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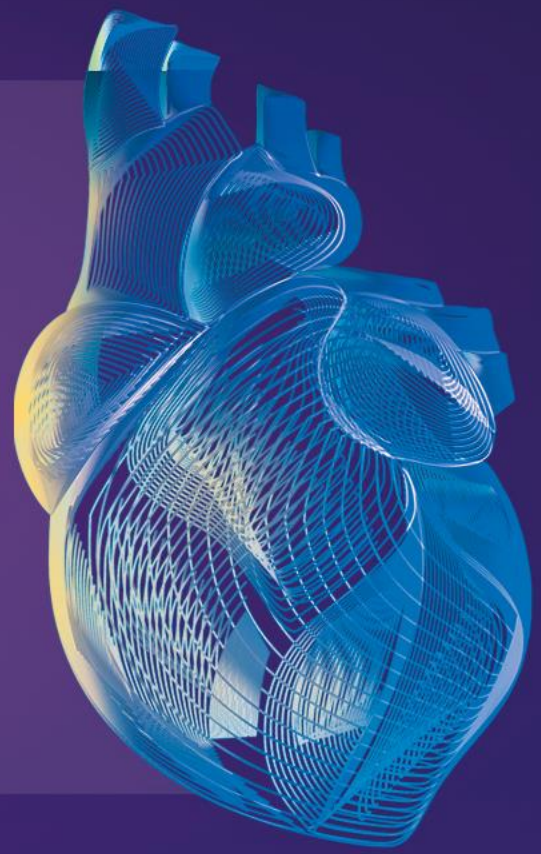
CLINICAL CASES
IRON DEFICIENCY AND ANAEMIA

HEART FAILURE CASE STUDIES



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CASE STUDY 1

TREATMENT OF IRON DEFICIENCY IN A PATIENT WITH WORSENING HEART FAILURE AND A REQUIREMENT FOR CANCER SURGERY

Contributing author: Dr Carla Plymen, Consultant Cardiologist, Imperial College Healthcare NHS Trust, London, UK

PATIENT INFO

Age 57

Sex M

CASE HISTORY

- Type-II diabetes mellitus treated with metformin alone
- Myocardial infarction in 2014
- Developed heart failure in 2016
- LVEF 28%
- Treated with bisoprolol, spironolactone, ramipril and furosemide
- Implantable cardioverter defibrillator implanted in 2017

Owing to the COVID-19 pandemic, the last contact with this patient was by telephone in 2020. He was clinically stable at that time and no changes in medication were made.

Following the above review, the patient's renal function progressively declined. The general practitioner reduced the dose of ramipril and referred him to the renal team. Investigations identified ureteric cancer, and the patient was also noted to have worsening symptoms and signs of heart failure.

IDENTIFICATION AND DIAGNOSIS OF IRON DEFICIENCY

Patient called the heart failure service with increasing breathlessness and swelling of legs. He was brought to a face-to-face clinic during lockdown. Deteriorating exercise capacity and increasing peripheral oedema were noted and were attributed to worsening heart failure.

The patient's cancer surgery was postponed owing to the severity of his heart failure. After discussion with the oncology team, it was agreed that treatment for heart failure should be optimised before undertaking cancer surgery. Standard laboratory blood tests were requested, including serum ferritin and TSAT.

Heart rate 74 bpm in sinus rhythm (confirmed by electrocardiogram). Blood pressure 128/76 mmHg. An echocardiogram confirmed no significant change in LVEF.

Blood test results:

- Serum potassium: 4.8 mmol/L
- eGFR: 44 mL/min/1.73m^2
- B-type natriuretic peptide: 1400 ng/L
- Hb: 11.8 g/dL
- Ferritin: 28 µg/L
- TSAT: 14%

CONSIDERATIONS

The main immediate consideration for this patient was to improve control of heart failure to enable curative cancer surgery. The patient understood why surgery should be delayed.

Heart failure medications were optimised first, as this could be done in the community without a hospital stay – furosemide was increased during the first face-to-face consultation, and a switch from ramipril to sacubitril/valsartan was undertaken by the HFSN team with a combination of face-to-face and telephone reviews).

Iron deficiency was discussed with the patient. The normal IV iron service had been stopped owing to the COVID-19 pandemic.

