Mastering the art of iron therapy

Ferinject משווק ע"י כצט. רח' החרש 4 הוד השרון 45240 טל. 09-7626333

ferinject®

Iron. Liberated.

A breakthrough in the treatment of iron deficiency!

A stable iron complex that allows controlled delivery of iron

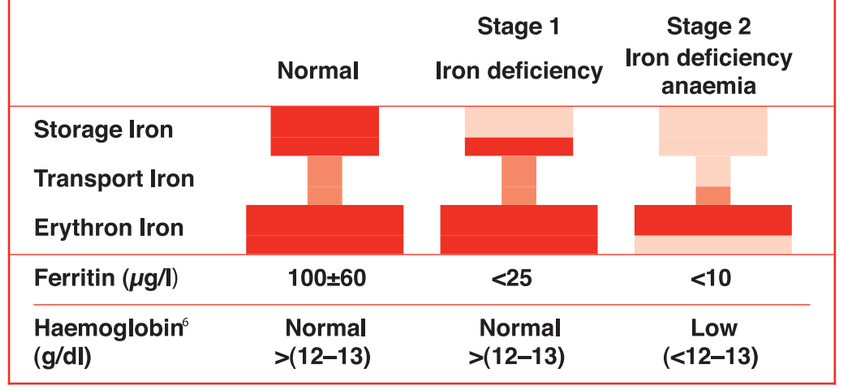
Vifor Pharma

Iron deficiency can result in anaemia

Signs and symptoms of iron deficiency with or without anaemia [1,2]

- Shortness of breath
- Chronic fatigue
- Reduced physical performance and endurance
- Decreased concentration span
- Reduced vitality
- Increased susceptibility for infections
- Pale skin colour, hair loss and brittle nails

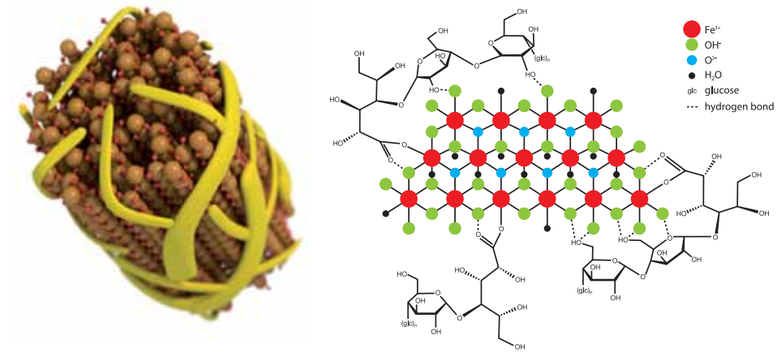
Iron status without inflammation [2]



Ferinject® – Breakthrough next generation I.V. iron

Ferric carboxymaltose

Low immunogenic potential and iron-induced toxicity [4]



High single dose and fast administration

Designed to overcome current I.V. iron limitations

Effective correction of iron deficiency [3,6]

- Unique carbohydrate shell
  - Highly stable, type I iron complex
  - Dextran-free
  - pH 5–7, physiological osmolarity
- Rapid and selective delivery from plasma to
  - RES* of the liver
  - Bone marrow

- Single dose up to 1000 mg
- No test dose required

Low risk of immunogenicity and injection site reactions [7,8]

