

Maternity – Intravenous Iron Infusion

Monofer Prescribing and Administration Guideline

The purpose of this guideline is to advise medical and nursing staff on the safe prescribing and administration of Monofer®. Please refer to the summary of product characteristics (SPC available at www.medicines.org.uk) for full prescribing information.

1. Dosage and frequency of use

The dose of Monofer is expressed in milligrams (mg) of elemental iron. The cumulative dose of iron using Monofer is determined based on the patient's body weight and haemoglobin (Hb) level and must not be exceeded. It is the prescriber's responsibility to ensure this is done correctly. The following table should be used to determine the cumulative iron dose required:

| Hb (g/L) | Patients with booking body weight 50kg to ≤75kg | Patients with booking body weight > 75kg |
|----------|---|--|
| ≥90 | 1000mg | 1500mg |
| <90 | 1500mg | 2000mg |

Note:

- Actual booking body weight should be used for patients with body mass index (BMI) <30
- Ideal body weight should be used for obese patients (BMI ≥30) (see appendix 1) at booking
- Individualised dosing using the Ganzoni formula (see the SPC) is recommended for patients weighing <50kg at booking
- Maximum dose is 20mg/kg in a single infusion. If cumulative iron dose exceeds 20mg/kg it must be delivered in divided infusions 1 week apart. Alternatively Hb can be repeated 2 weeks post 20mg/kg maximum infusion and further infusion arranged only if anaemia persists.

See Appendix 1. for Dose Calculation Flow chart

Referral for iron infusion on CLOMA

- Once decision for antenatal iron infusion has been made by Obstetrician, a phone call to Day Assessment Unit (DAU) should be made (ext 33846) to arrange date and time of infusion.
- A drug chart with iron prescription, ancillary medications and given infusion date should be brought to CLOMA. The labour ward pharmacist will review and authorise the prescription prior to patient appointment.
- Patients should be provided with an **information sheet** at time of referral
 - Basic information about iron infusion & what to expect

- Appointment date and time
- Directions to Labour ward (CLOMA)
- Contact information
- Instruction to call labour ward on morning of planned IV iron infusion to confirm availability. Ext 33849 (If labour ward/CLOMA very busy the appointment may need to be rescheduled)
- Fatigue score form for completion at time of infusion (may also be attached to drug chart and patient requested to fill out on day of iron infusion)

2. Patient monitoring before, during and after infusion

- A set of observations (blood pressure (BP), pulse rate (HR), saturations (SaO₂%), temperature (T)) and MEWS score should be recorded **prior to infusion**.
- Ask the woman whether she has felt baby move normally/has any concerns **prior to infusion**. If concerns will need a CTG in triage.
- If the patient has any signs or symptoms of infection inform a doctor (bleep 1901 to speak to labour ward anaesthetic registrar). They will decide whether it is appropriate to delay the infusion until the infection has resolved.
- Relevant past medical history and allergies on should have been reviewed by the doctor at time of dose calculation/prescription (see **Appendix 1**) and should be confirmed by midwife administering the infusion.
- **During infusion** observations should be monitored **every 15 minutes** (BP, HR, SaO₂, MEWS score).
- **Following infusion** observations should be monitored **every 15 minutes for 30 minutes** (BP, HR, SaO₂, MEWS score).
- If patient feels unwell, observations become unstable or you suspect a hypersensitivity reaction the infusion should be stopped. Most reactions are self-limiting and infusion can be restarted and delivered more slowly. Alert doctor (bleep 1901 labour ward anaesthetic registrar).
- Anaphylactic reactions are characterised by sudden onset respiratory and or cardiovascular collapse +/- rashes/itching/swelling within the first few minutes of infusion.
They can be fatal.
Infusion must be stopped and disconnected immediately.
Appropriate resuscitation equipment and skilled help must be readily available (crash call 2222 via switchboard).
Drugs required for management of suspected anaphylaxis are available in the clinical area in a pre-prepared 'ANAPHYLAXIS KIT'

See Appendix 2 for reaction management algorithm and anaphylaxis protocol

3. Method of administration

- Doses should be diluted in 100ml sodium chloride 0.9% (although volumes up to 500ml are acceptable where appropriate) and administered by IV infusion. Only sodium chloride 0.9% should be used for dilution and flushing of cannula pre and post infusion.
- Doses up to 1000mg to be administered over 15 minutes.
- Doses above 1000mg to be administered over 30 minutes.
- No other therapeutic agents should be added.