CASE STUDY 1

PATIENT EXPERIENCES

The patient's renal function deteriorated significantly when switched to sacubitril/valsartan (peak serum creatinine 315 µmol/L), probably exacerbated by the increase in diuretic dose.

Hyperkalaemia also prevented titration beyond spironolactone 25 mg three times per week (Monday, Wednesday, Friday). A potassium-binding agent was not available at this time.

The risks and potential benefits were explained to the patient. A day case admission to the hospital was arranged, for him to receive IV iron (ferric carboxymaltose) as recommended in the ESC guidelines.[1] Admission was delayed several weeks following blood tests owing to logistics, and to see if changing heart failure medicines would help. Symptoms and signs persisted.

To reduce the risk of COVID-19 transmission, the patient came to a side room alone for as short a time as possible to receive the IV iron infusion.

INTERVENTIONS

Follow-up included several weekly reviews with HFSN to optimise guideline-directed therapy, plus one-off attendance in hospital for IV iron infusion (the patient weighed <70 kg, so a single dose could be given in one visit).

OUTCOME

Administration of IV iron was associated with marked improvements in breathlessness and general fatigue within 4 weeks (ferritin 232 µg/L; TSAT 33%; iron 23 µmol/L; Hb 13.6 g/dL). The patient underwent successful cancer surgery. His renal function is now normal, and heart failure symptoms have been stable in the 8 months since surgery.

LEARNING POINTS / KEY CLINICAL POINTS

1. IV iron can be an important adjunctive therapy for HFrEF, in addition to other interventions including intensification of loop diuretic dose, switch to sacubitril/valsartan and (now) addition of an SGLT2 inhibitor. Unlike many other treatments for heart failure, IV iron has no adverse impact on renal function.
2. Worsening heart failure is often associated with deteriorating renal function – this should not stop attempts to optimise therapy.
3. The COVID-19 pandemic hampered delivery of outpatient IV therapies (including iron) and the ability to see patients face-to-face (and therefore blood tests). There are probably many patients with undiagnosed iron deficiency in the community and on our wards; we are now actively checking all admissions for iron deficiency and treating as appropriate prior to discharge.

1. McDonagh TA et al. Eur J Heart Fail. 2021;42(36):3599–3726.

COVID-19, coronavirus disease 2019; eGFR, estimated glomerular filtration rate; Hb, haemoglobin; HFrEF, heart failure with reduced ejection fraction; HFSN, heart failure specialist nurse; IV, intravenous; LVEF, left ventricular ejection fraction; SGLT2, sodium-glucose co-transporter 2; TSAT, transferrin saturation.

CASE STUDY 2

MANAGEMENT OF IRON DEFICIENCY IN A PATIENT WITH HEART FAILURE, ISCHAEMIC HEART DISEASE, HIV AND ULCERATIVE COLITIS

Contributing author: Dr Susan Piper, Consultant Cardiologist, King's College Hospital NHS Foundation Trust, London, UK

PATIENT INFO

Age 61

Sex M

CASE HISTORY

Known heart failure secondary to ischaemic heart disease, with an LVEF of 35%. Other comorbidities included hypercholesterolaemia, ulcerative colitis and HIV.

The patient had received oral iron supplements in the past but discontinued owing to side effects of constipation and nausea.

The patient experienced a further inferior ST elevation myocardial infarction requiring primary angioplasty to left circumflex artery, which was followed by cardiac rehabilitation for optimisation of heart failure medications (diuretics, ramipril, eplerenone and bisoprolol).

The gastroenterology and HIV teams provided regular input regarding potential drug interactions and disease control that might impact on symptoms.

IDENTIFICATION AND DIAGNOSIS OF IRON DEFICIENCY

Several months after the primary angioplasty, the patient presented with increasing shortness of breath on exertion and fatigue (NYHA class III). At rest, there were no obvious signs of congestion. The patient was not clinically anaemic, further gastrointestinal investigations were considered unnecessary and his HIV was well controlled on medication.

