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)

<table>
<thead>
<tr>
<th>Medicine (or other)</th>
<th>Reaction / type / date</th>
<th>Initials</th>
</tr>
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Sign: ______________________ Print: ______________________ Date: __________

**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

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

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

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

<table>
<thead>
<tr>
<th>Hb (g/L)</th>
<th><em>Body weight 35 to &lt;50 kg</em></th>
<th><em>Body weight 50 to &lt;70 kg</em></th>
<th><em>Body weight ≥70 kg</em></th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Hb above 100 g/L</em></td>
<td>Total iron deficit: 1000 mg</td>
<td>Total iron deficit: 1000 mg</td>
<td>Total iron deficit: 1500 mg</td>
</tr>
<tr>
<td>1st dose: 500 mg</td>
<td>1st dose: 1000 mg</td>
<td>1st dose: 1000 mg</td>
<td></td>
</tr>
<tr>
<td>2nd dose: 500 mg</td>
<td>2nd dose: not required</td>
<td>2nd dose: 500 mg*</td>
<td></td>
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<tr>
<td><em>Hb 70 - 100 g/L</em></td>
<td>Total iron deficit: 1400 mg</td>
<td>Total iron deficit: 1500 mg</td>
<td>Total iron deficit: 2000 mg</td>
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<tr>
<td>1st dose: 700 mg*</td>
<td>1st dose: 1000 mg</td>
<td>1st dose: 1000 mg</td>
<td></td>
</tr>
<tr>
<td>2nd dose: 700 mg*</td>
<td>2nd dose: not required</td>
<td>2nd dose: 500 mg*</td>
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</tr>
</tbody>
</table>

* 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.
* 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

BloodSafe TP-L3-420, v1.0, 01/08/2017  Review Date 01/08/2019
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.

**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. 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:**

**References:**

**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

Reasonable care has been taken to ensure this information is up to date & accurate at the time of creation. SA Health does not warrant its completeness and excludes liability where permitted by law. Health care professionals must continue to rely upon their own skill, care and inquiries taking into account the individual circumstances of each patient when providing medical advice.