INTRAVENOUS IRON INFUSION

IN PREGNANCY

(MONOFER®)

Speciality:	Maternity
Approval body:	Antenatal Forum
Approval Date:	11th May 2018
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GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol
Abertawe Bro Morgannwg
University Health Board

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A. INTRODUCTION

Monofer® is a solution of iron (III) isomaltoside used to treat iron deficiency anaemia or to improve iron stores, in patients over 18 years old. This product has been included on the BHR formulary as, it may be used for total dose infusions. The intravenous administration of Monofer® by the total dose infusion method (TDI) should be restricted to hospital use only.

B. DEFINITIONS

GMC General Medical Council

Hb Haemoglobin

IV Intravenous

NMC Nursing and Midwifery Council

SPC Summary of Product Characteristics

TDI Total Dose Infusion

C. AIMS AND OBJECTIVES

This protocol exists to ensure the safe administration of Monofer® to all appropriate patients, that staff involved are appropriately trained and to ensure safe practice at all times. This policy should be read in conjunction with:

- NMC Code of Professional Conduct.
- NMC Scope of Professional Practice.
- Policy for the Care, Custody, and Safe Prescribing & Administration of Medicines.
- Policy for the Safe Use and Management of Medical Devices.
- Resuscitation Policy (Incorporating Anaphylaxis).
- “Good Medical Practice” – updated Sep. 2010 by GMC UK

D. SCOPE

Medical, nursing, midwifery and pharmacy staff involved in the dispensing prescribing and administration of iron therapy.

E. CONSENT

Explain the procedure to the patient and gain informed consent. Give information leaflet

F. PRESCRIBING AND ORDERING MONOFER®

The treatment will be prescribed by the patient's clinician on the drug chart.
The product is available through the Pharmacy Department.

G. THERAPEUTIC INDICATIONS

For adults only (over 18 years of age).

Monofer® is indicated for the treatment of iron deficiency in the following circumstances:

- When oral iron preparations are ineffective or cannot be used.
- Where there is a clinical need to deliver iron rapidly.
- The diagnosis of iron deficiency must be based on appropriate laboratory tests (e.g. serum ferritin, serum iron, transferrin saturation, haemoglobin and hypochromic red cells).

H. CONTRAINDICATIONS

- Hypersensitivity to active substance or any of its excipients.
- Non-iron deficiency anaemia (e.g. haemolytic anaemia).
- Iron overload or disturbances in utilisation of iron (e.g.haemochromatosis, haemosiderosis).
- Decompensated liver cirrhosis and hepatitis.
- Active ongoing bacteraemia.

I. SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Parenteral administration of all iron complexes may cause immediate, severe and potentially lethal hypersensitivity reactions (anaphylactoid reactions).

Facilities and personnel trained in cardio-pulmonary resuscitation must be available wherever parenteral iron is administered.

- Risk is enhanced in patients with known allergies including drug allergies or atopic allergy.

- Risk of hypersensitivity reactions may also increase in patient s with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis).
- Parenetral iron should be used with caution in cases of acute or chronic infection.
- Hypotensive episodes may occur if the intravenous injection is administered too rapidly.
- Patients should be closely observed during the infusion.

J. INTERACTIONS

- Monofer® injection should not be administered concomitantly with oral iron preparations as the absorption of oral iron will be reduced. Oral iron therapy should not be started earlier than 5 days after the last injection of Monofer®.
- Large doses of iron dextran (5ml or more) have been reported to give a brown colour to serum from a blood sample drawn four hours after administration.
- The drug may cause falsely elevated values of bilirubin and falsely decreased values of serum calcium.

K. PREGNANCY AND LACTATION

- A careful risk/benefit evaluation is required before considering use in pregnancy. Monofer® **should not** be used during the first trimester.
- Iron deficiency anaemia occurring in the first trimester of pregnancy can, in most cases, be treated with oral iron.
- Monofer® use should be confined to second and third trimesters.
- There is no available information on the excretion of Monofer® in the human breast milk.

