Iron sucrose (Venofer) 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 2]**)** 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 **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 conditions (eg systemic lupus erythematosus, rheumatoid arthritis)
- **Maximum dose per single administration is 200mg-** for doses higher than this, use an alternative iron preparation
- **Paravenous leakage** must be avoided because leakage of Venofer at the site of injection may lead to pain, inflammation, tissue necrosis and brown discolouration of the skin

Available preparations

Venofer 100mg per 5mL vial

Reconstitution

Already in solution

Infusion fluids

Sodium chloride 0.9%

Methods of intravenous administration

Intravenous infusion (preferred method) (maximum dose 200mg) (administer using an electronically controlled infusion device)

- Add 50mg iron to a maximum 50mL infusion fluid
- Add 100mg iron to a maximum of 100mL infusion fluid

- Add 200mg iron to a maximum of 200mL infusion fluid (i.e. remove 60mL from 250mL bag before addition of drug)
- Administer dose at a rate not exceeding 100mg per 15 minutes
- For 50mL infusion volume: the residual volume in the infusion line must be flushed through at the same rate to avoid significant underdosing
- **For doses greater than 200mg use alternative iron preparation**

Slow intravenous injection (maximum dose 200mg)

- No further dilution of injection is necessary
- Each 100mg dose must be given over at least 5 minutes
- Can also be administered during a haemodialysis session directly into the venous line of the dialysis machine
- **For doses greater than 200mg use alternative iron preparation**

Dose in adults

CAUTION: Venofer is only suitable for gradual replenishment of iron stores. If it is required that the total dose is required as a single dose infusion - use alternative iron preparation

Iron deficiency anaemia

- The normal recommended dose is 100 to 200mg iron given one to three times per week.
- The course length depends on the total iron requirements -see under Further Information for dose calculations

Monitoring

- Monitor for adverse effects for at least 30 minutes after each administration
- See attached document for guidance on the management of hypersensitivity reactions

Further information

- See next page for Dose calculations
- The **European Medicines Agency** has issued new guidance on the administration of intravenous iron (ref 1)
- 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.
- For stability reasons, concentrations less than 100mg per 100mL are not permissible
- Venofer must **only** be administered by the **intravenous route**
- Oral iron is not to be given until 5 days after the last injection

How to calculate the actual dosage which a patient will require to be administered over several weeks

- The **total number** of ampoules required to correct iron deficiency depends on the patients weight and haemoglobin levels, plus an additional amount to replenish iron stores. The following formulas are used:

- **For patients weighing more than 35kg**
    - Dose required = Bodyweight (kg) x (target Hb-actual Hb) x 2.4 +500mg
    - (Hb = Haemoglobin in g/dL, the additional 500mg is to replenish iron stores, suggested target Hb is 15g/dL)

  For patients weighing less than 35kg
    - Dose required = Bodyweight (kg) x (target Hb-actual Hb) x 2.4 +15mg/kg
    - (Hb = Haemoglobin in g/dL, the additional 15mg/kg is to replenish iron stores, suggested target Hb is 13g/dL)

  For example:
    - For a patient weighing 70kg with a Haemoglobin level of 8.5g/dL, the total dose of iron required is:
    - 70 x (15-8.5) x 2.4 +500 = 1592mg = 16 ampoules (100mg ampoule)
    - This can be given as one ampoule up to three times weekly for 16 doses, or if more rapid replenishment is required, two ampoules given up to three times weekly for 8 doses

Storage

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

References

Venofer SPC October 2019

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

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

Therapeutic classification

Parenteral iron