high bioavailability of 69%.
- Its low molecular weight allows the use of lower effective doses.
- It is 30–150 times safer than equivalent doses of soluble iron salts.
- It is better tolerated than other iron salts, with fewer adverse effects such as constipation and black stools.
- During conversion in the gastrointestinal tract, elemental iron changes into the ionic form (Fe^{2}) and enters the bloodstream directly.
- Therefore, it does not cause tooth discolouration or a metallic taste in the mouth.
- The particle size of 7–10 µm ensures a precise release profile with optimal absorption of approximately 15 minutes.
- This minimises the risk of excessive iron ion levels, which may promote the growth of pathogenic microorganisms.

3. Precise and easy dose measurement and administration
The pack contains a dosing syringe with a precise graduated scale, allowing the recommended dose to be measured and administered easily and accurately.
The Ferrosal Junior oral suspension syringe scale indicates the amount of well-mixed suspension corresponding to a specific iron dose:

Syringe marking / amount of suspension	Iron dose
0.1mL	1 mg
0.2 mL	2 mg
…	
1.0 mL	10 mg
…	
3.0mL	30 mg

4. Important information about Ferrosal Junior
- Ferrosal Junior is intended for newborns, including premature babies, infants and children.
- It contains no cow's milk proteins, lactose or gluten and may be used by people who are intolerant to these ingredients.
- It contains no preservatives, colours, flavours or sweeteners.
- It has a pleasant odour and taste.
- It does not cause tooth discolouration.
- Do not use in case of hypersensitivity to any ingredient of the product.
- It is not intended for parenteral administration

5. Recommended daily dose

Age	Recommended single dose of Ferrosal Junior oral suspension (mL)	Recommended frequency	Recommended daily dose
0-6 months	0.6 mL	Once daily	0.6 mL
7 months-3 years	1.0 mL	Once daily	1.0 mL
4-6 years	0.7 mL	Twice daily	1.4 mL
7-11 years	1.0 mL	Twice daily	2.0 mL

The dose and duration of Ferrosal Junior oral suspension use depend on the degree of iron deficiency. Consult a healthcare professional before taking this food supplement.

6. Directions for use
Shake the oral suspension well before use. Shake the bottle vigorously for 30 seconds. A properly mixed suspension is dark in colour. After the recommended shaking time, the suspension remains homogeneous for at least 3 minutes. If the dose is not administered within 3 minutes, shake the product again.It is recommended to shake the bottle before each use, even when the dose is administered within 3 minutes of the previous shaking. Measure the appropriate dose, remove the protective cap and administer it directly into the mouth. For hygiene purposes, rinse the syringe under running water after use.

7. Ingredients:
Elemental iron and MCT oil (medium-chain triglycerides).

8. Storage conditions:
Store in a dry place below 25°C, in the original packaging, in order to protect the contents from sunlight. Keep away from sources of heat, direct sunlight and moisture. Keep out of the reach of children.
Use within 90 days after opening.

9. Additional information:
Shelf life: 3 years.
Food supplements should not be used as a substitute for a varied and balanced diet and a healthy lifestyle.

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