Iron deficiency anaemia in pregnancy

Anaemia is defined as a low haemoglobin (Hb) concentration, and is highly prevalent throughout pregnancy.

In pregnancy, physiological expansion of plasma volume exceeds the increased production of red blood cells and haemoglobin, resulting in a physiologically lowered Hb level.
Pregnancy is associated with an increased requirement for iron

During pregnancy, the increased production of red blood cells and the needs of the developing foetus increases the requirement for iron. When there are insufficient maternal iron stores to meet the demands of pregnancy, iron deficiency anaemia may develop. Iron deficiency is the most common cause of anaemia in pregnancy.

<table>
<thead>
<tr>
<th>Haemoglobin concentration:</th>
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</thead>
<tbody>
<tr>
<td>&lt;110 g/l in first trimester</td>
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<tr>
<td>&lt;105 g/l in second and third trimesters</td>
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<tr>
<td>&lt;100 g/l postpartum</td>
</tr>
</tbody>
</table>

Anaemia in pregnancy

Iron deficiency anaemia in pregnancy is associated with:

- Increased risk of both maternal and perinatal morbidity and mortality
- Important potential implications for the future neuro-development of the infant
Iron deficiency should be considered in all pregnant women

- Hb concentration should be routinely measured at booking and at around 28 weeks' gestation
- Systems must be in place for timely review of blood test results, including monitoring the response to therapy

In anaemic women, oral iron should be used for diagnostic and therapeutic purposes

- If anaemia without an obvious other cause is detected, a diagnostic trial of oral iron should be given without delay, with a repeat full blood count in 2–3 weeks
- If there has been no improvement in Hb following 2 weeks of optimal therapy and compliance with oral iron, more definitive testing and treatment is required

Non-anaemic women at risk of iron deficiency should also be identified

- Many iron-depleted women are not yet anaemic when they first present in pregnancy
- Non-anaemic women at risk of iron deficiency* should be given prophylactic iron empirically or have serum ferritin checked first

*Women with previous anaemia, multiparity ≥P3; twin or higher order multiple pregnancy; interpregnancy interval <1 year; women who have poor dietary habits; those following a vegetarian/vegan diet; pregnant teenagers; recent history of clinically significant bleeding
Management of iron deficiency anaemia in pregnancy

Dietary advice

- All pregnant women should receive dietary advice, but it is not possible to ensure repletion in iron-deficient pregnant women through diet alone.

Oral iron preparations

- 40–80 mg of ferrous iron salts every morning is recommended*.
- Specialist medical care is required if anaemia is severe (Hb <70 g/l) and/or associated with significant symptoms or advanced gestation (>34 weeks), or if the Hb is failing to respond after 2–3 weeks of correctly taken oral iron.

Intravenous iron therapy

IV iron should be considered for women:

- With confirmed iron deficiency anaemia who are intolerant of, or do not respond to, oral iron from the second trimester onwards.
- Who present after 34 weeks' gestation with confirmed iron deficiency anaemia and an Hb of <100 g/l.

*Optimal absorption may occur from alternate day dosing due to higher hepcidin levels with consecutive day dosing. A balance between optimal absorption, compliance and the need for a rapid response influence dosing frequency.
Summary of fast and high dose IV iron preparations available in the UK

<table>
<thead>
<tr>
<th></th>
<th>Ferinject (iron [III] carboxymaltose)</th>
<th>Monofer (ferric derisomaltose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max single dose for infusion</td>
<td>Up to 20 mg/kg bw (maximum of 1000 mg/week)</td>
<td>Up to 20 mg/kg bw</td>
</tr>
<tr>
<td>Infusion time</td>
<td>15 min</td>
<td>Up to 1000 mg: &gt;15 min &gt;1000 mg: ≥30 min²</td>
</tr>
<tr>
<td>Use in pregnancy</td>
<td>Avoid in first trimester</td>
<td>Avoid in first trimester</td>
</tr>
<tr>
<td>Lactation</td>
<td>&lt;1% iron passed into milk; unlikely to be significant</td>
<td>Low transfer of iron into milk; unlikely to be significant</td>
</tr>
<tr>
<td>Adverse drug-related events*</td>
<td>Risk of anaphylactoid reaction &gt;1/10 000 to &lt;1/1000</td>
<td>Risk of anaphylaxis/anaphylactoid reactions &gt;1/10 000 to &lt;1/1000</td>
</tr>
</tbody>
</table>

*Foetal bradycardia may occur following administration of parenteral irons. It is usually transient and a consequence of a hypersensitivity reaction in the mother. The unborn baby should be carefully monitored during IV iron administration²

Safety profile of IV iron

Genuine hypersensitivity is not common and no difference between the risk for hypersensitivity reactions has been identified among IV iron products available in the UK.

