Government of South Australia
SA Health

FERRIC CARBOXYMALTOSE (Ferinject®) Infusion

For ADULTS with confirmed iron deficiency and indications for IV iron

For Primary Care Use Only

Allergies and Adverse Drug reactions (ADR)

☐ Nil known ☐ Unknown (tick or complete details below)

Medicine (or other)	Reaction / type / date	Initials

Sign: …… Print: …… Date: ……

Family name: ……

Given names: ……

D.O.B: …… Sex: ……

Doctor: ……

⚠WARNING **Use this protocol for administration of iron carboxymaltose (Ferinject®) ONLY. Maximum dose per infusion, rate of infusion and dilution are NOT interchangeable between iron preparations.**

- ***Cardiopulmonary resuscitation facilities MUST be available***. IV iron can cause hypersensitivity reactions (including anaphylactoid), which may be fatal & can occur after previously uneventful doses
- Patients with systemic allergy to iron polymaltose (Ferrum H®, Ferrosig®) SHOULD NOT receive ferric carboxymaltose (Ferinject®), as incidence of cross reactivity is unknown: Consult an expert regarding the use of iron sucrose (Venofer®).
- In pregnant women or those with a history of hypersensitivity to IV iron, administer IV iron in a hospital setting.
- Use with caution in asthma, eczema or atopic allergies, consider in hospital use – seek expert advice

Availability: Ferric carboxymaltose (Ferinject®) is available in 100 mg / 2mL or 500 mg / 10 mL vials.
500mg vials are listed on the Pharmaceutical Benefits Scheme (PBS) for iron deficiency anaemia (IDA) where oral treatment is ineffective or cannot be used.

Prescribing Checklist: See under 'Resources' on page 2 for indications, contraindications & precautions for IV iron & seek expert advice if unsure

PRESCRIPTION:

- Calculate and complete the required dose(s) as determined by the methods below.
- **For Renal Unit patients**, dosing should be determined by their renal physician and administered as per page 2 of this protocol. Commonly patients with pre-dialysis chronic kidney disease have functional iron deficiency and receive a single 500mg dose (however the actual dose should be determined by the patient's renal physician).

Weight: ……kg **(Ideal body weight:** kg) **Hb:** g/L **Ferritin:** mcg / L

Date	**Ferric carboxymaltose (Ferinject®) in 100 mL of sodium chloride 0.9% over 15 minutes** Maximum dose per infusion is 20 mg/kg up to a maximum dose of 1000 mg (use ideal body weight if overweight)	Given by	Checked by	Start time	Stop time
……/……/……	**1st dose:** 20 mg/kg up to a maximum of 1000 mg				
……/……/……	Flush line: 50 mL sodium chloride 0.9%				
……/……/…… **At least 1 week later**	**2nd dose:** Remainder of total body iron deficit not exceeding 20 mg/kg up to 1000 mg given ≥1 week later				
……/……/……	Flush line: 50 mL sodium chloride 0.9%				

Medical Officer: **Signature** **Date: / /** **Contact No:**

ADULT DOSING TABLE: Total body iron deficit & dosage per infusion of ferric carboxymaltose (Ferinject®)

Hb (g/L)	*Body weight 35 to <50 kg	*Body weight 50 to <70 kg	*Body weight ≥70 kg
+Hb above 100 g/L	**Total iron deficit: 1000 mg** 1st dose: 500 mg 2nd dose: 500 mg	**Total iron deficit: 1000 mg** 1st dose: 1000 mg 2nd dose: not required	**Total iron deficit: 1500 mg** 1st dose: 1000 mg 2nd dose: 500 mg^
#Hb 70 - 100 g/L	**Total iron deficit: 1400 mg** 1st dose: 700 mg§ 2nd dose: 700 mg§	**Total iron deficit: 1500 mg** 1st dose: 1000 mg 2nd dose: 500 mg^	**Total iron deficit: 2000 mg** 1st dose: 1000 mg 2nd dose: 1000 mg

+ **If Hb is within the normal range** give only the first dose from the Hb ≥100 g/L section of the table above.

If Hb is <70 g/L calculate the total body iron deficit more precisely using Ganzoni formula (see product information or page 2). The first dose can be guided by the Hb <100 g/L section of the table above.

^ **In patients with ongoing blood loss or requiring surgery** with substantial blood loss, give 1000 mg for 2nd dose.