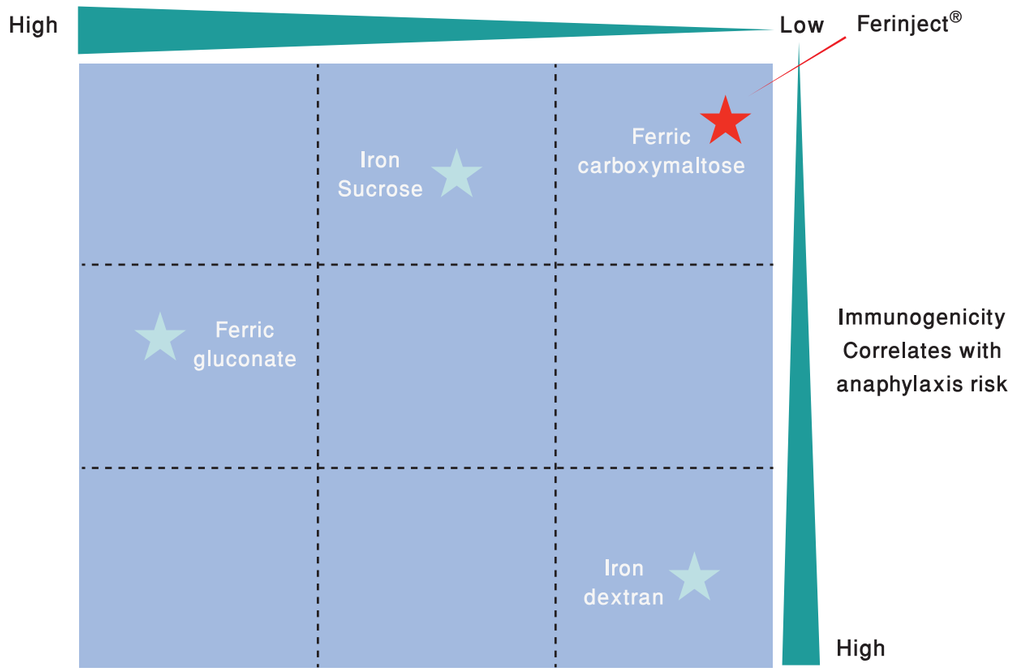
No dextran, low risk of immunogenicity with Ferinject®

- Ferinject® does not contain immunogenic triggers [7]
- Ferinject® does not cross-react with anti-dextran antibodies [1]

Low rate of injection site reactions due to a physiological pH and osmolarity

- Ferinject® has a near-neutral pH, limiting the likelihood of injection site reactions [7]
- Ferinject® osmolarity is comparable to that of blood [8]

Ferric carboxymaltose, the active ingredient of Ferinject® is a stable complex free of dextran and its derivatives that allows delivery of up to 1,000 mg in 15 mins [9]

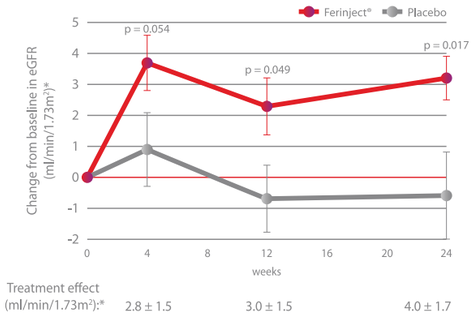


Balance of the risks for the development of oxidative stress reactions versus hypersensitivity reactions for parenteral iron preparations

Ferinject® improves renal function [11]

FAIR-HF

Impact of Ferinject® on renal function#

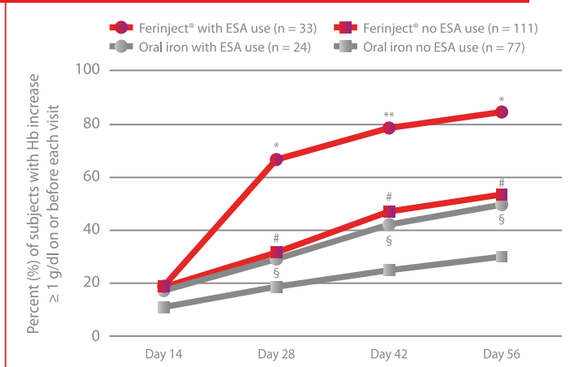


Baseline renal function: Ferinject®: 64 ± 21 ml/min/1.73m², Placebo: 65 ± 25 ml/min/1.73m²
* least squares mean ± standard error

- Ferinject® significantly improved eGFR from week 12 onwards, compared with placebo
- The response to Ferinject® was independent of the level of renal function at the start of the study, age, gender, CHF severity, underlying CHF aetiology or the presence of anaemia

Ferinject® optimizes iron deficiency anaemia management

1 in 2 patients respond to Ferinject® alone [10]



