Medicine Guideline

Ferric Derisomaltose (Monofer®)

Areas where Protocol/Guideline applicable	Outpatient
Authorised Prescribers:	Medical Officers
Clinical condition	Iron deficiency anaemia (i.e., ferritin < 30 µg/L and/or transferrin saturation < 20%)
Indication for use	Supply obtained in the community via the PBS (General Schedule without restriction) for administration to non-admitted patients. For the treatment of iron deficiency in adults, 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	• Pregnancy and Breastfeeding – no formal studies • 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 ferric derisomaltose 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 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).
Important Drug Interactions	The infusion should not be mixed with any other substances.

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Dosage

Dose to be calculated by the treating Medical Officer.

Ferric Derisomaltose (Monofer®) *mg indicates elemental iron, not Ferric Derisomaltose		
Hb (g/L)	**Bodyweight**	
	50 to < 70 kg	**≥ 70 kg**
< 100	1500 mg	2000 mg*
≥ 100	1000 mg	1500 mg
* Single doses above 1500 mg are not recommended. Divide dose or consider alternative iron preparation.		

Alternatively, 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 = 3 ampoules Iron (as Ferric Derisomaltose) (Monofer®) 500 mg/5 mL

Renal patients are infused:

- 500 – 1000 mg in a single infusion, OR,
- 250 mg of iron weekly for 4 doses.

Prescribing Instructions

The intramuscular (IM) route is discouraged. It is no safer than the IV route. IM iron injections tend to be painful and there is significant risk of permanent skin staining.

Calculate dose (Refer to Dosage)

Volume and Infusion Rate

Ferric Derisomaltose (Monofer®) * indicates elemental iron, not Ferric Derisomaltose			
Dose	**Up to 500 mg***	**Up to 1 g***	**Over 1 g***
Route	IV bolus injection	IV infusion	IV infusion
Volume	Maximum 20 mL	Maximum 500 mL	Maximum 500 mL
Rate	Over 2 minutes	Over 20 minutes	Over at least 30 minutes
Prescription	NIMC	Intravenous Adult Fluid Order Form.	

Order Details
The infusion is ordered as elemental iron and should include dosage, diluent, and infusion rate.
e.g., "Iron (as ferric derisomaltose) _x_ mg in _x_ mL sodium chloride 0.9%. Infuse over _x_ minutes"

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Administration Instructions	• Ferric Derisomaltose (Monofer®) must only be mixed with sterile 0.9% sodium chloride. No other intravenous dilution solutions should be used. No other therapeutic agents should be added. The diluted solution for injection should be visually inspected prior to use. Use only clear solutions without sediment. • Ferric Derisomaltose (Monofer®) must be administered by the intravenous route either by injection or by infusion. • Ferric Derisomaltose (Monofer®) may be administered during a haemodialysis session directly into the venous limb of the dialyser under the same procedures as outlined for intravenous bolus injection.

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

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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
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 Monofer® Injection. Pfizer Australia Pty Ltd. Revised 01 November 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: Ferric Derisomaltose. <Accessed 20 February 2023>
Groups consulted in development of this guideline	Haematology, Cardiology, Women's and Children's, Ambulatory Care Units, Obstetrics, Nephrology, Transfusion Medicine and Pharmacy.

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