Previous investigations had shown an Hb of 13.4 g/dL, and eGFR 63 mL/min/1.73m^2. Blood tests for markers of iron deficiency were requested, which showed a serum ferritin of 281 µg/L, a TSAT of 14%, and Hb 13.1 g/dL. High-sensitivity CRP was 4 mg/dL, consistent with low-grade inflammation secondary to ulcerative colitis but excluding active infection. Urine protein dipstick test was negative.

CONSIDERATIONS

The diagnosis of iron deficiency was explained to the patient and that correction with IV iron might improve symptoms and exercise capacity more quickly and with fewer gastro-intestinal side effects than oral iron. The need to administer IV iron under close supervision because of rare but potentially serious adverse reactions was discussed and it was proposed to do this as a day-case. The patient was keen to see what benefit IV iron might confer.

No evidence of infection was found, either clinically or from blood tests, before proceeding with IV iron replacement therapy.

CASE STUDY 2

PATIENT EXPERIENCES

The infusion was uneventful apart from a skin reaction due to the dressing around the cannula, which was reported as an adverse drug reaction.

Response to treatment over the following 12 weeks was excellent and the patient reported improved exercise capacity and less fatigue.

INTERVENTIONS

Blood tests at 1 month after iron infusion showed serum ferritin 461 µg/L, TSAT 28% and Hb 13.8 g/dL.

Six months post-infusion, the patient complained of further shortness of breath on exertion with mild peripheral oedema. Blood tests did not suggest recurrence of iron deficiency, or deterioration in renal function. Ramipril was stopped for 48 hours and sacubitril/valsartan initiated (managed by the cardiac rehabilitation team). Symptoms of heart failure again improved.

Approximately 7 months after the above review (more than a year after the initial IV iron infusion), the patient complained again of fatigue. Blood tests confirmed recurrence of iron deficiency (ferritin 90 µg/L; TSAT 18%; Hb 12.3 g/dL). He was subsequently given 1.5 g IV iron as ferric carboxymaltose in two divided doses at least 1 week apart, which was the required dose for his bodyweight and Hb level.

Repeat blood tests 1 month post-infusion showed a good response to treatment (ferritin 473 µg/L; TSAT 27%; Hb 13.4 g/dL). Routine blood tests over the following 24 months showed stable ferritin, TSAT and Hb; on one occasion the patient had raised ferritin and CRP (1250 µg/L and 71 mg/dL, respectively); however, these were attributed to a chest infection and normalised with antibiotic treatment.

OUTCOME

Symptoms of fatigue improved substantially with IV iron therapy and this was maintained whilst iron stores remained replete. Currently, the patient reports feeling well, with few heart failure symptoms (NYHA class I) and an LVEF of 41%; no further changes to medication have been required, although we do intend to start him on an SGLT2 inhibitor in view of recent trial evidence. Blood tests for iron deficiency are done routinely at each 6 month follow-up visit.

LEARNING POINTS / KEY CLINICAL POINTS

1. It is important to be aware of infection, particularly in immunosuppressed patients, and the effect this can have on serum ferritin. Fears exist that IV iron might exacerbate active infections. Although the evidence is weak, it seems wise to control infection before giving iron.

2. There is a little awareness of how common iron deficiency is in patients with heart failure even in the absence of anaemia (at least as defined by WHO). Inflammatory conditions including HIV, inflammatory bowel disease and heart failure itself increase serum ferritin, which can confound interpretation. TSAT may be the better marker of iron deficiency in patients with underlying inflammation.

3. For patients with heart failure and iron deficiency, IV iron replacement can improve symptoms and exercise capacity, adding to the benefits of other treatments for heart failure. Comprehensive therapy can lead to sustained improvements in patient wellbeing.

CRP, C-reactive protein; eGFR, estimated glomerular filtration rate; Hb, haemoglobin; HIV, human immunodeficiency virus; IV, intravenous; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; TSAT, transferrin saturation; WHO, World Health Organisation.

CASE STUDY 3

ROUTINE SCREENING FOR IRON DEFICIENCY IN HEART FAILURE AND ADMINISTERING IV IRON IN A PRIMARY CARE SETTING

Contributing author: Ms Norma Caples, Advanced Nurse Practitioner Heart Failure, University Hospital Waterford, Ireland

PATIENT INFO

Age 68

Sex F

CASE HISTORY

This patient initially presented with blood-stained sputum, fatigue and breathlessness in February 2021. Medical history included smoking, hypertension, family history of ischaemic heart disease and a percutaneous coronary intervention to left anterior descending artery. Prescribed medications included aspirin, pantoprazole, rosuvastatin, lercanidipine and ramipril.

