Iron dextran (Cosmofer) Intravenous for Adults

Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

- Patient information leaflet below: print out and give to patient
- Risk management poster for IV infusion reactions - below
- Caution should be exercised to **avoid paravenous leakage** when administering intravenous iron. Paravenous leakage of intravenous iron at the administration site may lead to **irritation of the skin and potentially long lasting brown discolouration** at the site of administration. **To minimise risk, it is recommended that the smallest gauge cannula (22 gauge** [ref 3]**)**is placed in the biggest vein possible. **In the case of paravenous leakage, iron administration must be stopped immediately.**
- The European Medicines Agency has issued guidance on the administration of intravenous iron: [ref 1] Summarised below- see Further information for full details
- **Test dose no longer required**- caution with **every dose** of intravenous iron that is given, even if previous administrations have been well tolerated.
- Monitor closely **during and for at least 30 minutes following each dose** of an intravenous iron medicine.
- In case of hypersensitivity reactions, **stop the iron administration** immediately
- Certain patients are at higher risk of hypersensitivity reactions e.g. patients with a history of **severe asthma, ecezma or other atopic allergy** or with immune or inflammatory conditions such as systemic lupus erythematosus or rheumatoid arthritis
- Rapid IV use may lead to **hypotension**

Available preparations

CosmoFer 100mg (iron dextran) per 2mL ampoule

Reconstitution

Already in solution

- **Draw up using a 5 micron filter needle**
- **Dilute further prior to administration**

Infusion fluids

Sodium chloride 0.9% (preferred as less risk of thrombophlebitis [ref 1]) or Glucose 5%

Methods of intravenous administration

Method 1: GRADUAL replenishment - intravenous infusion (Preferred route) (Administer using an electronically controlled infusion device)

- Add the required dose (100 or 200mg) to 100mL infusion fluid
- On each occasion, administer the first 25mg over 15 minutes. If no adverse reaction during this time,

the remaining portion can be given at an infusion rate of maximum of 100mL over 30 minutes
- See 'monitoring' section for details on monitoring requirements

Method 2: TOTAL replenishment: Total dose infusion (Administer using an electronically controlled infusion device)

- **Important:** Increased risk of hypersensitivity reactions (in particular, delayed hypersensitivity reactions) when using this route
- See under 'dose' section for calculations and suggested regimens
- Add dose **(up to a maximum of 20mg/kg)** to 500mL of infusion fluid
- Administer the first 25mg over 15 minutes. If no adverse reactions during this time, the remainder of the infusion can be given over 4 to 6 hours [ref 2]
- See 'monitoring' section for details on monitoring requirements

Dose in adults

- The doses given below are based on what is common practice within GUH.
- For guidance on how to work out the actual dose required please see under '**Further information**' below

Total dose infusion

- While it is outside of licensed indications, it is common practice in this hospital to use a standard dose of 500 to 1000mg, repeated once if necessary (often prescribed by renal team)
- For guidance on how to calculate the dose more accurately see Further information
- NOTE: A maximum of 20mg/kg bodyweight may be given as a total dose infusion

Gradual replenishment

- Give 100mg to 200mg three times per week - the total number of doses to be given is determined by the formulas given under 'Further information'

Monitoring

- See **Important information** for details of monitoring requirements
- Monitor for adverse reactions for at least 30 minutes after each administration
- See attached document for guidance on the management of hypersensitivity reactions

Further information

EMA advice June 2013

- All intravenous iron preparations can cause serious hypersensitivity reactions which can be fatal
- As there are data indicating that allergic reactions may still occur in patients who have not reacted to a test dose, a test dose is no longer recommended. **Instead caution is warranted with every dose** of intravenous iron that is given, even if previous administrations have been well tolerated
- Intravenous iron medicines should only be administered when staff trained to evaluate and manage anaphylactic and anaphylactoid reactions are immediately available as well as **resuscitation facilities**
- Patients should be closely observed for signs and symptoms of hypersensitivity reactions **during and for at least 30 minutes following each injection of an intravenous iron medicine**
- In case of **hypersensitivity reactions**, healthcare professionals should immediately stop the iron administration and consider appropriate treatment for the hypersensitivity reaction
- Intravenous iron-containing products are contraindicated in patients with hypersensitivity to the active substance or excipients. Intravenous iron-containing products must also not be used in patients with

serious hypersensitivity to other parenteral iron products.
- Contraindicated in patients with a history of **severe asthma, eczema or other atopic allergy**, or in those with rheumatoid arthritis with signs of active inflammation
- Intravenous iron products should not be used during **pregnancy** unless clearly necessary. Treatment should be confined to the second or third trimester, provided the benefits of treatment clearly outweigh the potential serious risks to the foetus such as anoxia and foetal distress.
- All prescribers should **inform patients** of the risk and seriousness of a hypersensitivity reaction and the importance of seeking medical attention if a reaction occurs.

- **If using doses other than standard GUH doses- see below**

Step 1	**Calculate dose indicated using the guidance given below**
Step 2	**Decide on method of administration (gradual replenishment or total dose infusion)**
Example	If the required dose is 1800mg, there are two options for giving this
	a: gradual replenishment: give 200mg three times per week for three weeks (9 x 200mg)
	b: Total dose replenishment: give 1800mg as a single dose (but cannot exceed 20mg/kg as a single dose. Also, increased risk of allergic reactions with this route of administration)

An accurate way of calculating dose requirements is given as follows:

The dose is worked out differently depending on whether you need to:

A: Replenish iron stores

B: Replace blood lost during an acute bleed

Once the dose is worked out - then it can be administered either by gradual replenishment or total dose infusion.

A: REPLENISHMENT OF IRON STORES

In iron-deficiency anaemia, **total mgs iron** required (provided body weight greater than 35kg) = body weight (kg) x 2.4 x (target haemoglobin - actual haemoglobin (g/dL)) + 500

Example

Actual Haemoglobin	Total mg Iron Required (nearest 50mg) (for 70kg patient where target haemoglobin is 15g/dL)
6g/dL	2000mg
7.5g/dL	1750mg
9g/dL	1500mg
10.5g/dL	1250mg
12g/dL	1000mg
13.5g/dL	750mg

In the above example - a patient with an initial Hb of 9g/dL could receive **either** a total dose infusion of 1500mg (provided it does not exceed 20mg/kg) **or** a gradual replenishment of 200mg three times a week for 7 or 8 doses

B: REPLACEMENT OF BLOOD LOST DURING AN ACUTE BLEED

Method 1: Volume of blood lost unknown

200mg of elemental iron results in a rise in the Hb which is 'equivalent' to 1 unit of blood

Method 2: Low haemoglobin

mg iron required = body weight (kg) x 2.4 x (target haemoglobin - actual haemoglobin (g/dL)

e.g. 60kg patient with a haemoglobin of 8 g/dL , target Hb is 12 g/dL

mg iron required = 60 x 2.4 x (12 - 8) = 576 mg iron

NOTE: A maximum of 20mg/kg bodyweight may be given as a total dose infusion

Other notes

- Oral iron is not to be given until 5 days after the last injection.
- Slow IV injection - not practical (would entail slow iv injection over 10 minutes)

Storage

Store below 25^{0}C

Do not freeze

References

SPC March 2023

1: European Medicines Agency. New recommendations to manage risk of allergic reactions with intravenous Iron-containing medicines 28th June 2013

2: Injectable medicines guide Medusa. Downloaded 06/01/2025

(3) Local specialist recommendation as to size of needle- email on file 10th November 2020

Therapeutic classification

Parenteral iron