Storage and handling

- Inspect vials for sediment and damage before use and only use if sediment free.
- Store vials at room temperature.
- Each vial is intended for single use. Any unused product should be discarded.

See Appendix 3 for prescription stickers for Monofer infusion and as required medicines.

4. Contraindications, cautions, and side effects

- Contraindications to iron infusion
 - Previous history of allergy to iron preparations or true iron allergy
 - Iron overload or disturbances of iron utilisation (eg haemochromatosis)
 - Hypersensitivity to the active substance
- Cautions
 - Active infection
 - Symptomatic asthma, eczema, atopy
 - Decompensated liver disease
 - Rheumatoid arthritis/SLE

If any of the above conditions are present the patient is at greater risk of hypersensitivity reactions.
- Side effects and reactions
 - **Immediate**
 - Hypersensitivity (see **Appendix 2** for reaction management algorithm)
 - Anaphylaxis (see **Appendix 2** for reaction management algorithm)
 - Extravasation
 - Stop infusion, aspirate residual medicine via cannula, elevate limb
 - Can contact doctor and Medicines Advice Service (ext 33114)
 - Tissue damage is rare though permanent skin staining can occur.
 - **Delayed** (hours to days post infusion)
 - Uncommon** ($\geq 1:1000$ to $< 1:100$)
 - Flushing, rash
 - Cramps

- GI symptoms (nausea, vomiting, abdominal pain, constipation)
- Blurred vision, numbness
- Difficulty breathing

Rare ($\geq 1:10000$ to $< 1:1000$)

- Palpitations
- Chest pain
- Seizure, dizzy, tremor
- Myalgia, arthralgia

Any side effects however minor should be reported to a doctor (bleep 1901 labour ward anaesthetic registrar or 1707 admin anaesthetic SpR).

The patient should be advised to telephone the on call obstetric registrar (switchboard 0207 794 0500 B1p 2345) if they experience any side effects at home.

Reporting suspected adverse reactions is important for continual monitoring of risk and benefit of the medicinal product. Report any reaction via the Yellow Card Scheme (website www.mhra.gov.uk/yellowcard)

See Appendix 2 for reaction management algorithm and anaphylaxis protocol

5. Roles and responsibilities

Medical staff

- It is the referring doctor's responsibility to ensure that treatment with intravenous iron is appropriate and other causes of anaemia have been excluded using antenatal anaemia pathway (see **Appendix 4**).
- Contraindications and cautions should have been reviewed and documented and the risk-benefit ascertained. IV iron is not licenced for use in pregnant women of < 13 weeks gestation.
- Patients should be provided with an information leaflet at time of referral for iron infusion.
- An appropriate dose based on patients Hb and booking weight and not exceeding maximum single dose of 20mg/kg should be calculated using Dose Calculation Flow Chart (see **Appendix 1**).
- It is the referring doctor's responsibility to ensure the iron infusion is prescribed (pre-printed stickers to be completed with appropriate dose, signed and placed on drug chart). This will be done by an obstetrician. (See **Appendix 3**)
- It is the referring doctor's responsibility to review post infusion blood tests (Hb & ferritin) that will be organised by nursing staff via outpatient phlebotomy (4 weeks post infusion).
- It is the referring doctor's responsibility to act appropriately upon follow up blood tests (eg identify and organise repeat infusion if necessary where there is ongoing anaemia).

- A member of the medical team must be contactable for advice or to attend if the patient requires cannulation, becomes unwell or develops a hypersensitivity or anaphylactic reaction during infusion. Emergency point of contact is the anaesthetic registrar on bleep 1901. Consultant anaesthetist on the labour ward is also available for advice or assistance (ext 34933 anaesthetic department).

