

5 reasons to consider Ferinject[®]

Adverse events should be reported.
Reporting forms and information can be found at
<https://yellowcard.mhra.gov.uk>
Adverse events should also be reported to Vifor
Pharma UK Ltd. Tel: +44 1276 853633.
Email: MedicalInfo_UK@viforpharma.com

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Ferinject[®] (ferric carboxymaltose) Iron deficiency anaemia treatment for ND-CKD patients

From the pioneers of iron-based therapies

Ferinject[®] is indicated for the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used or if there is a clinical need to deliver iron rapidly. The diagnosis of iron deficiency must be based on laboratory tests.¹

Prescribing information can be found on the last page

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Ferinject[®] can be used to treat iron deficiency (ID) – one of the most common causes of anaemia in ND-CKD^{1,2}

Anaemia affects up to 75% of patients with ND-CKD and kidney failure,³ with 42–53% of anaemic stage 3–5 ND-CKD patients diagnosed as iron deficient.*²

According to NICE guidelines:

- **Patients should be tested to diagnose ID** and determine potential responsiveness to iron therapy,^{†4} and
- **Iron therapy should be offered** to correct ID **before** considering or when starting ESAs **and** during maintenance ESA therapy⁴

Patients also need to be iron replete before initiating anaemia treatment with the HIF-PHI therapy roxadustat.^{5,6}

* ID was defined as ferritin <100 µg/L or TSAT <20%, and kidney failure was defined as eGFR <15 mL/min/1.73 m²

† Long-term iron requirements also should be monitored every 3 months

Ferinject® – dosing that achieves high ferritin levels^{1,7}

Results from the FIND-CKD study showed that treating ID with Ferinject® and a dosing strategy that achieves high ferritin levels (400–600 µg/L) allowed **76.5%** (117/153) of patients to maintain a Hb level of ≥ 10 g/dL or not require further anaemia treatment, compared with dosing strategies that achieved lower ferritin levels of 100-200 ug/L with either Ferinject® (67.8%, 104/153, p=0.082) or oral ferrous sulphate (68.2%, 210/308, p=0.026).

- FIND-CKD was a 56-week, 3-arm, open-label, randomised study comparing the efficacy and safety of Ferinject®, targeted to different ferritin levels, with oral ferrous sulphate therapy in 626 pts with ND-CKD and iron deficiency anaemia
- The primary endpoint was the time to initiation of further anaemia management or Hb trigger
- Key secondary endpoints included the percentage of pts with an Hb increase ≥ 1 g/dL, change in eGFR, and the % of pts discontinuing study drug due to intolerance



Ferinject® – a well-characterised safety profile and licence for use in adults and paediatric patients aged 1 or older¹

The safety and tolerability profile of Ferinject® is based on data reported in clinical studies and post-marketing surveillance from **>9,000 patients, including >100 children and adolescents aged 1–17.**¹

- In FIND-CKD, treating iron deficiency anaemia (IDA) with Ferinject® to achieve high ferritin levels was not associated with an increased AE rate vs achieving lower ferritin levels with Ferinject®
- Common ADRs ($\geq 1/100$ to $< 1/10$) include nausea, injection/infusion site reactions, hypophosphataemia, headache, flushing, dizziness and hypertension¹
- The most serious ADR with Ferinject® is anaphylactic reactions, which is rare ($\geq 1/10,000$ to $< 1/1,000$); fatalities have been reported¹
- For more information on the facilities required for identifying and managing anaphylactic reactions, please refer to the SmPC





***Ferinject® – infusion/injection time
from only 15 minutes¹***

Offering a minimum administration time of 15 minutes for doses of 1000 mg of iron, which must be followed by a 30-minute observation period.¹

Refer to the SmPC for further information.

***Ferinject® is backed by >15 years
of post-marketing experience¹***

Discover the high-dose IV iron treatment with more than 15 years and 26.7 million patient-years' exposure.^{1,8}



With over 15 years of heritage, *Ferinject*[®] helps your patients with ND-CKD and ID anaemia get back to what matters

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References

1. Ferinject[®] Summary of Product Characteristics. **2.** Wong MMY et al. Clin Kidney J 2019; 13: 613–624. **3.** McClellan W et al. Curr Med Res Opin 2004; 30: 1501–1510. **4.** NICE guideline [NG203]. Published 25 August 2021. Available at <https://www.nice.org.uk/guidance/ng203>. Accessed September 2023. **5.** NICE technology appraisal guidance [TA807] Published: 13 July 2022. Available at <https://www.nice.org.uk/guidance/ta807>. Accessed September 2023. **6.** Roxadustat Summary of Product Characteristics. **7.** Macdougall IC et al. Nephrol Dial Transplant 2014; 29: 2075–2084. **8.** Vifor Pharma, Data on File 149.

ADR: Adverse drug reaction; **AE:** Adverse event; **eGFR:** Estimated glomerular filtration rate; **ESA:** Erythropoiesis stimulating agent; **Hb:** Haemoglobin; **HIF-PHI:** Hypoxia-inducible factor prolyl-hydroxylase inhibitor; **ID:** Iron deficiency; **IDA:** Iron deficiency anaemia; **IV:** Intravenous; **ND-CKD:** Non-dialysis chronic kidney disease; **NICE:** National Institute for Health and Care Excellence; **PTS:** Patients; **SmPC:** Summary of Product Characteristics; **TSAT:** Transferrin saturation.

Prescribing Information

Ferinject® (ferric carboxymaltose) Prescribing Information - UK

For full prescribing information refer to the Summary of Product Characteristics (SmPC)

Active ingredient:

Ferric carboxymaltose (50mg/mL)

Presentation:

Dispersion for injection/infusion.