The patient was initially reviewed by a respiratory consultant. CT thorax showed cardiac enlargement but bronchoscopy was normal. The patient's symptoms gradually worsened with dyspnoea on minimal exertion NYHA class III and fatigue.

The patient was in sinus rhythm with a blood pressure of 162/104 mmHg. An echocardiogram showed an LVEF of 55% and a dilated left atrium with an NT-proBNP of 1702 ng/L. Breathlessness improved and systolic blood pressure fell by 7 mmHg with bumetanide. An exercise stress test was inconclusive. An angiogram showed patent coronary arteries. The patient was referred to the OutReach heart failure clinic based in primary care.

IDENTIFICATION AND DIAGNOSIS OF IRON DEFICIENCY

All OutReach clinic patients are routinely screened for iron deficiency at their first visit.

The blood test confirmed iron deficiency (ferritin 15 µg/L; TSAT 15%; Hb 11.2 g/dL) and eGFR of 56 mL/min/1.73m^2. A faecal immunochemical test was negative.

CONSIDERATIONS

The diagnosis of iron deficiency and treatment options were explained to the patient.

Haemoptysis was considered an unlikely cause of iron deficiency. Intermittent gastrointestinal blood loss exacerbated by aspirin or reduced iron absorption due to pantoprazole and/or heart failure itself were considered more likely causes.

The patient was initially prescribed oral iron but did not tolerate the treatment. After 3 months, IV iron was prescribed.

As this patient works full-time, it was more convenient for her to attend her local primary care centre for the IV iron infusion appointment, which could be done together with her heart failure review. This avoided a long journey to the hospital and admission to the medical day ward in the hospital.

CASE STUDY 3

PATIENT EXPERIENCES

The IV iron infusion was well-tolerated.

INTERVENTIONS

The patient received an IV iron infusion (ferric carboxymaltose) during her scheduled OutReach heart failure clinic appointment 2 weeks after the diagnosis of iron deficiency. Blood tests were repeated after 3 months and showed correction of iron deficiency (serum ferritin 168 µg/L; TSAT 32%). Hb has risen to 13.4 g/dL.

OUTCOME

The patient's symptoms improved post-infusion.

In view of persisting hypertension (blood pressure 152/96 mmHg) and low serum potassium (3.7 mmol/L), spironolactone 25 mg/d was initiated.

Annual checks on iron stores will be carried out unless Hb declines, or symptoms increase.

ESC RECOMMENDATIONS FOR IV IRON

In symptomatic patients with HFrEF and HFmrEF, and iron deficiency, IV iron supplementation with ferric carboxymaltose or ferric derisomaltose should be considered to reduce the risk of HF hospitalisation – IV iron supplementation is also recommended to alleviate HF symptoms and improve quality of life.[1]

Currently, there are limited data available for the treatment of ID with IV iron in HFpEF patients. Oral iron should thus be first-line treatment. Only where patients do not tolerate oral iron or where oral iron has not been effective, is treatment with IV iron indicated.

LEARNING POINTS / KEY CLINICAL POINTS

1. All patients with heart failure should be routinely screened for iron deficiency, because it is common and treatable. This is true for HFpEF as well as HFrEF.

   Administering IV iron in a primary care setting may be preferred by patients and can be done provided the facility is equipped and staff trained to manage rare but potentially serious adverse reactions.

2. Fatigue, reduced exercise capacity and breathlessness may all be symptoms of iron deficiency.

3. Treating comorbidities such as iron deficiency, anaemia and hypertension often improve symptoms of HFpEF and might also improve prognosis.

1. McDonagh TA et al. Eur Heart J. 2023;ehad195.

CT, computerised tomography; eGFR, estimated glomerular filtration rate; Hb, haemoglobin; HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; IV, intravenous; LVEF, left ventricular ejection fraction; NT-proBNP, N-terminal pro b-type natriuretic peptide; NYHA; New York Heart Association; TSAT, transferrin saturation.

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

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

Additional information is available on request

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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

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