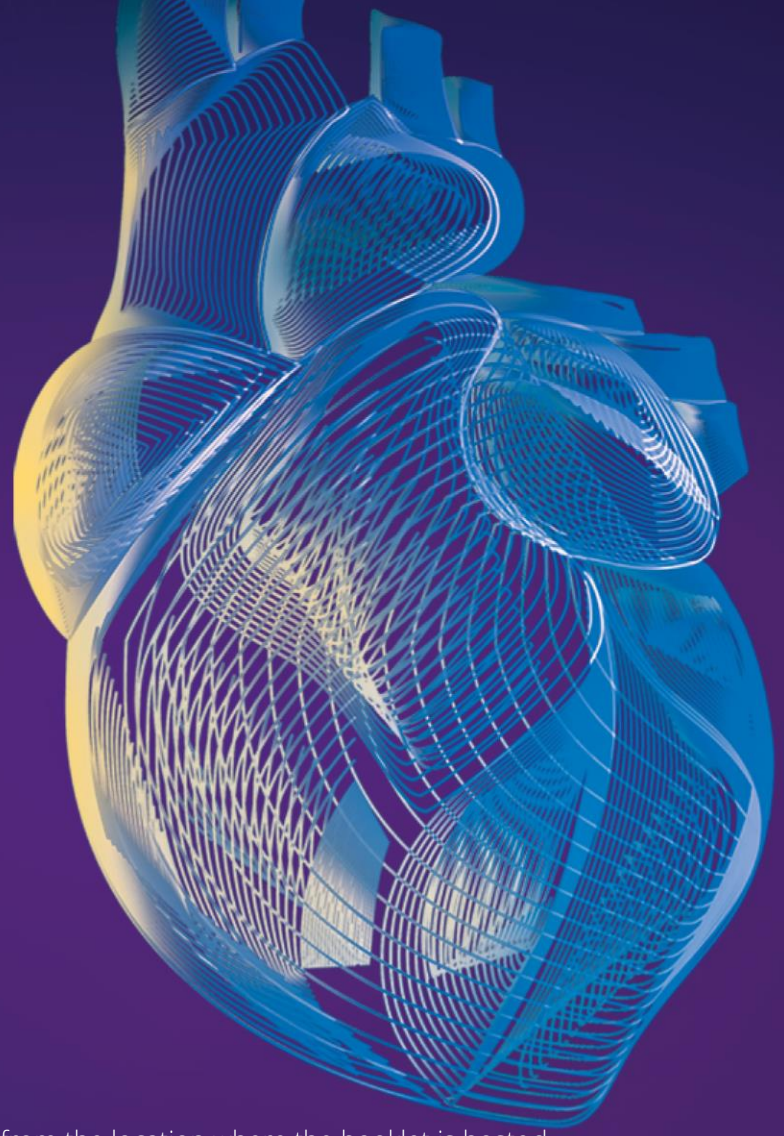
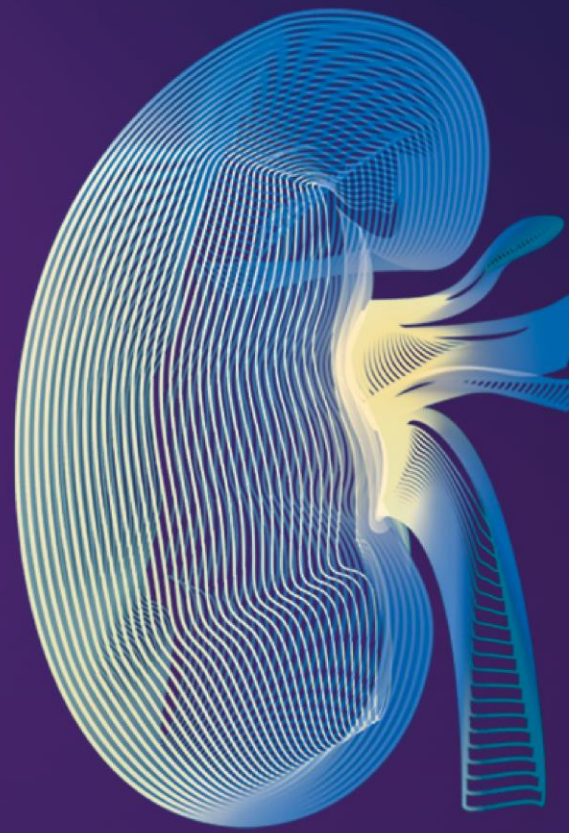
CSL Vifor

# HEART AND KIDNEY IN FOCUS

## CLINICAL CASES
IRON DEFICIENCY AND ANAEMIA

## FOREWORD





Prescribing information is available at the end of this chapter, or is available from the location where the booklet is hosted.

Adverse events should be reported.
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Adverse events should also be reported to Vifor Pharma UK Ltd Tel: +441276853633 Email: medicalinfo_UK@viforpharma.com.

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This booklet is intended for healthcare professionals only.

