Appendix 2

Protocol for infusion of Monofer®

Dosage and administration
Total dose infusion (TDI):
Monofer® given as total dose infusion is administered as a single dose of up to 20 mg iron/kg body weight as an intravenous drip infusion.

Doses up to 1g must be infused **over at least 15 minutes**.

Doses exceeding 1g must be infused **over at least 30 minutes.**

If the total iron dose exceeds 20 mg iron/kg body weight, the dose must be split in two administrations with an interval of at least one week. SPC recommends that wherever possible to give 20mg iron/kg in the first administration.

Monofer® should be added to 100ml sterile 0.9% sodium chloride.

From a microbiological point of view, the product should be used **immediately** if prepared at ward level.

Total dose infusion (TDI) has been associated with an increased incidence of adverse reactions, in particular delayed hypersensitivity-like reactions. The intravenous administration of Monofer® by the total dose infusion method should be restricted to hospital use only.

Calculation of the total iron dose:
The Ganzoni formula may be used for patients who are likely to require individually tailored dosing, e.g. patients with anorexia nervosa, cachexia, obesity, pregnancy or anaemia due to bleeding. Details are in the SPC for Monofer®
Use the following table for simplified dosing.

Iron need:

Hb (g/L)	Patients body weight 50kg to<70kg	Patient body weight ≥70kg
≥ 100	1000mg	1500mg
<100	1500mg	2000mg

Iron deficiency anaemia will not appear until essentially all iron stores have been depleted. Iron therapy should therefore replenish both haemoglobin iron and iron stores. After the total iron deficit has been corrected, patients may require continued therapy with Monofer® to maintain target levels of haemoglobin and acceptable limits of other iron parameters.
Evidence of a therapeutic response can be seen within a few days of administration of Monofer® as an increase in the reticulocyte count.
Serum ferritin peaks within days after an intravenous dose of Monofer® and slowly returns to baseline after about 3 weeks.

Adverse Effects
Acute, severe anaphylactoid reactions may occur with parenteral iron preparations, although they 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; fatalities have been reported. Other less severe manifestations of immediate hypersensitivity are also uncommon and include urticaria, rashes, itching, nausea and shivering. Administration must be stopped immediately if signs of an anaphylactoid reaction are observed.
Delayed reactions may also occur and can be severe. 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. In addition, exacerbation of joint pain in rheumatoid arthritis can occur and local reactions may cause pain and inflammation at or near injection site and a local phlebitic reaction.

Summary of advice for prescribers
- Use the simplified dose table to decide on the appropriate dose for most patients.
- Prescribe on HEPMA as iron isomaltoside, as an intravenous infusion. The dose is also prescribed on a fluid prescription chart with the dose, dilution and rate for the nurses to administer. Most doses may be added to a 100ml bag of sodium chloride 0.9%.
- Remember to mention the IV iron in the discharge letter and advise the GP on appropriate follow up.

Summary of advice for nursing staff
- Add the monofer to a 100ml bag of sodium chloride 0.9% and use immediately.
- Check pulse and BP before and at the end of the infusion. Ask the patient to report any itching, nausea, shivering or other signs of acute reactions. Observe the patient for 30 minutes after the infusion is complete.

Appendix 2. Prescribing & Administration Information for Monofer® (Iron Isomaltoside 1000)

STEP 1 – Calculate dose for intravenous injection

The dose of IV iron must be individually calculated based on a calculation of the patient's total iron deficit.

Monofer® (iron isomaltoside 1000) **doses for range of Haemoglobin (Hb) and body weight**				
Weight	**Hb <100g/L**		**Hb ≥100g/L and <130g/L**	
<50kg	Ganzoni formula should be used to calculate dose. Contact clinical pharmacist or medicines information department for advice.			
50 – 69kg	Week 1	1,000mg	Week 1	1,000mg
	Week 2	500mg	Week 2	-
70 – 74kg	Week 1	1,000mg	Week 1	1,000mg
	Week 2	1,000mg	Week 2	500mg
75 – 99kg	Week 1	1,500mg	Week1	1,500mg
	Week 2	500mg	Week 2	-
≥100kg	Week 1	2,000mg	Week 1	1,500mg

STEP 2 – Prescribe on ONCE ONLY section of kardex

The following is an example for a patient who weighs between 50-69kg and has a Hb <100g/L.

ONCE ONLY AND PREMEDICATION DRUGS

DATE	DRUG	DOSE	ROUTE	TIME (24hr)	PRESCRIBER (PRINT & SIGN)	GIVEN BY	TIME GIVEN (24hr)
Week 1	Monofer® (iron isomaltoside 1000)	1,000mg	IV	0900	A. Prescriber	A. Nurse	0900
Week 2	Monofer® (iron isomaltoside 1000)	500mg	IV	0900	A. Prescriber	A. Nurse	0900

STEP 3 – Prescribe on infusion chart

The table below provides information on the preparation of Monofer® (iron maltoside 1000) for a range of doses. This information should be transcribed onto an infusion chart for administration.

Monofer® (iron isomaltoside 1000)				
	Maximum weekly dose = 20mg iron/kg body weight			
Dose	500mg	1,000mg	1,500mg	2,000mg
Dose (volume) of 100mg/ml vial	500mg (5ml)	1,000mg (10ml)	1,500mg (15ml)	2,000mg (20ml)
Infusion fluid	100ml sodium chloride 0.9%*			
Drug concentration	5mg/ml	10mg/ml	15mg/ml	20mg/ml
Infusion rate	200ml/hour over 30 minutes			

Adapted with permission from GGC protocol. July 2020.