L. UNDESIRABLE EFFECTS

- Approximately 1% of patients can be expected to experience adverse reactions. Severe reactions to Monofer® are uncommon or rare.
- Acute, severe anaphylactoid reactions are uncommon. They usually occur within the first few minutes of administration and are generally characterised by the sudden onset of respiratory difficulty and/or cardiovascular collapse.
- **Stop administration immediately if anaphylaxis signs are observed**.

- **In the event of an anaphylactoid reaction, please refer to 6.8 of the Trust Resuscitation Policy**
- Delayed reactions are well described and may be severe, although uncommon. They are characterised by arthralgia, myalgia and sometimes fever. The onset varies from several hours up to four days after administration. Symptoms usually last two to four days and settle spontaneously or following the use of simple analgesics, such as paracetamol.
- Exacerbation of joint pain in rheumatoid arthritis can occur.
- Local reactions reported are soreness and inflammation at or near injection site and local phlebitic reaction.

M. DOSE CALCULATION

Target Hb of 110g/L

Actual Hb concentration g/L

Booking weight Kg	**50**	**60**	**70**	**80**	**90**	**100**
40	**1075**	**975**	**875**	775	675	575
45	**1125**	**1025**	**925**	800	700	600
50	**1200**	**1100**	975	850	725	600
55	**1275**	**1150**	1025	875	750	625
60	**1350**	1200	1075	925	775	625
65	**1425**	1275	1100	950	800	650
70	**1500**	1325	1150	1000	825	650
75	**1575**	1400	1200	1025	850	675
80	**1650**	1450	1250	1075	875	675
85	1700	1500	1300	1100	900	700
90	1775	1550	1350	1125	925	700

- In left hand column, find the booking body weight of the patient
- Read across this row to the column headed by the haemoglobin value that matches the patient's current state. The reading at this point is the dose required expressed as mg of iron. Monofer provides 100mg iron per ml of solution. Therefore if the result is 675, add 6.75mls of Monofer (100mg/ml iron) into 100mls normal saline

- If the women's weight is above 90kg, calculate the dose using 90kg as body weight; then check Hb. and ferritin levels in 2 weeks to assess need for further iron infusion.

The dose above is expressed as mg of iron
Monofer provides 100mg iron per ml - Hence a dose of 1450 is 14.5mls of Monofer

