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ferinject®

Iron. Liberated.

A breakthrough in the treatment of iron deficiency!

A stable iron complex that allows controlled delivery of iron

Vifor Pharma

SINCE 1921

Iron deficiency can result in anaemia[2]

Signs and symptoms of iron deficiency with or without anaemia[2,11]

- 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

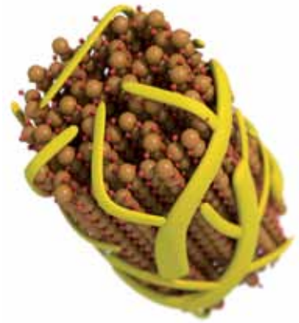
Iron status without inflammation[2]

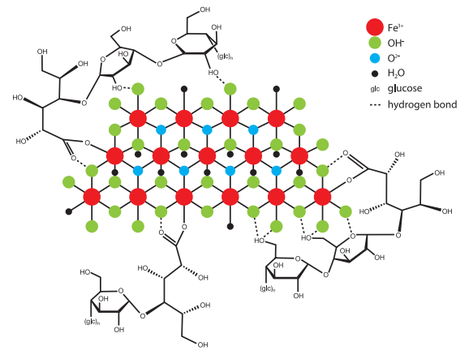
	Normal	Stage 1 Iron deficiency	Stage 2 Iron deficiency anaemia
Storage Iron			
Transport Iron			
Erythron Iron			
Ferritin (µg/l)	100±60	<25	<10
Haemoglobin[6] (g/dl)	Normal >(12–13)	Normal >(12–13)	Low <(12–13)

Ferinject® – Breakthrough next generation I.V. iron

Ferric carboxymaltose

Low immunogenic potential and iron-induced toxicity[1]





High single dose and fast administration

Designed to overcome current I.V. iron limitations

Effective correction of iron deficiency[2,3]

- 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

ferinject®

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

No dextran, low risk of immunogenicity with Ferinject®

- Ferinject® does not contain immunogenic triggers
- Ferinject® does not cross-react with anti-dextran antibodies

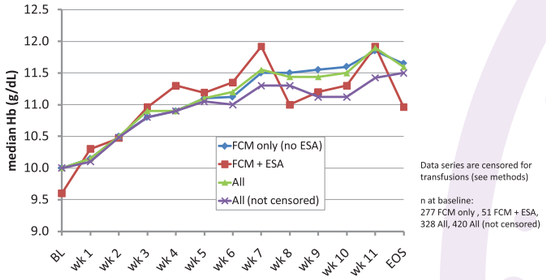
Low rate of injection site reactions due to a physiological pH and osmolarity

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

- **FCM alone or in combination with ESAs effectively improved and stabilised Hb levels at 11–12 g/dL in anaemic cancer patients [10]**

Effectiveness

Similar increase in Hb levels of FCM-treated patients with or without concomitant ESA

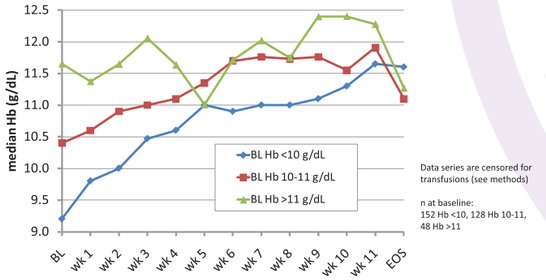


Data series are censored for transfusions (see methods)

n at baseline:
277 FCM only , 51 FCM + ESA,
328 All, 420 All (not censored)

- Median Hb levels increased steadily after first FCM administration. From week 5 onwards, median Hb levels remained stable in the range of 11-12 g/dL
- Comparable Hb levels were reached in patients treated with FCM only and FCM+ESA
- Median increase in Hb levels was similar in the overall population (1.4 g/dL [0.2, 2.3]) and patients censored for transfusions during the study (1.4 g/dL [0.3, 2.3])

Increase and stabilisation of Hb levels independent of baseline Hb

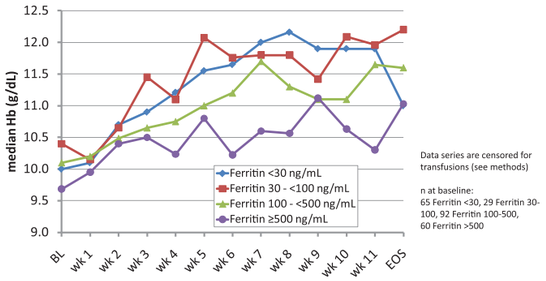


Data series are censored for transfusions (see methods)

n at baseline:
152 Hb <10, 128 Hb 10-11,
48 Hb >11

- Median Hb levels improved and stabilised above 11 g/dL in both patients with mild (baseline Hb 10-11 g/dL) and moderate-to-severe (baseline Hb <10 g/dL) anaemia
- Median Hb levels in patients with baseline Hb >11 g/dL remained stable within 11-12.5 g/dL

