

This procedure is for the administration of Iron Carboxymaltose FERINJECT® ONLY

Do NOT use for any other form of iron as the doses, rate of infusion, dilution are not interchangeable.

Ensure you have the correct product.

This protocol is for adults with confirmed Iron Deficiency and indications for Intravenous Iron.

1 Purpose

This procedure describes the process for the intravenous infusion of iron (ferric) Carboxymaltose

2 Scope

This procedure relates to patients requiring iron carboxymaltose for the treatment of iron deficiency.

References: WA Health Department – re: iron infusion

3 Procedure

- A medical order must be obtained for the iron infusion. Check the prescription for dose, volume of fluid and rate of infusion.
- Previous reactions, sensitivities or allergic reactions to iron must be determined prior to the infusion for the doctor to assess if clinically significant.
- Weigh the patient.
- Obtain a set of baseline observations: temperature, pulse, respirations and blood pressure, and oxygen saturation (finger oximetry).
- Inform the patient to notify staff if any symptoms of;
 - Sudden Gastrointestinal distress and/or anxiety
 - Chest tightness
 - Shortness of breath
 - Racing heart
 - Nausea

- Pain at the cannula site.
- Emergency trolley, including Adrenaline 1:1000mg x 3 amps.
- Ensure a Medical Practitioner will be in the vicinity and easily contactable for the duration of the iron infusion and for 30 minutes post infusion.
- **The nurse or doctor administering the iron infusion needs to stay with the patient at all times during the iron infusion. Owing to the risk of anaphylaxis during and post infusion, the patient must not be left alone at any stage up to 30 minutes post infusion.**
- Insert an intravenous cannula – sited in the distal area of an upper extremity, avoiding the dorsal metacarpal veins. Flush the cannula with saline 0.9% to ensure patency, before commencing iron infusion. Ensure pt. is comfortable and has no burning or pain at site when flushed.
- Document site and gauge of cannula inserted in medical chart

Iron Formulation

Ferinject[®] is the available formulation of iron (ferric) Carboxymaltose. It contains 50mg of iron per ml. A two (2) mL ampoule contains 100 mg of elemental iron and a ten (10) mL ampoule contains 500mg of elemental iron. This procedure relates only to this formulation of iron.

Interactions

- Oral iron therapy should preferably not be recommenced until at least one week following an iron infusion.
- **This preparation must not be used in the first trimester of pregnancy.**

Contraindications

- Known hypersensitivity to Ferinject[®] or to any of its excipients;
- Use with caution in pts. with elevated liver enzymes or active substance abuse.
- Confirmed previous reaction to intravenous iron to be assessed by Medical Practitioner
- Anaemia not attributed to iron deficiency, e.g. other causes of microcytic anaemia;
- Evidence of iron overload or disturbances in utilisation of iron;
- **Pregnancy in the first trimester.**

Cautions:

Pregnancy – if Ferinject is to be used after the first trimester then the Joondalup Health Campus or King Edward Memorial Hospital obstetric protocols need to be used. As a general rule, the preferred option is for these to be done in hospital because of the small risk of anaphylaxis.

Dosage

The adequate cumulative dose of Ferinject[®] must be calculated for each patient individually and must not be exceeded. The dose of Ferinject[®] is expressed in mg of elemental iron.

Patient's weight:		kg	Ideal body weight:		kg	Total body iron deficit:
						mg

Date	Ferric Carboxymaltose (Ferinject®): in 100mLs of Sodium chloride 0.9% over 15 minutes Maximum dose per infusion is 20mg/kg up to a maximum of 1000mg (use ideal body weight if overweight)	Start Time	Administered by:	Checked by:
...../...../.....	First dose: 20mg/kg up to a maximum of 1000mg			
...../...../..... At least 1 week later	Second dose: Remainder of total body iron deficit (not exceeding 20mg/kg up to 1000mg) given ≥1 week later			

Medical Officer: .Signature.....Date: /...../.....

