Medicine Guideline

Iron Sucrose (Venofer®)

Areas where Protocol/Guideline applicable	SESLHD
Authorised Prescribers:	Medical Officers
Clinical condition	Iron deficiency anaemia
Indication for use	1. **Paediatrics patients:** Treatment of iron deficiency in haemodialysis patients receiving erythropoietin. 2. Supply obtained in the community via the PBS (General Schedule without restriction) for administration to non-admitted patients. 3. Adult inpatients **unable to tolerate alternative preparations of IV iron**, for the treatment of iron deficiency, under the following conditions: • When oral iron preparations are ineffective or cannot be used. • Where there is a clinical need to deliver iron rapidly. • The diagnosis must be based on laboratory tests.
Proposed Place in Therapy	Refer to SESLHD/753 - Iron Infusion Procedure for decision algorithm
Contra-indications	• Anaemia not caused by simple iron deficiency (e.g., Haemolytic anaemia, megaloblastic anaemia caused by vitamin B12 deficiency, disturbances in erythropoiesis, hypoplasia of the marrow) • Hypersensitivity to iron sucrose or any excipients • Iron overload (e.g., haemochromatosis, haemosiderosis) • Active infections • Decompensated hepatic cirrhosis • Administration via an AV fistula/graft
Precautions	• Chronic polyarthritis • Bronchial asthma • Uncontrolled hyperparathyroidism • Hyperphosphataemia • Hepatic disease including hepatic impairment and infection hepatitis • Pregnancy ≤ 14 weeks should only be administered if clinically necessary Patients with the following conditions may be at higher risk of adverse reactions: • Low iron binding capacity • Folate deficiency • History of allergic disorders (including drug allergies) • Cardiovascular disease • Autoimmune or inflammatory conditions may be at particular risk of delayed reactions, including fever and exacerbation or reactive joint pain (e.g., rheumatoid arthritis, inflammatory bowel disease, ankylosing spondylitis, and lupus erythematosus). • Oral iron must be ceased 24 hours before IV iron and should not be given until 5 days after last parenteral administration.

Important Drug Interactions	The infusion should not be mixed with any other substances.
Dosage	Dose to be calculated by the treating Medical Officer. **Iron Sucrose (Venofer®)** ***mg indicates elemental iron, not iron hydroxide sucrose complex**
	Adults: The following formula can be used to calculate the dose: **Iron dose (mg) = [bodyweight (kg) x (target Hb* – actual Hb in g/L) x 0.24] + iron depot **** Patients > 34kg bodyweight: *Target Hb = 150g/L **Iron depot = 500mg Patients ≤ 34kg bodyweight: *Target Hb = 130g/L **Iron depot = 15mg/kg Example of calculation: 60 kg patient with actual Hb = 80g/L, target Hb of 150g/L and iron depot of 500mg Required iron dose = [60 x (150 – 80) x 0.24] + 500mg = 1008mg + 500mg = 1508mg This approximates to 1500mg iron = 15 ampoules Iron (as Iron Sucrose) (Venofer®) 100 mg/5 mL
	Adult haemodialysis patients: The recommended dosage of Venofer for the treatment of iron deficiency in haemodialysis patients receiving erythropoietin therapy is: - 100 mg of iron (5 mL of Venofer) delivered intravenously during the dialysis session. No more than three times per week. Most patients will require a minimum cumulative dose of 1000 mg of iron, administered over 10 sequential dialysis sessions, to achieve a favourable haemoglobin or haematocrit response.
	Paediatric Haemodialysis patients ≥ 2 years: **Initial REPLETION therapy** **Initial dose:** 1 mg/kg (max 100 mg) IV during dialysis weekly for 10 weeks. If response is inadequate dose may be increased to 3 mg/kg (max 100 mg). Further courses can be given as required if response is inadequate. **MAINTENANCE therapy** 0.5 – 1 mg/kg (max 100 mg) IV during dialysis every 2 – 4 weeks for 12 weeks. Adjust to maintain ferritin levels between 300 – 800 microg/L and % iron saturation between 25-50%. May repeat if clinically indicated.

Iron Sucrose (Venofer®)

Prescribing Instructions

Calculate dose (Refer to Dosage)

Volume and Infusion Rate

Iron Sucrose (Venofer®)
*** indicates elemental iron, not iron hydroxide sucrose complex**

Haemodialysis Patients ONLY	Inject 100–200 mg undiluted into the venous limb of the dialysis line at a rate of 1 mL/minute

IV Infusion

Dose	**Volume**	**Infusion Time**
≤ 100 mg	50-100 mL*	Over at least 15 minutes
101 - 200 mg	50-100 mL*	Over at least 30 minutes
201 – 300 mg	250 mL	Over 1.5 hours
301 – 400 mg	250 mL	Over 2.5 hours
401 – 500 mg	250 mL	Over 3.5 hours

* Do not dilute to a concentration less than 1 mg/mL

IV use for infants and children:
Dilute to not less than 1 mg/mL with sodium chloride 0.9%.
Infuse the dose at 1–1.3 mL/minute.
The maximum rate is 3.3 mg/minute.

Inpatient
Prescribing on the eMR via eFluids.

Outpatient
Prescribing on the Intravenous Adult Fluid Order Form.
The infusion is ordered as elemental iron and should include dosage, diluent, and infusion rate.

e.g., “Iron (as iron sucrose) _x_ mg in _x_ mL sodium chloride 0.9%.
Infuse over _x_ minutes”

Administration Instructions

- Iron Sucrose (Venofer®) must only be administered by intravenous route. Ampoules should be visually inspected for sediment and damage before use. Use only those containing a sediment-free and homogenous solution.
- Do not mix Iron Sucrose (Venofer®) with other medication or add to parenteral nutrition solutions for intravenous infusion.