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# FOREWORD

We are delighted to present this collection of clinical case studies made possible by our medical colleagues across the UK and Republic of Ireland.

Managing patients with chronic diseases, particularly those with complex inflammatory disorders (including heart failure and chronic kidney disease), requires a considered multidisciplinary approach to maintain quality of life (QoL) and improved outcomes.

Iron deficiency (with or without anaemia) is common, affecting approximately 50% of patients with heart failure and up to 70% of those with chronic kidney disease (CKD); many patients will have both conditions.[1,2] Iron deficiency is associated with impaired QoL and exercise capacity, and worse outcomes in these patient populations.[3–6] With this in mind, fellow healthcare professionals in cardiology and nephrology have provided clinical cases that not only illustrate their personal experience of diagnosing and managing iron deficiency but also deliver important learning points that should help improve patient care.

In this booklet you will find an overview of iron homeostasis, the pathophysiology of iron deficiency in chronic inflammatory conditions and the laboratory assays used for the diagnosis of iron deficiency. It is followed by case studies in heart failure and CKD, where the identification and management of iron deficiency and its relationship to anaemia are discussed in detail, spotlighting the unique and overlapping features for each specialty.

We hope that you find this collection of case studies helpful for your own daily practice and a useful tool to support education of the clinical teams that are the foundation of good care for patients with chronic long-term illnesses such as heart failure and/or CKD.

**Professor John Cleland**

Cardiologist and Director of the Robertson Centre for Biostatistics, University of Glasgow, UK

**Professor Donal Reddan**

Consultant Nephrologist and General Physician, Galway University Hospital, Ireland

**References**
**1.** Klip IT et al. Am Heart J. 2013;165:575–82.e3. **2.** Fishbane S et al. Clin J Am Soc Nephrol. 2009;4(1):57–61. **3**. Jankowska EA et al. Eur J Heart Fail. 2021;00:1–11. **4.** Kalra PR et al. Lancet. 2022: doi: 10.1016/S0140-6736(22)02083-9. [Epub ahead of print]. **5**. Macdougall IC et al. N Engl J Med. 2019;380:447–58. **6**. Macdougall IC et al. J Am Soc Nephrol. 2020;31(5):1118–27.

Please note that these case studies reflect the experiences and opinions of the individual healthcare professionals. Patients referenced in this booklet are anonymised and do not necessarily represent those at your local practice.

# 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 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 (≥1/100 to <1/10): Hypophosphataemia, headache, dizziness, flushing, hypertension, nausea, injection/infusion site reactions. Rare (≥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
**MA Number:** PA0949/004/001
**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**

Document number: IE-FCM-2300011
Date of preparation: 06/2023

**Additional information is available on request**

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

# Venofer® (iron sucrose)

**Prescribing Information - Ireland**
**For full prescribing information refer to the Summary of Product Characteristics (SmPC)**
**Active ingredient:** Iron sucrose (20 mg/mL)
**Presentation:** Solution for injection/infusion. Available as a 5 mL vial (as 100 mg of iron).
**Indication:** Treatment of iron deficiency where there is a clinical need for a rapid iron supply, in patients who cannot tolerate oral iron therapy or who are non-compliant, in active inflammatory bowel disease where oral iron preparations are ineffective, and in chronic kidney disease when oral iron preparations are less effective. The diagnosis of iron deficiency must be based on appropriate laboratory tests.
**Dosage and Administration:** The total cumulative dose of Venofer, equivalent to the total iron deficit (mg), must be individually determined for each patient, based on haemoglobin level and body weight and calculated with the Ganzoni formula. The total single dose must not exceed 200 mg of iron given not more than three times per week.
Administration for intravenous drip infusion:
Venofer must be diluted only in sterile 0.9% m/V sodium chloride solution up to a maximum dilution of 1 mg/mL. For iron doses of 50 mg, minimum infusion time is 8 minutes. For doses of 100 mg, minimum infusion time is 15 minutes. For doses of 200 mg, the minimum administration time is 30 min.
Intravenous injection: Venofer may be administered by slow intravenous injection at a rate of 1 mL undiluted solution per minute and not exceeding 10 mL Venofer (200 mg iron) per injection.
Administration into dialysis machine: Venofer may be administered during a haemodialysis session directly into the venous line of the dialysis machine under the same conditions as for intravenous injection.
**Contraindications:** Hypersensitivity to Venofer 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/anaphylactoid 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).
Venofer 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. 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. 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 Venofer 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 Venofer.
**Special populations:** The use of Venofer has not been studied in children. A careful risk/benefit evaluation is required before use during pregnancy. Venofer 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): Dysgeusia, hypotension, hypertension, nausea and injection/infusion site reactions. Frequency not known: Anaphylactoid/anaphylactic reactions and Kounis syndrome. Please consult the SmPC in relation to other undesirable effects.
**Legal category:** POM
**MA Number:** PA 949/001/002
**Date of Authorisation:** 11.09.2009
**MA Holder:** Vifor France, 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris La Défense Cedex, France

**Venofer® is a registered trademark**

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**Additional information is available on request**

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