§ Where dose is >500 mg and <1000 mg use 500 mg vials (PBS listed) and discard excess.

* **Use ideal body weight in overweight patients**. If underweight, use actual body weight.

- Females: 45.5 kg + 0.9 kg/cm for each cm over 152 cm of height
- Males: 50 kg + 0.9 kg/cm for each cm over 152 cm of height

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Use this protocol for administration of ferric carboxymaltose (Ferinject®) ONLY. Maximum dose per infusion, rate of infusion and dilution are NOT interchangeable between iron preparations.

Family name: ……
Given names: ……
D.O.B: …… Sex: ……
Doctor: ……

Administration:

- Add prescribed dose of ferric carboxymaltose (Ferinject®) to a bag of 100 mL sodium chloride 0.9% (for stability reasons, dilutions to concentrations less than 2 mg/mL are not permissible).
- After dilution infuse immediately using a volumetric infusion pump over 15 minutes.
- Flush IV access with sodium chloride 0.9% to ensure patency.
- On completion attach a 100 mL bag sodium chloride 0.9% and infuse 50 mL (at the current rate) to ensure the drug is flushed through completely.
- ⚠CAUTION Long-lasting brown discoloration (staining) of the skin may occur due to leakage of the drug into the tissues around the IV insertion site. This may be permanent. In case of paravenous leakage STOP infusion immediately.
- Do not administer more than 1000 mg of ferric carboxymaltose (Ferinject®) per week.

Monitoring:

- When given in a clinic setting, the doctor is to be present onsite during the infusion and for 30 mins after.
- Facilities for cardiopulmonary resuscitation must be available. Visual observation of the patient is important.
- Monitor IV insertion site & educate patient to report any discomfort, burning, redness or swelling.
- Baseline temperature, pulse, respirations (TPR) & blood pressure (BP) & check for existing skin rashes.
- TPR & BP after 5 minutes. Ensure monitoring of IV insertion site continues.
- TPR & BP on completion, check if symptomatic (ensure patient doesn't feel faint upon mobilising).
- Patients should be observed for adverse effects for at least 30 minutes following each infusion.
- Provide patient with information sheet (see 'Resources') & include contact details in event of delayed reaction.

Adverse Effects:

Common (≥1/100, <1/10), Uncommon (≥1/1,000, <1/100), Rare (≥1/10,000, <1/1,000)

Hypersensitivity: Uncommon: hypersensitivity reactions**.** Rare: anaphylactoid reactions.

Vascular: Uncommon: hypotension, flushing.

Gastrointestinal: Common: nausea. Uncommon: vomiting.

CNS: Common: headache, dizziness.

Musculoskeletal: Uncommon: myalgia, back pain, arthralgia.

Respiratory: Uncommon: dyspnea.

Dermatological: Uncommon: pruritus, urticaria, rash.

General*:* Common: injection site reactions. Uncommon: pyrexia, fatigue, peripheral oedema.

Adverse Reaction Management:

- Stop the infusion immediately. Institute emergency care and notify medical officer.
- In case of acute allergic reaction, refer to local acute allergic reaction / anaphylaxis management guideline.

Resources:

Iron deficiency anaemia (IDA) APP at www.bloodsafelearning.org.au or clinical update on IDA at www.mja.com.au

IV iron prescribing checklist at www.sahealth.sa.gov.au/bloodsafe

IV iron patient information leaflet including translations at www.sahealth.sa.gov.au/bloodsafe

References: Vifor. Ferinject®. Product Information AU E10. Vifor Pharma Pty Ltd, Victoria. 1 July 2016;
CALHN. Ferric Carboxymaltose (Ferinject®): Infusion protocol for Non-Renal, Adult Patients. Version 2.0. Dec 2015.

GANZONI formula for calculation of total body deficit: (round dose to nearest 100mg)

Total body iron deficit in mg = iron depot + [weight in kg x 0.24 x (target Hb in g/L – actual Hb in g/L)]

- Use ideal body weight if overweight / obese
- Iron depot (iron stores):
  - 500 mg for body weight greater than or equal to 35 kg
  - 15 mg/kg body weight for body weight less than 35 kg
- Target Hb:
  - 150 g/L for body weight greater than or equal to 35 kg
  - 130 g/L for body weight less than 35 kg