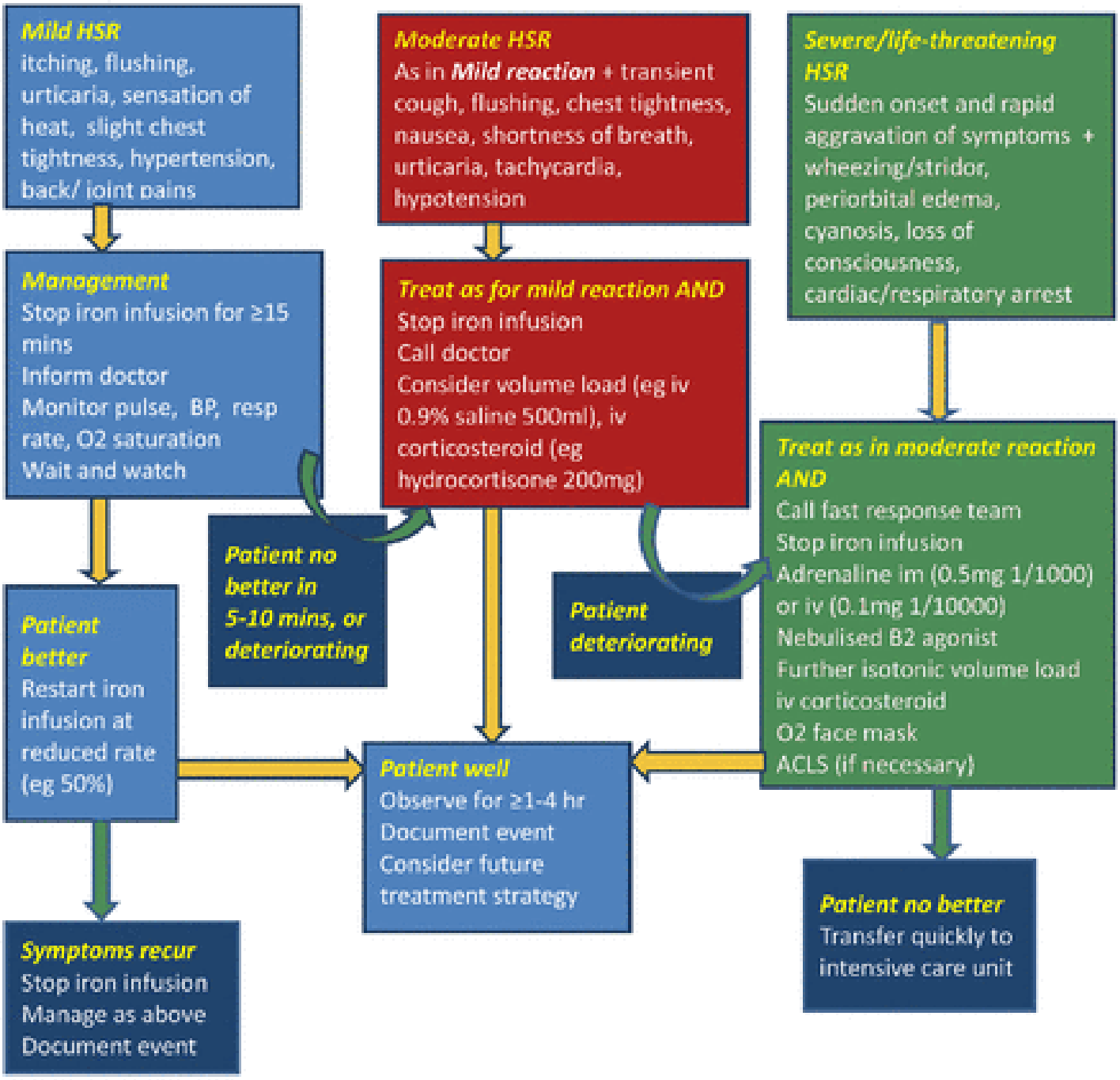
N. ADMINISTRATION OF MONOFER®

- No test dose required prior to administration.
- Staff administering Monofer® must be competent in recognising the signs and symptoms of anaphylaxis and providing immediate interventions including the delivery of intramuscular adrenaline.
- Patients receiving Monofer® should be placed in an area affording good visual observation from staff.
- Doses up to 1000mg can be administered over at least 30 minutes.
- Doses exceeding 1000mg must be administered over at least 60 minutes.
- **If the dose that you arrive at is in bold then it must be divided for administration because it is above the upper limit of 20mg/kg body weight for total dose infusion.Doses exceeding 20 mg iron/kg body weight MUST be split in two administrations at least a week apart. This can be done by giving half of the dose on each day, or by giving up to 20mg/kg in the first infusion and the remainder in the second infusion**.
- Monofer® should be added aseptically to a maximum 500mL of 0.9% sodium chloride for infusion. Once made up, the infusion should be used immediately but is stable for 48 hours at room temperature (25°C) in dilutions up to 1:250.
- Explain the procedure to the patient and gain informed consent.
- Record baseline observations: BP, pulse and temperature. Document on administration form.
- Insert appropriate cannula and test patency.
- Repeat BP and pulse every 15 minutes until infusion is completed. Document on administration form.
- Flush the cannula with 50ml 0.9% sodium chloride via pump prior to removal.
- Observe the patient for 30 minutes following the infusion. Perform and document set of observations prior to patient being discharged.

- Provide patient with blood form for Hb, ferritin and iron studies to assess their response prior to the next review.

O. HYPERSENSITIVITY

Grading and management of acute hypersensitivity reactions to intravenous iron infusions



Taken from Rampton, D. et al. (2014) Hypersensitivity reactions to intravenous iron: guidance for risk minimization and management. *Haematologica* 99(11) pp. 1671-6.