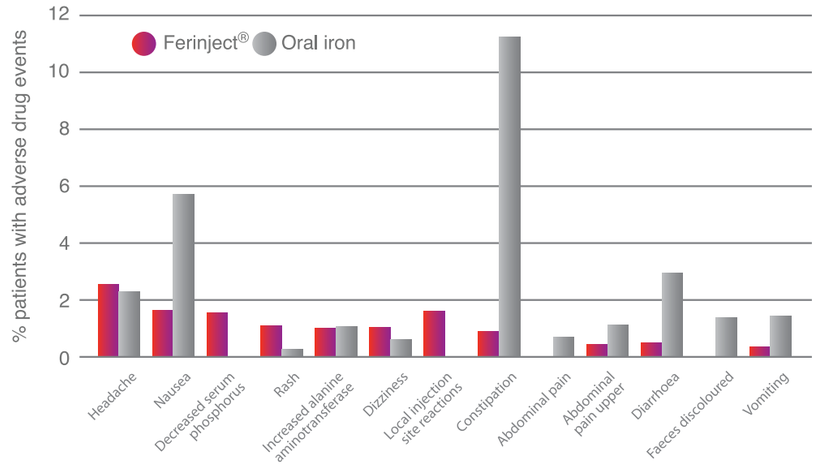
Results based on last observation carried forward
* < 0.001 FCM with ESA use vs. FCM no ESA use; ** p < 0.01 FCM with ESA use vs. FCM no ESA use; # p = ns FCM no ESA use vs. oral iron with ESA use; § p = ns oral iron with ESA use vs. oral iron no ESA useDuring the study in the FCM group in five patients the ESA dose was increased and in one patient initiated, in the oral iron group in two subject ESA dose was increased.

- Comparable Hb increase with Ferinject® alone vs. the oral iron + ESA group
- Significantly higher Hb increase in the Ferinject® + ESA group vs. the oral iron + ESA group
- "These data suggest, that some patients could be successfully treated with I.V. iron alone, thus reducing both the costs and the potential for adverse events related to ESA use"

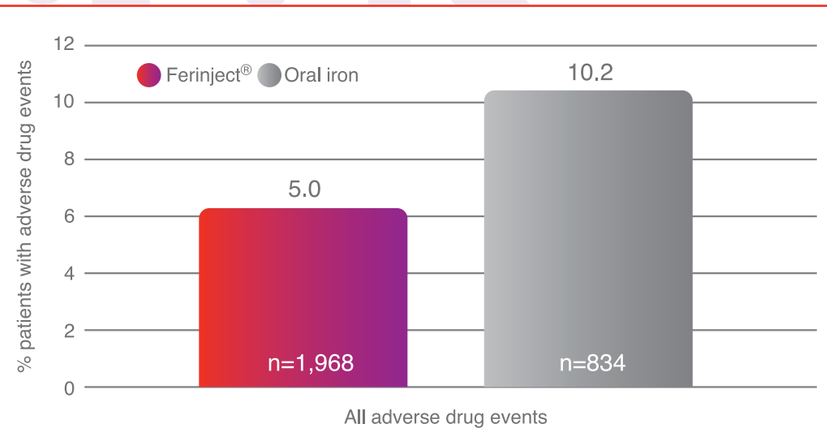
Study design: Open-label, randomized, active-controlled, multicenter trial in 255 ND-CKD patients with iron deficiency anaemia.
Inclusion criteria: Glomerular filtration rate (GFR) ≤ 45 ml/min/1.73m² ; Haemoglobin (Hb) < 11 g/dl,
Serum ferritin ≤ 300 ng/ml, Transferrin saturation (TSAT) ≤ 25%.
Primary objectives: % of patients achieving an increase in Hb ≥ 1 g/dl anytime during the study.
Treatment regimen: Ferinject® arm: first max. dose of 1000 mg iron i.v. over 15 min (with up to 2 additional doses of 500 mg iron i.v.). Oral iron (ferrous sulfat) arm: orally 325 mg (65 mg iron) three times a day throughout the study.

Ferinject® – Favourable safety profile [5]

Well tolerated even at single doses up to 1,000mg*



Ferinject® cumulative dose: ≥1,000 mg iron in 88% of patients (n = 1,736)



Pooled analysis of 10 multi-centre, randomised controlled clinical trials involving 2,800 patients until September 2007.

- No serious drug related adverse events were observed [5]

References

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