Iron as Iron Isomaltoside (Monover) 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
- **MAXIMUM SINGLE dose:** 20mg/kg by **infusion** (500mg as **bolus**)
- 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 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 with immune or inflammatory conditions such as systemic lupus erythematosus or rheumatoid arthritis

Available preparations

Monover 100mg (ferric derisomaltose) per 1mL vial

Monover 500mg (ferric derisomaltose) per 5mL vial

Monover 1000mg (ferric derisomaltose) per 10mL vial

Reconstitution

Already in solution

Infusion fluids

Sodium chloride 0.9%

Methods of intravenous administration

Intravenous infusion (preferred method) (administer using an electronically controlled infusion device)

- Add required dose to 100 to 500mL of 0.9% sodium chloride
- See table below for rates of administration
- Maximum dose by this route is 20mg/kg
- If the cumulative (total) iron dose exceeds 20mg/kg , the dose must be split into two administrations with a interval of at least one week. It is preferable to give 20mg/kg in the first administration

Iron dose (mg)	Administration time
1000mg (or less than)	Over more than 15 minutes
over 1000mg	30 minutes or more

Bolus intravenous injection

- May be administered by this route up to maximum dose of 500mg
- Doses of up to 500mg may be administered up to three times a week
- Maximum administration rate of 250mg iron/minute. 500mg dose must be given over at least two minutes
- May be administered undiluted or diluted in a maximum of 20mL 0.9% sodium chloride

Dose in adults

Cumulative iron dose (simplified table)

Hb(g/dL)	<50kg	50kg to <70kg	70kg or more
10 or more	500mg	1000mg (to a maximum of 20mg/kg)	1500mg (to a maximum of 20mg/kg)
Less than 10	500mg	1500mg (to a maximum of 20mg/kg)	2000mg (to a maximum of 20mg/kg)

*If the dose is 20mg/kg or below, the entire dose may be administered as an intravenous drip infusion in one visit.

*If the dose exceeds 20mg/kg , the dose must be split in multiple administrations of up to 20mg/kg with an interval of at least one week. It is preferable to give 20mg/kg in the first administration

If patient weighs <50kg- use the doses in this simplified table, or calculate dose using Ganzoni formula

Ganzoni formula (if patient greater than 35kg) - still cannot exceed 20mg/kg/dose

- Iron need(mg iron) = Body weight(kg*) x (Target Hb(g/dL) - actual Hb(g/dL)) x 2.4 + 500mg

*It is recommended to use the patient's ideal body weight for obese patients or pre-pregnancy weight for pregnant women

Monitoring

- See important information for detailed monitoring requirements
- See attached document for guidance on the management of hypersensitivity reactions

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
- Monover may only be administered by the intravenous route, or, in haemodialysis, via the venous limb of the dialyser
- Oral iron must not be given until 5 days after the last injection

Storage

- Store below 25^{0}C

References

Monover SPC July 2022

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