

CosmoFer® Total Dose Infusion Guideline

Indication

This guideline outlines the prescribing, administration and required monitoring for **total dose** CosmoFer® (iron dextran) infusion for adult patients with iron deficiency anaemia.

The following intravenous iron preparations used in GHNHSFT are not covered by this guideline:

- Ferinject®/Monofer®
- Diafer®

Contraindications

- Non-iron deficiency anaemia
- Iron overload or disturbances in utilization of iron (e.g. haemochromatosis, haemosiderosis)
- Decompensated liver cirrhosis and hepatitis
- Acute renal failure
- Acute or chronic infection, because parenteral iron administration may exacerbate bacterial or viral infections.
- Drug hypersensitivity to the active substance or excipient in CosmoFer®, or any serious hypersensitivity to other parenteral iron preparations.

Cautions

Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic/anaphylactoid reactions. Hypersensitivity reactions have also been reported after previously uneventful doses of parenteral iron complexes.

The risk 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).

In these patients intravenous iron should only be used if the benefits outweigh the risk.

Dose calculation

$$\text{Dose (mg)} = [(A - B) \times C \times 0.24] + 500 \quad (\text{See SPC for explanation of equation})^1$$

Where: **A** = Target Haemoglobin (g/l) (Approx. Adult Male 130-180 g/l, Female 115-165g/l)²

B = Actual Haemoglobin (g/l)

C = Body weight (kg) (use ideal body weight (IBW) if [BMI](#)>30, use pre-pregnant weight if 2nd/3rd trimester)

Dose should be rounded to the nearest 25mg for ease of administration and **must not exceed 20mg/kg**

To calculate IBW, use the following equation:

$$\text{IBW (Male)} = 50\text{kg} + (2.3\text{kg} \times \text{height in inches over 5 feet})$$

$$\text{IBW (Female)} = 45.5\text{kg} + (2.3\text{kg} \times \text{height in inches over 5 feet})$$

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- Divide the calculated dose by the patient's weight (IBW if BMI >30, or actual body weight (ABW) if BMI ≤30) to **ensure it does NOT exceed 20mg/kg**.
- If dose exceeds 20mg/kg it should be rounded down to 20mg/kg OR administration of the total dose has to be split and given 7 days apart.
- Doctors – when prescribing, please ensure the patient's weight, ideal body weight (if needed), height, current Hb and target Hb are written on the drug chart.

Observations

- Check blood pressure and pulse prior to the start of the infusion.
- All patients must continue to have blood pressure and pulse checked every 15 minutes for the first hour of the total dose infusion, then every 30 minutes for the remainder of the infusion and continue for 30 minutes **after the end** of the infusion
- Hypersensitivity reactions can be delayed with total dose iron infusions; respiratory difficulty and/or cardiovascular collapse and fatalities have been reported, and so should only be administered when staff trained to evaluate hypersensitivity reactions as well as resuscitation facilities are immediately available. If there are any signs of hypersensitivity (e.g. urticaria, rashes, itching, nausea and shivering) or intolerance at any stage of the infusion, administration must be stopped immediately.

Administration

- The first 25mg should be given no faster than over 15 minutes. This is no longer classed as a test dose and should be given to every patient every time they receive CosmoFer® as a total dose infusion.³
- Add 25mg to a 50ml bag of sodium chloride 0.9% and give over 15 minutes. This dilute bag will run at 200ml per hour for 15 minutes
- If no adverse effects occur the remaining dose should be added to 500ml sodium chloride 0.9%.
- Suggested rate is 50ml per hour for 60minutes. If no adverse reactions occur, increase the rate to 100ml per hour for the next 60 minutes then increase further to 150ml per hour for the remainder of the infusion. (Hence 500ml would run over 4 hrs and 20minutes.).⁴
- Please ensure the cannula is flushed with 0.9% sodium chloride pre and post infusion, as per PGD.

Further information

When will full effects of the dose take effect?

The full effect of iron on serum Hb levels would not be seen until around 4 weeks post infusion. A clinically acceptable response would be 20g/L in 4-6 weeks post infusion; this may vary significantly between patients.⁵

Other adverse effects

Delayed reactions such as arthralgia, myalgia and sometimes fever are well described and may be severe. They can occur from several hours to four days post infusion. Symptoms may last 2-4 days and settle spontaneously or following the use of simple analgesics. Patients should be advised of this and advised to contact their GP if they experience any side effects at home after the infusion.

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.¹

It is imperative that the **discharge summary**, sent to the GP, **states that the patient has received CosmoFer®** and what the potential side effects may be. The GP should be advised to re-check FBC and ferritin at 3 months.

References:

1. Summary of Product Characteristics for CosmoFer® 50mg/ml solution for infusion and injection. Electronic Medicines Compendium. Date of revision of the text: Jan 2019
<http://www.medicines.org.uk/emc/medicine/14139>
2. GHNHSFT. Full Blood Count (FBC). Pathology. Available from: <https://www.gloshospitals.nhs.uk/our-services/services-we-offer/pathology/tests-and-investigations/full-blood-count-fbc/> [Accessed 05/06/19]
3. Intravenous iron and serious hypersensitivity reactions: new strengthened recommendations to manage and minimise risk. Drug Safety Update vol 7, issue 1 August 2013: A1.
<http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON300398>
4. Medusa. Iron Dextran (CosmoFer®). Injectable Medicines Guide. Date of revision of the text: 28/08/2018. Available from: <http://medusa.wales.nhs.uk/IVGuideDisplay.asp> [Accessed 05/06/19].
5. Personal communication. Pharmacosmos Ltd - Medical Information Department. 11/05/2017