Hb levels improve in patients with low as well as elevated ferritin levels



Data series are censored for transfusions (see methods)

n at baseline:
65 Ferritin <30, 29 Ferritin 30-100, 92 Ferritin 100-500, 60 Ferritin >500

- Patients with baseline ferritin levels <100 ng/mL achieved Hb levels >11 g/dL earlier (week 3-4) than those with higher (100 - <500 ng/mL) baseline ferritin levels (week 7)
- In patients with very high ferritin levels (≥ 500 ng/mL), Hb levels increased slowly suggesting that other factors (e.g. impaired erythropoietin production) in addition to low iron availability may have limited erythropoiesis in these patients

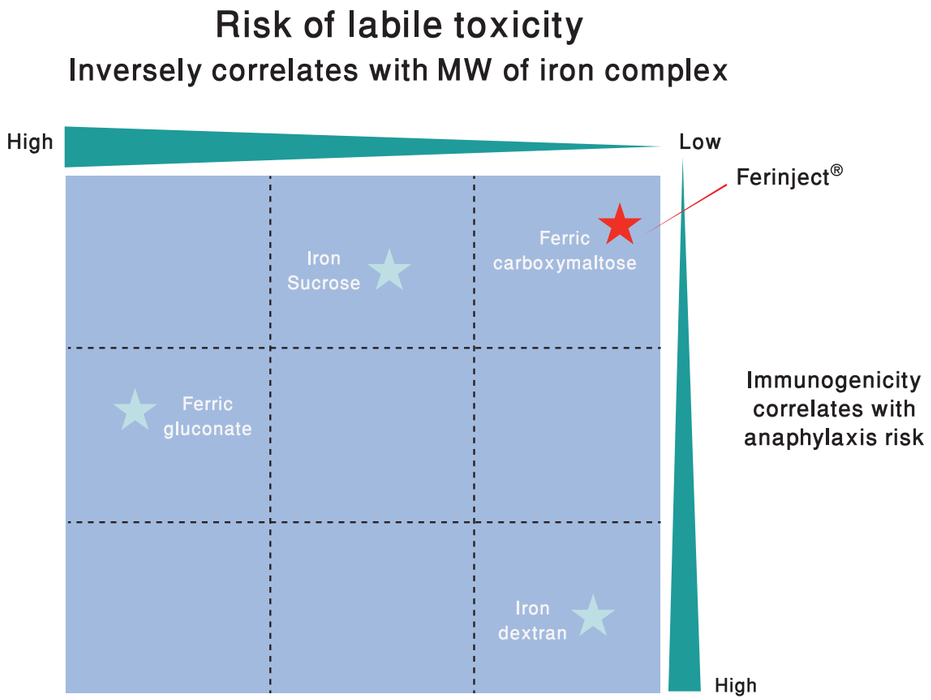
Tolerability

- FCM was well tolerated. Possibly or probably drug-related adverse events (AEs), mainly nausea and diarrhoea, were reported for 2.3% (n=14) of patients
- Three serious AEs comprised one fatal case after a possibly related respiratory insufficiency and two unlikely related events of tachycardia and dyspnoea

- **The observed improvement in Hb levels of FCM-treated cancer patients was independent of baseline Hb levels**
- **The study results suggest a role for I.V. iron alone in the correction of anaemia in cancer patients with absolute or functional iron deficiency**