Due to limited clinical data on Monofer the quoted side effects are primarily based on safety data for other parenteral iron solutions. The risk of hypersensitivity reaction is enhanced for patients with known allergies (including drug allergies) including patients with a history of severe asthma, eczema or other atopic allergy. There is also an increased risk of hypersensitivity reactions to parenteral iron complexes in patients with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis).

- Adverse events should be reported.
- Also DATIX all reactions.
- Reporting forms and information can be found at www.yellowcard.gov.uk.

P.MONITORING

Patient Hb, ferritin and iron studies should be measured but not before 3 weeks after the last Monofer® infusion to confirm the predicted increases. Most patients are expected to be reviewed in outpatients 6 – 12 weeks after the infusion to assess overall response and saturation of iron stores.

Q. REFERENCES

Monofer® SPC – Electronic Medicines Compendium, November 2015.
Protocol for the administration of Cosmofer® Total Dose Infusion – BHRUT, June 2008.

RELATED GUIDELINES OR DOCUMENTS

Resuscitation Policy.

http://howis.wales.nhs.uk/sites3/Documents/926/CID340%20RESUSCITATION%20POLICY%202016%20%20v3.pdf

Monofer® support line

Contact our Iron Therapy Support (Mon-Fri 9am - 5.30pm):

01844 269 007

support@pharmacosmos.co.uk

PRE MONOFER® PRESCRIPTION INFUSION CHECKLIST

ADDRESSOGRAPH

WOMAN OVER 18 Y/N

IN SECOND OR THIRD TRIMESTER OF PREGNANCY Y/N

Hb _____

FERRITIN _____

HAS BEEN TAKING FERROUS SULPHATE/FUMARATE FOR 2 WEEKS AND TOLERATING Y/N

ALLERGIC TO IRON PREPARATIONS Y/N

If yes to answers below more susceptible to react to IV iron.

LIVER DISEASE Y/N

ASTHMA Y/N

ECZEMA Y/N

SLE/RHEUMATOID DISEASE Y/N

Appendix A

Monofer Administration

Addressograph	Date: Hb: Wbc: Serum Ferritin: **Decision for IV iron made by:** (Should be a SPR or Consultant)

Booking weight (Kg):_____

EDD : _____ Fetal Movements:_____ Auscultation:_____

Date of last dose of oral iron:_____(Should have stopped 24 hours prior to infusion)

Allergies: _____ **1st dose** Date : _____

Initial observations

Time:_____ BP:_____/_____ mmhg Pulse: _____ Resp rate:_____

O2 Saturation: _____% Temperature: _____

Time infusion started:_____ Doseage:_____

Monofer batch Number;_____

Peripheral intravenous cannula care bundle completed □

Inform medical team Infusion commencing □

Observations during infusion:

15 minute observations throughout infusion

Time:_____ BP:_____/_____mmhg Pulse: _____

Time:_____ BP:_____/_____mmhg Pulse: _____

Time:_____ BP:_____/_____mmhg Pulse: _____

Observations 30 minutes after dose:

Time:_____ BP:_____/_____mmhg Pulse: _____

Follow up plan .

_____

_____

Signed:_____

Print Name: Date:

Maternity Services

Checklist for Clinical Guidelines being Submitted for Approval by Maternity Quality & Safety Group

Title of Guideline:	Intravenous Iron Infusion In Pregnancy (Monofer®)
Name(s) of Author:	Jayne Bowden
Chair of Group or Committee supporting submission:	Antenatal Forum
Issue / Version No:	2
Next Review / Guideline Expiry:	11th May 2021
Details of persons included in consultation process:	AN Forum
Brief outline giving reasons for document being submitted for ratification	Renew existing policy which required updating in line with current practise
Name of Pharmacist (mandatory if drugs involved):	Ann Wilson
Please list any policies/guidelines this document will supercede:	Iron Infusion in Pregnancy (Jan 2017)
Please indicate key words you wish to be linked to document	Iron, infusion, monofer, anaemia, anaemic
Date approved by Antenatal Forum	11th May 2018
File Name: Used to locate where file is stores on hard drive	