Adverse Effects	IV administration of iron and carbohydrate complexes may result in fatal anaphylactoid reactions, consequently it is only suitable for IV administration in a medically supervised setting.
	Anaphylactoid reactions, characterised by sudden onset of respiratory difficulties, tachycardia and hypotension, occur most frequently within the first minutes of administration.
	If any signs or symptoms of reaction develop, infusion is to be stopped immediately and medical assistance called for.
	Cardiovascular resuscitation equipment MUST be readily available
	
	Adverse effects may be delayed 1-2 days post infusion.
	Immediate Adverse Effects
	• Anaphylaxis
	  ○ Bronchospasm with dyspnoea
	  ○ Faintness, syncope, tachycardia, hypotension, circulatory collapse
	  ○ Loss of consciousness
	• Central nervous System
	  ○ Headache, dizziness
	• Gastrointestinal
	  ○ Nausea, vomiting (may indicate excessive infusion rate)
	• Musculoskeletal
	  ○ Joint and muscle pain
	• Dermatological
	  ○ Rash, urticarial
	  ○ Infiltration and extravasation (Staining of surrounding tissue) If this occurs STOP infusion immediately and seek a medical review
	  ○ General - Flushing, sweating
	Delayed Adverse Effects
	• Central Nervous System
	  ○ Dizziness
	  ○ Musculoskeletal
	  ○ Arthralgia, myalgia, sensation of stiffening of arms, legs or face
	• Haematological
	  ○ Generalised lymphadenopathy
	• Dermatological
	  ○ Angioneurotic oedema, rash, urticaria
	• General
	  ○ Chills, fevers, chest and back pain

Monitoring requirements	• Baseline observations are to be recorded pre-infusion, 5 minutes after commencement of infusion and at the end of the infusion. • Patient must be observed for any adverse reaction during the infusion and for 30 minutes after the completion of the infusion. • Monitor patients for signs of extravasation during administration. Iron infusions may cause pain, inflammation, tissue necrosis, sterile abscess and permanent brown discolouration of the skin

	Maternity specific In pregnant women, fetal bradycardia may rarely occur with parenteral iron administration. Fetal heart monitoring for antenatal woman - intermittent auscultation at commencement and conclusion is adequate unless other risk factors For all pregnant and postnatal women, the eMR Standard Maternity Observation chart (SMOC) must be completed. Remain with woman at the commencement of the infusion and perform standard observations at baseline and every 30 minutes during iron infusion. Refer to site specific Workplace Instruction for further details.
Management of Complications	**Treatment of Anaphylaxis** 1. **STOP the infusion** 2. Call for help as per local clinical emergency response 3. Lie patient flat and raise their feet, if breathing is compromised sit in high fowlers position 4. Administer 100 % oxygen via mask via non rebreather mask 5. Obtain intravenous access in adults in the event of hypotension and give IV normal saline (20mL/kg) rapidly and consider large bore IV access 6. Medical Officer to give adrenaline (1:1000) immediately (0.01 mg/kg to a maximum dose of 0.5 mg) IM (repeat at 5-minute intervals if necessary) followed by hydrocortisone (4 mg/kg to a maximum of 100 mg if < 12 years or 300 mg if > 12 years) IV and promethazine (0.5 mg/kg to a maximum 50 mg) IV if required. 7. Commence CPR in the event of a respiratory or cardiac arrest. **For mild reactions:** 1. **STOP the infusion** 2. Medical Officer review to consider prescribing promethazine, hydrocortisone and/or paracetamol. If deemed safe to restart the infusion following medical review, recommence infusion at a slower rate as instructed by the treating Medical Officer If extravasation is suspected: 1. **STOP the infusion** 2. Assess the site 3. Disconnect the giving set 4. Consider aspirating any fluid back from PIVC 5. Remove the cannula 6. Apply a cold compress and elevate the affected limb 7. Seek medical review 8. Document the volume of iron infused The type of infusion related complication and action taken needs to be clearly documented in the patient's health care record and notified through ims+ for investigation.
Resources	A General Guide to Iron and Iron Deficiency: Information for Patients, Families and Carers (CEC)

Basis of Protocol/Guideline: (including sources of evidence, references)	1. MIMS Online 2023 Product Information Venofer®. Vifor Pharma Pty Ltd. Revised 01 October 2021. <Accessed 20 February 2023> 2. Rossi, S. Australian Medicines Handbook. South Australia: Australian Medicines Handbook Pty Ltd, 2019. 3. Australian Injectable Drugs Handbook 8th Edition online 2022. The Society of Hospital Pharmacists. Revised 22 November 2022. Monograph: Iron Sucrose. <Accessed 20 February 2023> 4. Meds4Kids Dosing Guide. The Children's Hospital at Westmead 2023. Monograph: Iron Sucrose. < Accessed 23 February 2023> 5. Qassim, A., Mol, B.W., Grivell, R.M. and Grzeskowiak, L.E. (2018), Safety and efficacy of intravenous iron polymaltose, iron sucrose and ferric carboxymaltose in pregnancy: A systematic review. Aust N Z J Obstet Gynaecol, 58: 22-39.
Groups consulted in development of this guideline	Haematology, Cardiology, Women's and Children's, Ambulatory Care Units, Obstetrics, Nephrology, Transfusion Medicine and Pharmacy.

AUTHORISATION	
Author (Name)	Erica Wales
Position	Quality Use of Medicines, Lead Pharmacist
Department	Clinical Governance Unit
Position Responsible for ongoing maintenance of Protocol	Quality Use of Medicines, Lead Pharmacist
GOVERNANCE	
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