Midwifery staff

- Most outpatient antenatal IV iron infusions will be administered on CLOMA.
- Check for contraindications and cautions and discuss with medical team if any concerns.
- Cannulate patient if trained to do so. If not contact obstetric SHO on bleep to assist.
- Ensure infusion is prepared and administered safely and appropriately.
- Inform the patient about risk of skin discoloration and request that they tell nursing staff immediately if they experience any pain at the cannula site.
- Undertake appropriate monitoring of observations before, during (every 15 mins) and after (every 15 mins for 30 mins) infusion and record on MEWS chart.
- Document clinical episode in nursing notes: attendance, observations, patient status, any events or complications, confirm provision of patient information leaflet and provide emergency contact details.
- Place completed Fatigue score forms in designated folder in CLOMA.
- If an adverse reaction occurs it should be managed according to the reaction management algorithm (see **Appendix 2**) and must be reported via the yellow card system.

Appendix 1 Dose Calculation Flow Chart

Patient eligible for rapid IV iron infusion with Monofer (according to antenatal anaemia pathway)
Ensure relevant PMH/allergies assessed and recorded and contraindications/cautions considered
Obtain patient information: Hb, height, weight, BMI

Is patient obese (BMI ≥ 30)?

NO: use actual booking weight

YES: use ideal body weight and maximum single dose calculations

Calculate dose required for full repletion

| Hb (g/L) | Patients with pre pregnancy body weight 50kg to <75kg | Patients with pre pregnancy body weight ≥ 75 kg |
|-----------|---|--|
| ≥ 90 | 1000mg | 1500mg |
| <90 | 1500mg | 2000mg |

Is this dose more than the maximum single dose of 20mg/kg?

NO: the full dose can be given as single infusion

YES: the full dose must be split over 2 infusions

1. The 20mg/kg dose
2. The remainder of the calculated dose 1 week later

Calculation of ideal body weight if BMI ≥ 30
Female (kg): $[(\text{height (cm)} - 154) \times 0.9] + 45.5$

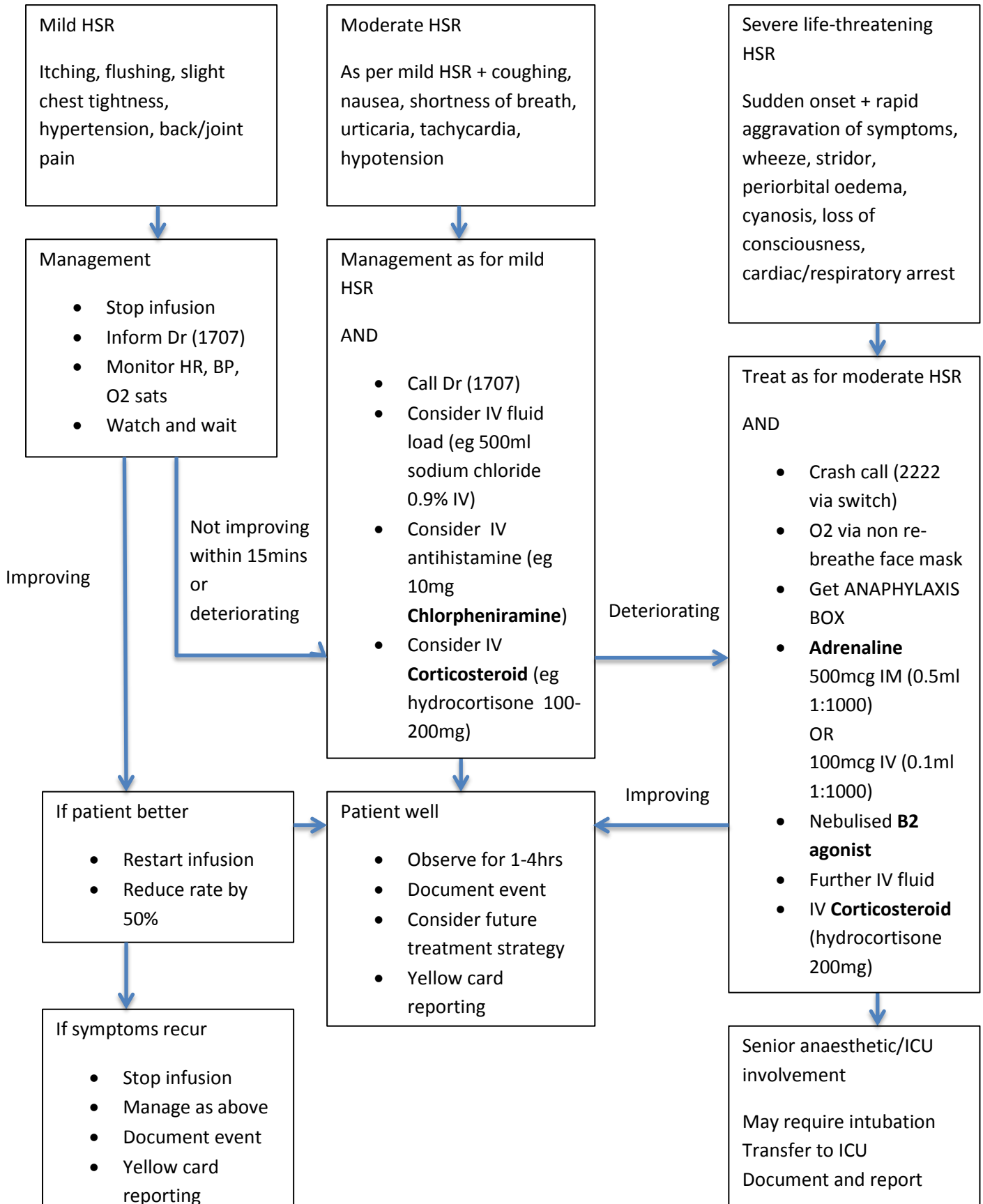
* Ganzoni formula if weight <50kg
Iron dose = Weight Kg x (Target Hb – Actual Hb g/L) x 0.24 + 500mg Suggested target Hb = 12g/L