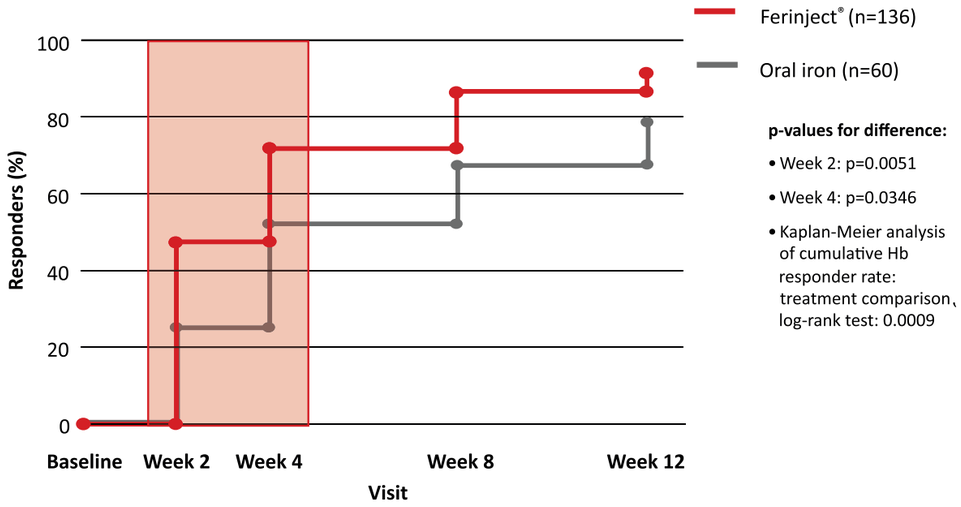
ferinject®

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® – provides a more rapid correction of iron deficiency compared with oral iron (IBD)[6]

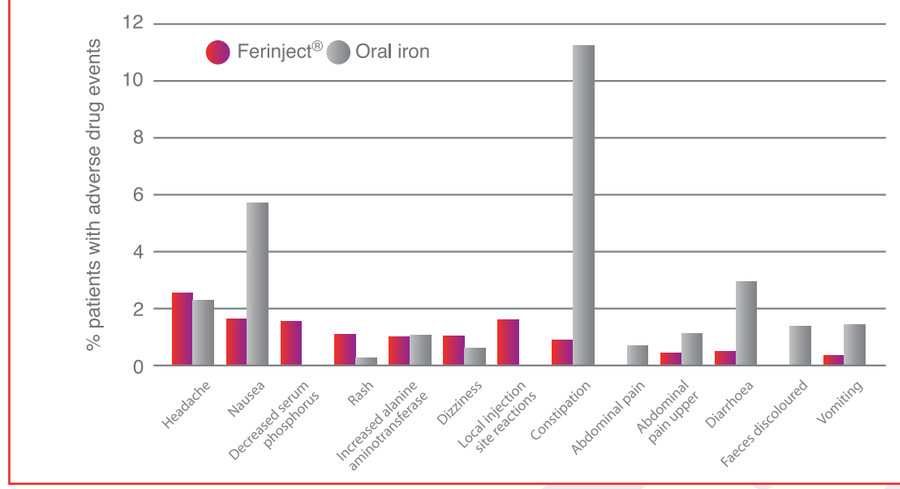


p-values for difference:

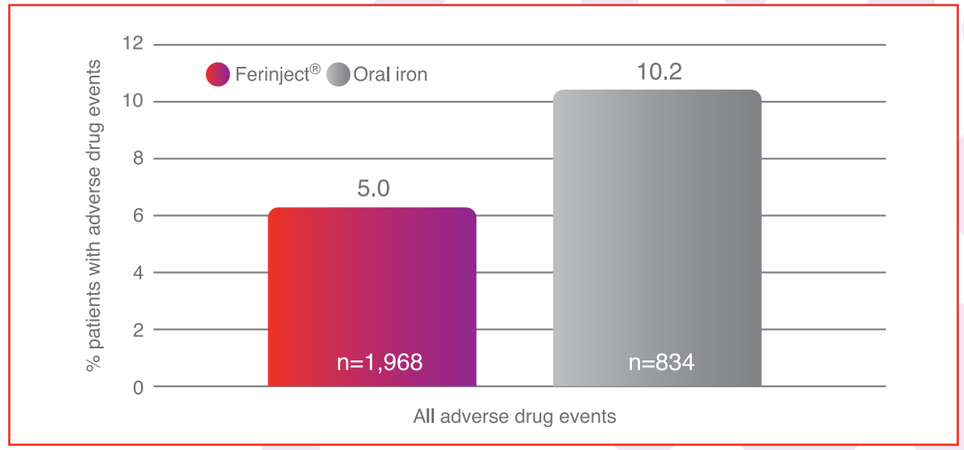
- Week 2: p=0.0051
- Week 4: p=0.0346
- Kaplan-Meier analysis of cumulative Hb responder rate: treatment comparison, log-rank test: 0.0009

Ferinject® – Favourable safety profile[1]

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



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[1]

*Maximum dose 15 mg/kg body weight

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