Available as a 2mL vial (as 100mg of iron), 10mL vial (as 500mg of iron) and 20mL vial (as 1000mg of iron).

Indication: Treatment of iron deficiency when oral iron preparations are ineffective or cannot be used or if there is a clinical need to deliver iron rapidly. The diagnosis must be based on laboratory tests.

Dosage and Administration:

The posology of Ferinject follows a stepwise approach:

Step 1: Determination of the iron need:

The individual iron need for repletion using Ferinject is determined based on the patient's body weight and haemoglobin (Hb) level, using the simplified table in the SmPC. Two doses may be required to replenish the total iron need.

Step 2: Calculation and administration of the maximum individual iron dose(s):

Based on the total iron need determined, the appropriate dose(s) of Ferinject should be administered: In adults and adolescents aged 14 years and older, the maximum single dose is 15 mg iron/kg body weight (for administration by intravenous injection) or 20 mg iron/kg body weight (for administration by intravenous infusion) and the maximum recommended cumulative dose of Ferinject is 1,000 mg of iron (20 mL Ferinject) per week.

In children and adolescents aged 1 to 13 years, the maximum single dose is 15 mg iron/kg body weight, and the maximum recommended cumulative dose of Ferinject is 750 mg of iron (15 mL Ferinject) per week. In all cases, if the total iron need is higher, then the

administration of an additional dose should be a minimum of 7 days apart from the first dose.

Administration rates for intravenous injection using undiluted dispersion:

For iron doses of 100mg to 200mg, there is no prescribed administration time. For doses >200mg to 500mg, Ferinject should be administered at a rate of 100mg iron/min. For doses >500mg to 1,000mg, the minimum administration time is 15 min.

Administration of intravenous drip infusion:

For iron doses of 100mg to 200mg, there is no prescribed administration time. For doses >200mg to 500mg, Ferinject should be administered in a minimum of 6 mins. For doses >500mg to 1,000mg, the minimum administration time is 15 mins.

Ferinject must only be diluted in 0.9% m/V NaCl but should not be diluted to concentrations less than 2 mg iron/mL.

Step 3: Post-iron repletion assessments

Contraindications: Hypersensitivity to Ferinject or any of its excipients. Known serious hypersensitivity to other parenteral iron products. Anaemia not attributed to iron deficiency. Iron overload or disturbances in utilisation of iron.

Special warnings and precautions: Parenterally administered iron preparations can cause potentially fatal anaphylactic reactions. The risk is enhanced for patients with known allergies, a history of severe asthma, eczema or other atopic allergy, and in patients with immune or inflammatory conditions. There have been reports of hypersensitivity reactions which progressed to Kounis syndrome (acute allergic coronary arteriospasm that can result in myocardial infarction). Ferinject should only be administered in the presence of staff trained to manage anaphylactic reactions where full resuscitation facilities are available (including 1:1000 adrenaline solution). Each patient should be observed for 30 minutes following administration. If

hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately. Symptomatic hypophosphataemia leading to osteomalacia and fractures requiring clinical intervention has been reported. Patients should be asked to seek medical advice if they experience symptoms. Serum phosphate should be monitored in patients who receive multiple administrations at higher doses or long-term treatment, and those with existing risk factors. In case of persisting hypophosphataemia, treatment with ferric carboxymaltose should be re-evaluated. In patients with liver dysfunction, parenteral iron should only be administered after careful risk/benefit assessment. Careful monitoring of iron status is recommended to avoid iron overload. There is no safety data on the use of single doses of more than 200mg iron in haemodialysis-dependent chronic kidney disease patients. Parenteral iron must be used with caution in case of acute or chronic infection, asthma, eczema or atopic allergies. It is recommended that treatment with Ferinject is stopped in patients with ongoing bacteraemia. In patients with chronic infection a benefit/risk evaluation has to be performed. Caution should be exercised to avoid paravenous leakage when administering Ferinject. The efficacy and safety of Ferinject has not been investigated in children below 1 year of age. Ferinject is therefore not recommended for use in children in this age group.

Special populations: In adults and adolescents aged 14 years and older, a single maximum daily dose of 200 mg iron should not be exceeded in haemodialysis-dependent chronic kidney disease patients. In children aged 1 to 13 years with chronic kidney disease requiring haemodialysis, the efficacy and safety of Ferinject has not been investigated. Ferinject is therefore not recommended for use in children aged 1 to 13 years with chronic kidney disease requiring haemodialysis.

A careful risk/benefit evaluation is required before use during pregnancy. Ferinject should not be used during pregnancy unless clearly necessary and should be confined to the second and third trimester. Foetal bradycardia may occur during administration of parenteral irons, as a consequence of hypersensitivity. The unborn baby should be carefully monitored during administration to pregnant women.

Undesirable effects: Common ($\geq 1/100$ to $< 1/10$): Hypophosphataemia, headache, dizziness, flushing, hypertension, nausea, injection/infusion site reactions. Rare ($\geq 1/10,000$ to $< 1/1,000$): Anaphylactic reactions. Frequency not known: Kounis syndrome, hypophosphataemic osteomalacia. Please consult the SmPC in relation to other undesirable effects.

Legal category:

POM
Price: pack of 5 x 2mL = £95.50; pack of 5 x 10mL = £477.50; pack of 1 x 20mL = £154.23

MA Number: 15240/0002

Date of Authorisation: 19.07.2007

MA Holder: Vifor France, 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris La Défense Cedex, France

Ferinject® is a registered trademark

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