Pre-administration questionnaire
If any of the below apply the patient will be at greater risk of hypersensitivity reactions

| PMH & Allergies (tick) | Liver disease | Rheumatoid arthritis Or SLE | |
|------------------------|---------------|------------------------------|--|
| | Asthma | Previous sensitivity to iron | |
| | Eczema | Other drug allergies | |

Appendix 2 Reaction management algorithm

Grading and management of acute hypersensitivity reactions to intravenous iron infusions



Appendix 3 (prescription stickers to be completed, signed and placed on patients drug chart)

| Patient details (attach sticker) | | | Height (cm) | | | Dosing calculation (booking weight) | | | | | |
|-------------------------------------|---------|-----------|----------------------------|-------------|--|--|------------|----------|------------|---|--|
| | | | | | | | | | | Booking Weight (kg) | |
| Name: | | | BMI | | | Hb (g/L) | | | | | |
| MRN: | | | Current Hb (g/L) | | | 50 to ≤ 75kg | | ≥90 | | >75kg | |
| DOB: | | | Target Hb 120 (g/L) | | | <90 | | 1000mg | | 1500mg | |
| Allergies: | | | | | | 1500mg | | 2000mg | | If BMI ≥30 use ideal body weight at booking | |
| | | | | | | If calculated dose >20mg/kg give as divided infusions 1 week apart (1x 20mg/kg, 1x remaining dose) rounded down to nearest 100mg | | | | | |
| Date of infusion | Drug | Dose (mg) | Infusion fluid | Route | Duration of infusion ≤1000mg over 15mins >1000mg over 30 mins via infusion pump | Batch number | Time given | Given by | Checked by | | |
| | MONOFER | | 100ml Sodium Chloride 0.9% | IV infusion | | | | | | | |
| Prescriber PRINT name & signature: | | | | | | Pharmacy | | | | | |
| Date: | | | | | | Screened by: | | | | | |
| | | | | | | Ordered by: | | | | | |

| | |
|--|------|
| PRN medicines | |
| Adrenaline 1:1000 500mcg (0.5ml) IM Stat Sign: Date: | Date |
| | Time |
| | Sign |
| Hydrocortisone 100mg (Max 500mg in 24hrs) IM or Slow IV Sign: Date: | Date |
| | Time |
| | Sign |
| Paracetamol 1g every 4-6 hours (Max dose 4g in 24hrs, reduced to 3g in 24hrs if <50kg) ORAL/IV Sign: Date: | Date |
| | Time |
| | Sign |
| Chlorpheniramine 10mg (Max 40mg in 24hrs) IV Sign: Date: | Date |
| | Time |
| | Sign |

Antenatal Anaemia Optimisation Pathway

