Effectively managing iron deficiency with Ferinject® in patients with heart failure (HF) could reduce hospitalisations and lower costs for the Irish healthcare system[1]

Ferinject® ferric carboxymaltose

in Ireland, **HF is associated with increased healthcare costs**, longer hospital stays, higher readmission rates and increased mortality outcomes compared with patients without HF[1]

Up to **50%**

Up to 50% of patients with CHF may have ID, and this can be associated with increased hospitalisation[2,3]

A multinational cost-effectiveness analysis using clinical trial data investigating IV iron use in patients with heart failure has shown that **costs can be saved**, due to reduced hospital admissions, by treating ID with Ferinject® in patients with HF[4]

A study by Wong B et al is the first to use an economic model to estimate the budgetary impact of treating eligible patients with Ferinject® in Ireland[1]

Retrospective data were collected from all HF patients newly referred to a secondary care hospital over a 1-year period[1]

115 HFrEF[1] patients were enrolled[1]

82 underwent serum iron studies[1,**]

44 had ID[1]

9 received Ferinject®[1]

[1]HFrEF was classed as an EF <50% by echocardiography or alternate imaging modality.
[**] The iron studies performed were TSAT and ferritin.

An existing German budget impact model was adapted and applied at Connolly Hospital, Dublin[1]

- The German model used data from four RCTs (n=833) of Ferinject® in HF with ID to create a decision analytic model to estimate the budget impact of treatment compared with no IV iron[5]
- The Irish model compared the annual direct costs of HF patients who received Ferinject® with HF patients who received no iron, and was used to predict changes in NYHA class, resource use and hospitalisations[1]

According to the model, treating 44 patients with HF and ID with Ferinject® could save:[1]

An estimated

40 hospital bed days

(model estimates that 6 out of 44 patients who received no iron would be hospitalised, compared with 2 patients if IV iron was received)

€21,063 in hospitalisation costs

(costs of €13,840 if treated with Ferinject vs €34,903 not treated with IV iron)

€7,600 total costs

(costs of €69,310 if treated with Ferinject vs €76,910 not treated with IV iron)

Resource use and unit cost for budget impact model[1]

	Resource use (per year)	Unit costs
Outpatient	3.5 visits[1]	€178 per visit[1]
GP	8.8 visits[1]	€48 per visit[1]
Hospitalisation		€6,788 per visit[1]
Ferinject®		€243.68 for 1g, €128.25 for 500mg[1]
Administration visits		€32 per visit[1]
Other medication		€301 per visit[1]

[1]The Heartbeat Trust, 2012; [2]Vifor Pharma. IHSE salary scales, 2018. Adapted from Wong B et al, 2021[1]

Treating ID with Ferinject® in patients with HF is **predicted to save costs** in an Irish healthcare setting[1]

Ferinject® is indicated for the treatment of iron deficiency when:[6]
- oral iron preparations are ineffective
- oral iron preparations cannot be used
- there is a clinical need to deliver iron rapidly

The diagnosis of iron deficiency must be based on laboratory tests.[6]

Ferinject® ferric carboxymaltose

CSL Vifor

References:

1. Wong B, et al. Br J Cardiol 2021;28:14–18. https://bjcardio.co.uk/2021/03/study-of-patients-with-iron-deficiency-and-hf-in-ireland-prevalence-and-treatment-budget-impact/. Last accessed: June 2021.
2. Klip I-T, et al. Ann Heart J 2013;165(4):575-582.
3. Martens P, et al. Acta Cardiol. 2018;73(2):115-123.
4. McEwan P, et al. Eur J Heart Fail. 2021; DOI: 10.1002/ejhf.2270.
5. Theobl U, et al. ESC Heart Failure 2017;4(3):274–281.
6. Ferinject® Summary of Product Characteristics.

Abbreviations:

CV, cardiovascular; **EF**, ejection fraction; **HF**, heart failure; **HFrEF**, heart failure with reduced ejection fraction; **HSE**, Health Service Executive; **ID**, iron deficiency; **IV**, intravenous; **NYHA**, New York Heart Association; **RCT**, randomised controlled trial.

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Ferinject® (ferric carboxymaltose)
Prescribing Information – Ireland

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 Ferinject dose(s) required:
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, the injection 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, the infusion should be administered at a rate of 100mg iron /min. 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 assessment.**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 (1/100 to <1/10): Hypophosphataemia, headache, dizziness, flushing, hypertension, nausea, injection/infusion site reactions. Rare (1/1,000 to <1/1,000): Anaphylactic reactions. Frequency not known: Kounis syndrome, hypophosphataemic osteomalacia. Please consult the SmPC in relation to other undesirable effects
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MA Number: PA0969/040/001
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MA Holder: Vifor France, 100-101 Terrasse Boieldieu, Tour Franklin La Defense 8, 92042 Paris La Defense Cedex, France

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Additional information is available on request

Adverse events should be reported.
Reporting forms and information can be found at: http://www.hpra.ie
Adverse events should also be reported to Vifor Pharma UK Ltd. Tel: +44 1276 853633
Email: medicalinfo_UK@viforpharma.com