Contact NO:

Calculation of the total body iron deficit:

- The cumulative dose of Ferric Carboxymaltose (Ferinject®) for repletion of the **total body iron deficit** is based on patient weight (use ideal body weight if overweight) & haemoglobin (Hb) and must not be exceeded.
- Many patients will require 2 infusions (at least 1 week apart) to cumulatively replace the total body iron deficit (because there is a maximum dose per infusion that CANNOT be exceeded - see 'Dosage per infusion' below).
- The total body iron deficit can be approximated using the table below. If the **Hb <70g/L** use the **Ganzoni Equation** (Appendix 1) to calculate the total body iron deficit more precisely. The first dose can however be guided by the <100g/L section of the table below (3 infusions at least a week apart may be required).
- Also calculate the total body iron deficit in **iron deficiency with a normal Hb** as it is less than in the table and generally only requires 1 infusion.

Dosage per infusion:

- Maximum dose of Ferric Carboxymaltose (Ferinject®) per infusion is **20mg/kg to maximum of 1000mg**. Use ideal body weight in overweight patients.
- **The first dose** of Ferric Carboxymaltose (Ferinject®) is given at 20mg/kg to a maximum of 1000mg.
- **A second dose** can be given ≥1 week later to replace the remainder of the calculated total body iron deficit (see table below) but not exceeding maximum dose per infusion of 20mg/kg to a maximum of 1000mg.

- **In patients with ongoing blood loss or requiring surgery** associated with substantial blood loss, 20mg/kg to a maximum of 1000mg can be given for both doses.

ADULT: Approximate 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 ≥100 g/L	Total deficit: 1000 mg	Total deficit: 1000 mg	Total deficit: 1500 mg
	1 st dose: 500 mg 2 nd dose: 500 mg	1 st dose: 1000 mg 2 nd dose: not required	1 st dose: 1000 mg 2 nd dose: 500 mg
#Hb <100 g/L	Total deficit: 1400 mg	Total deficit: 1500 mg	Total deficit: 2000 mg
	1 st dose: 700 mg 2 nd dose: 700 mg	1 st dose: 1000 mg 2 nd dose: 500 mg	1 st dose: 1000 mg 2 nd dose: 1000 mg

#If Hb normal or Hb <70 g/L, or when preferred by the prescriber, calculate total body iron deficit more precisely using the Ganzoni formula.

*Use ideal body weight in overweight/obese patients (If underweight, use actual body weight).

A woman's ideal body weight (medium frame) will be ≥50kg if her height is ≥157 cm or ≥5'2

A man's ideal body weight (medium frame) will be ≥50kg if his height is ≥152 cm or ≥5'0

Administration:

Preparation of the Infusion

Iron infusions must be delivered via a volumetric infusion device, no test dose is required.

Carboxymaltose (Ferinject)® must only be mixed with 0.9% Sodium Chloride as there is the potential for precipitation and/or interaction with other solutions and therapeutic agents.

Assemble equipment:

- Intravenous administration set
- Required ampoules of iron (Ferinject®)
- Required volume of Sodium Chloride 0.9%
- Additive label for the fluid bag
- Syringe/needles to draw up the iron and add to the fluid bag
- 70% Isopropyl Alcohol swabs

Add iron to the infusion fluid

- Perform hand hygiene
- Using aseptic technique, draw up the prescribed iron volume and add it to the infusion bag.
- Add the label, which includes the patient's name, the name and quantity of the drug, type and quantity of the fluid bag, time and date of preparation. The label is signed by general practitioner and a registered nurse or two (2) nurses, one of whom must be a registered nurse.

- Gently rotate the infusion bag to mix the contents.
- Spike an IV administration set and prime.
- Insert the administration set into the volumetric pump.
- Perform hand hygiene.
- Flush the intravenous cannula with at least 10ml 0.9% Sodium Chloride to ascertain patency of the cannula immediately prior to connecting the iron infusion.

