*Appendix 1*

**Protocol for infusion of Cosmofer®**

**How to select the correct dose of Cosmofer®**

In the left-hand column from the table below, find the body weight closest to the patient's body weight, read across this row to the column headed by the patients current haemoglobin value, **values for body weight and haemoglobin must be rounded up or down to the nearest stated value**. For patients >90kg, use ideal body weight rather than actual weight and for pregnant women in 2nd & 3rd trimesters, use pre-pregnancy weight to calculate the dose. The number at this point is the **dose** required (in milligrams of iron). The target Hb using the table shown is 130g/L which differs from the SPC (150g/L). Note: Labs report Hb as g/l rather than g/dL as per the SPC.

Target haemoglobin of 130g/L

| **Body weight (kg)** | **Actual haemoglobin concentration (g/L)** | | | | | |
|---|---|---|---|---|---|---|
| | 7 | 8 | 9 | 10 | 11 | 12 |
| 40 | *1000* | *900* | *800* | 700 | 600 | 500 |
| 45 | *1100* | *1000* | *900* | 800 | 700 | 600 |
| 50 | *1200* | *1100* | 900 | 800 | 700 | 600 |
| 55 | *1200* | 1100 | 1000 | 800 | 700 | 600 |
| 60 | *1300* | 1200 | 1000 | 900 | 700 | 600 |
| 65 | *1400* | 1200 | 1100 | 900 | 800 | 600 |
| 70 | *1500* | 1300 | 1100 | 1000 | 800 | 600 |
| 75 | *1500* | 1400 | 1200 | 1000 | 800 | 600 |
| 80 | *1600* | 1400 | 1200 | 1000 | 800 | 600 |
| 85 | 1700 | 1500 | 1300 | 1100 | 900 | 700 |
| 90 | 1700 | 1500 | 1300 | 1100 | 900 | 700 |

**Note: -** If the dose is shaded in grey, it exceeds the total upper limit for total dose infusion (20mg/kg body weight) and must be administered in divided doses, further explanation below the table.

**Example 74kg, current Hb 82g/L – use body weight 75kg and Hb 80g/l dose is 1400mg iron (28ml Cosmofer® injection) in 500ml Sodium Chloride 0.9%**

If the required dosage exceeds 20mg/kg, then it should be given on two separate days. This can be done either by giving half the dose on each day or by giving up to 20mg/kg in the first infusion, then the remainder in the second infusion.

An interval of one week for every 600mg of iron given in the first infusion should be allowed between the first and second doses. For example if 1200mg of iron was given in the first dose, then the second infusion containing the remaining iron should be given 2 weeks later.

**Administration of the infusion**

- Cosmofer® must be added to 500ml of Sodium Chloride 0.9% IV infusion and infused over 4 to 6 hours via an IV infusion pump. There is no upper concentration limit for the infusion to maintain product stability. From a microbiological point of view, the product should be used immediately if prepared at ward level and the patient should be monitored for 30 minutes after completion of the infusion.

- The requirement for a test dose has now been removed because it was shown not to be a reliable predictor of whether a patient would tolerate IV iron. The SPC does however still recommend that **the first 25mg is given over 15 minutes for EVERY dose**, regardless of whether the patient has previously tolerated IV doses of iron. During the first 15 minutes, the patient should be closely monitored for signs of hypersensitivity including BP and pulse.

- If the patient seems to be tolerating the first 25mg dose, increase the rate of infusion so that the remaining portion is given over 6 hours. Continue monitoring BP and pulse during the infusion every 30 – 60 minutes and 30 minutes after the end of the infusion. The patient should have the buzzer within reach and be able to alert nursing staff if they begin to feel unwell at any time.

**Management of adverse events**

In the event of a serious anaphylactic or allergic reaction **stop the infusion**, IM adrenaline should be administered and appropriate resuscitation measures initiated. Mild allergic reactions should be managed by stopping the infusion and administering antihistamines. Hypotensive episodes may occur if administration is too fast, so reduce infusion rate as clinically indicated.

**Treatment of obstetric patients with Cosmofer ®**

Cosmofer® should not be used during the first trimester but can be used during the second and third trimester and during lactation if oral iron therapy is ineffective or impracticable. Dosing for antenatal patients should be based on pre-pregnancy weight (or ideal body weight if obese prior to pregnancy).

**Follow-up**

Full blood count, reticulocyte and iron profile should be checked 3-4 weeks after the Cosmofer® infusion.

**Summary of advice for Prescribers**

- Cosmofer® is prescribed on HEPMA as iron dextran and must also be prescribed on a fluid prescription chart as follows

- Iron dextran xxxmg dose diluted in 500ml sodium chloride 0.9%

- First 25mg given over 15 minutes then remainder of dose over 6 hours.

- Remember to mention the IV iron in any discharge letter and advise the GP on appropriate follow up.

**Summary of advice for nursing staff**

- Dilute the required dose of Cosmofer® in a 500ml bag of sodium chloride 0.9%

- The first 25mg of the dose is given with close monitoring of BP and pulse and then once the rate is increased, monitor every 30 – 60 minutes during the remaining infusion time and 30 minutes after the end of the infusion.

- Leave the buzzer to hand and ask the patient to report feeling unwell at any time during the infusion.

- Avoid starting Cosmofer® infusions late in the afternoon as there are generally fewer staff around in the evenings if the patient reacts. It can usually wait until the next morning, or if the patient will be discharged, use Monofer® instead as it has a shorter infusion time. Refer to Appendix 2 for information.