The EMA concluded that the benefits of IV iron outweigh the risks in the treatment of iron deficiency when the oral route is insufficient or poorly tolerated.
Management of postpartum iron deficiency anaemia

Prompt recognition of iron deficiency in the antenatal period followed by iron therapy may reduce the risk of postpartum anaemia

Detection of iron deficiency

After delivery, check Hb within 48 h in the following circumstances:
- Blood loss >500 ml
- Uncorrected anaemia detected in the antenatal period
- Symptoms suggestive of anaemia postnatally

Treatment with oral iron

Offer oral elemental iron (40–80 mg/day) for at least 3 months to:
- Women with Hb <100 g/l within 48 h of delivery; and
- Who are haemodynamically stable, asymptomatic, or mildly symptomatic

Treatment with IV iron

Consider IV iron postpartum in women:
- Who are previously intolerant of, or do not respond to, oral iron; and/or
- In whom the severity of anaemia symptoms requires prompt management

The decision to transfuse women in the postpartum period should be based on careful evaluation, considering oral or parenteral iron therapy as alternatives
Monofer can support your management of iron deficiency anaemia in pregnancy*

- Monofer is the only fast IV iron that can be administered in single doses >1000 mg, up to 20 mg/kg²
- This may reduce the number of infusions required with Monofer vs other IV irons³

Potential benefits of Monofer include:

**Rapid and sustained correction of iron deficiency anaemia¹**

Iron deficiency anaemia has important potential implications for maternal outcomes and the future neuro-development of the infant¹

**Fewer infusions†³**

Fewer infusions can mean fewer appointments for your patients and improved cost-effectiveness and resource utilisation for your clinic³,⁴

**Low incidence of severe hypophosphataemia⁵–⁷**

Monofer offers an established safety profile, with studies showing no marked association with severe hypophosphataemia²,⁵–⁷

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* Treatment with IV iron should be confined to second and third trimester if the benefit is judged to outweigh the potential risk for both the mother and foetus⁸
† Compared with iron preparations that require multiple treatments⁴
Monofer® (ferric derisomaltose) prescribing information

This medicinal product is subject to additional monitoring, and healthcare professionals are asked to report any suspected adverse reaction

**Note:** Before prescribing please read full Summary of Product Characteristics

**Pharmaceutical form:** Ferric derisomaltose is a dark brown, non transparent solution for injection/infusion.

**Presentations:** In the form of ferric derisomaltose; 100 mg/ml available in vials of 100 mg/ml, 500 mg/5 ml and 1,000 mg/10 ml.

**Indications:** Monofer® is indicated in patients ≥18 years for treatment of iron deficiency when oral iron preparations are ineffective or cannot be used or when there is a need to deliver iron rapidly. The diagnosis must be based on laboratory tests. Each IV iron administration is associated with a risk of a hypersensitivity reaction. Thus, to minimise risk, the number of single IV iron administrations should be kept to a minimum. The iron need can be determined using either the Simplified Table, or the Ganzoni formula, or a fixed dose of 1,000 mg can be given to patients ≥50 kg body weight followed by re-evaluation for further iron need, please consult full Summary of Product Characteristics. Monofer® may be administered as an IV bolus injection of up to 500 mg at an administration rate of up to 250 mg iron/minute up to three times a week, during a haemodialysis session directly into the venous limb of the dialyser under the same procedures as outlined for IV bolus injection, or as an up to 20 mg iron per kg body weight infusion. If the iron need exceeds 20 mg iron per kg body weight, the dose must be split into two administrations with an interval of at least one week. It is recommended whenever possible to give 20 mg iron/kg body weight in the first administration. Dependent on clinical judgement the second administration could await follow-up laboratory tests. Doses up to 1,000 mg must be administered over >15 minutes; doses above 1,000 mg must be administered over ≥30 minutes. In case of infusion, Monofer® should be infused undiluted or diluted in 0.9% sodium chloride. For stability, Monofer® should not be diluted to concentrations less than 1 mg iron/ml and never diluted in more than 500 ml.

**Contraindications:** Non-iron deficiency anaemia, iron overload or disturbances in utilisation of iron, hypersensitivity to any of the ingredients, compensated liver disease, or known serious hypersensitivity to other parenteral iron products. Parenterally administered iron preparations can cause hypersensitivity reactions including potentially fatal anaphylactic/anaphylactoid reactions. The risk is enhanced for patients with known allergies, a history of severe asthma, eczema or other atopic allergy, and in patients with immune or inflammatory conditions. Monofer® should only be administered in the presence of staff trained to manage anaphylactic reactions where full resuscitation facilities are available (including 1:1000 adrenaline solution). Each patient should be observed for at least 30 minutes following administration. If hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately. In patients with compensated liver dysfunction, parenteral iron should only be administered after careful benefit/risk assessment. Careful monitoring of iron status is recommended to avoid iron overload. Parenteral iron should be used with caution in case of acute or chronic infection. Monofer® should not be used in patients with ongoing bacteraemia. Hypotensive episodes may occur if intravenous injection is administered too rapidly. Caution should be exercised to avoid paravenous leakage when administering Monofer®. **Pregnancy:** Monofer® should not be used during pregnancy unless clearly necessary. The treatment should be confined to second and third trimester. In rare cases, foetal bradycardia has been observed in pregnant women with hypersensitivity reactions. The unborn baby should be carefully monitored during intravenous administration of parenteral irons in pregnant women.

**Undesirable effects:** No very common (≥10 %) undesirable effects listed. Common undesirable effects (1 % to 10 %); nausea; rash; injection site reactions. For information on other undesirable effects, please consult full Summary of Product Characteristics. Legal Category: POM. **Package Quantities and basic Prices:** 5 vials of 1 ml, £84.75; 5 vials of 5 ml, £423.75; 2 vials of 10 ml, £339.00. **Marketing Authorisation Number/Holder:** PL 18380/001, Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark. **Date of preparation:** August 2020. Further information is available on request to Pharmacosmos UK.

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**Adverse events should be reported.** Reporting forms and information can be found at https://yellowcard.mhra.gov.uk.

**Adverse events should also be reported to Pharmacosmos UK Ltd.**

E: pvuk@pharmacosmos.co.uk

T: +44 1844 269 007

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