For stability reasons, dilutions to concentrations less than 2 mg iron/mL are not allowed.

Observations (documented)

- Temperature, pulse, respirations and blood pressure as per normal observations at baseline and at initial 5 minutes, and at the end of the infusion and at 30 minutes post infusion.
- Patients may be discharged 30 minutes post infusion if observations are satisfactory.
- Remove the intravenous cannula prior to discharge.

Adverse Effects

- If there are any adverse effects, cease the infusion immediately, and contact the medical practitioner on site.
- If the patient complains of pain cease the infusion immediately, do not disconnect line from pt. contact the medical practitioner on site for assessment and treatment.
- Hypotension is often dose related and the decision may be made to administer the infusion over a longer period of time.
- For mild reactions; give promethazine (Phenergan), hydrocortisone and paracetamol as ordered by medical practitioner.
- If anaphylaxis occurs, it is recommended that affected patients are not exposed to further infusions of Iron Carboxymaltose.

Immediate symptoms	Delayed symptoms
Bronchospasm with dyspnoea	Dizziness/syncope
Hypotension with circulatory collapse	Chest and/or back pain
Tachycardia	Chills, fever
Facial flushing, faintness, joint, muscle pain	Urticarial and rash
Vomiting and nausea	Stiffness in face and limbs
Headache	Angioneurotic oedema

Tissue infiltration (extravasation) with iron

Caution should be exercised to avoid Para venous leakage when administering Ferinject. Para venous leakage of Ferinject at the injection site may lead to irritation of the skin and potentially long lasting brown discoloration at the site of injection. In case of Para venous leakage, the administration of Ferinject must be stopped immediately.

The important indicator of the severity of the extravasation is **PAIN**. (No necrosis of the skin has ever been reported).

In the event of the iron infusion infiltrating tissue surrounding the intravenous cannula insertion site:

- Immediate cease the infusion DO NOT DISCONNECT THE LINE.
- Contact the medical practitioner on site for assessment and treatment

- Apply a cold compress. **DO NOT COVER THE SITE WITH BANDAGES**

References and Suggested Reading

Ballie, G.R.Mason, N.A Valaoras T.G 2010 “Safety and tolerability of intravenous ferric Carboxymaltose in patients with iron deficiency anemia” Hemodialysis International vol.14pp.47-54

<http://www.tga.gov.au/pdf/auspar/auspar-ferric.pdf>

NHS Tayside June 2008. *Extravasation Policy for All Drugs, Chemotherapy & Non-Chemotherapy*. Retrieved December 10, 2010 from <http://www.nhstaysideadtc.scot.nhs.uk/approved/policy/EXTRAV.PDF>

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4 Consultation

Key Stakeholders who reviewed this version are:

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|-------------------------|--|
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Audit Strategy

Level of risk	Medium
Audit strategy	To be determined
Audit tool attached	No
Audit date	Annual
Audit responsibility	To be determined
Key Elements/ Indicators / Outcomes	100% of patients prescribed this medication will have it administered as per the elements of this procedure

Appendix: 1. Ganzoni Equation:

The standard method for calculating the total iron deficit is the Ganzoni Equation. This formula gives the total iron deficit and dose in mg for restoration of haemoglobin (Hb) & repletion of body iron stores.

Round the calculated dose to the nearest 100mg. Note: vial sizes are 100mg and 500mg.

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 (store): >34kg weight =500mg; ≤34kg weight =15mg/kg weight to a maximum of 500mg
- Target Hb: >34kg weight=150g/L; ≤34kg weight=130g/L

Ideal body weight is calculated from the following formula (Australian Medicines Handbook):

www.amh.net.au/online/misc/idealweightcalculator.html

- **Females:** 45.5 kg + 0.9 kg/cm for each cm >152 cm. **Males:** 50 kg + 0.9 kg/cm for each cm >152 cm.
- Add 10% for a heavy frame; subtract 10% for a light frame.

