Iron as Ferric Carboxymaltose (Ferinject) 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
- The **maximum single dose** is 1000mg
- 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- 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**
- In case of hypersensitivity reactions, **stop the iron administration** immediately
- Certain patients are at higher risk of hypersensitivity e.g. patients with a history of **severe asthma, eczema or other atopic allergy,** or in immune or inflammatory disorders (eg systemic lupus erythematosus, rheumatoid arthritis)
- **Correct hypophosphatemia** prior to prescribing initial or repeat treatment [ref 2]

Available preparations

Ferinject 100mg (elemental iron) per 2mL vial

Ferinject 500mg (elemental iron) per 10mL vial

Ferinject 1000mg (elemental iron) per 20mL vial

Reconstitution

Already in solution

Infusion fluids

Sodium chloride 0.9%

Methods of intravenous administration

Can use either method of administration- choice depends on practicalities such as time available, fluid status of patient, etc.

Bolus intravenous injection

- Doses up to 200mg: Administer by bolus injection over up to two minutes
- Doses of between 201mg and 500mg- **maximum rate** is 100mg per minute
- Doses of between 501mg and 1000mg- administer over 15 minutes- **suggest IV infusion in preference**
- **Maximum** dose by this route is **15mg/kg** to a maximum of 1000mg

Intermittent intravenous infusion

- The MINIMUM PERMITTED concentration of ferric carboxymaltose is **2mg/mL,** see dilution table below for recommended volume of sodium chloride 0.9%
- **Maximum** dose by this route is **20mg/kg**, to a maximum of **1000mg**

Iron dose (mg)	Volume of Sodium chloride 0.9%	Administration time (minutes)
100 to <200	50mL *	No minimum time
200 to <500	100mL	Minimum 6 minutes
500 to 1000	250mL	Minimum 15 minutes

* The residual volume in the infusion line must be flushed through at the same rate to avoid significant underdosing

Dose in adults

- The following table should be used to calculate the **total (cumulative) iron dose**

TOTAL (cumulative) dose for repletion of iron			
Hb (g/dL)	**Body weight less than 35kg**	**Body weight 35 to less than 70kg**	**Body weight 70kg or more**
less than 10	30mg/kg	1500mg*	2000mg*
10 to 13.9	15mg/kg	1000mg	1500mg*
14 or more	15mg/kg	500mg	500mg

*** Important: this is the TOTAL (cumulative) dose that will be required**

- The **maximum single dose** is 1000mg (but maximum 15 mg/kg (IV injection), 20mg/kg (IV infusion))
- The **maximum weekly** dose is still 1000mg
- Therefore, patients who require a 2000mg dose will require **two separate doses** of 1000mg, **one week apart**

Monitoring

- See **important information** for detailed monitoring requirements
- See attached document for guidance on the management of hypersensitivity reactions
- **Monitor for hypophosphataemia** in patients who receive multiple high doses, or long term treatment, and in those with existing risk factors for hypophosphataemia

Further information

- The **European Medicines Agency** has issued guidance on the administration of intravenous iron.

- 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.
- The risk of hypersensitivity is increased in patients with **known allergies or immune or inflammatory conditions** and in patients with a history of **severe asthma, eczema or other atopic allergy**
- 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
- Oral iron must not be given until 5 days after the last injection

Storage

- Store below 25^{0}C
- Do not freeze

References

SPC September 2024

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

2. Injectable Medicines Administration guide, downloaded from Medusa 24th Feb 2025

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

Therapeutic classification

Parenteral iron