CSL Vifor

Ferinject® (ferric carboxymaltose)

Dosing and administration guide

Ferinject® is indicated for the treatment of iron deficiency when:
- **oral iron preparations are ineffective.**
- **oral iron preparations cannot be used.**
- **there is a clinical need to deliver iron rapidly.**

The diagnosis of iron deficiency must be based on laboratory tests.[1]

Safety information:

The most serious adverse drug reaction with Ferinject® (ferric carboxymaltose) is anaphylactic reactions with a frequency of rare (≥1/10,000 to <1/1,000). Ferinject® should only be administered when staff trained to evaluate and manage anaphylactic reactions is immediately available, in an environment where full resuscitation facilities can be assured. The patient should be observed for adverse effects for at least 30 minutes following each Ferinject® administration.[1]

Please refer to the Ferinject® SmPC for complete tolerability information.

Prescribing information can be found on the last page of this document.

Adverse events should be reported. Reporting forms and information can be found at: https://www.hpra.ie
Adverse events should also be reported to Vifor Pharma UK Ltd. Tel: +44 1276 853633 Email: medicalinfo_UK@viforpharma.com

IE-FCM-2300016
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ferinject®
ferric carboxymaltose

Ferinject® (ferric carboxymaltose)

Summary of Dosing and Administration instructions for Adults and Adolescents aged 14 years and above[1]

Please refer to the SmPC for dosing considerations in patients aged 1-13 years. Ferinject® is not recommended for use in children below 1 year of age.

The maximum weekly dose is 1000 mg iron, equivalent to 20 mL Ferinject®. If the total iron need is higher, then the administration of an additional dose should be a minimum of 7 days apart from the first dose.

IV infusion:
a single dose must not exceed 1000 mg iron or 20 mg/kg body weight.

IV injection:
a single dose must not exceed 1000 mg iron or 15 mg/kg body weight

For the maximum weekly dose for patients with body weight <35 kg, please refer to the SmPC.

A single maximum daily dose of 200 mg iron should not be exceeded in haemodialysis-dependent chronic kidney disease patients aged 14 years and above.

The individual total iron need for repletion using Ferinject® is determined based on the patient's body weight and haemoglobin (Hb) level. Two doses may be required to replenish the total iron need.

Determination of the total iron need.

Hb	Patient body weight	
g/dL	35 kg to <70 kg	70 kg and above
<10	1,500 mg	2,000 mg
10 to <14	1,000 mg	1,500 mg
≥14	500 mg	500 mg

Ferinject® administration by IV infusion or injection based on dose

IV Infusion[1]

Dose	Dilution range*	Minimum administration time
100 to 200 mg	1 – 50 mL	No time limit
>200 to 500 mg	1 – 100 mL	6 minutes
>500 to 1000 mg	1 – 250 mL	15 minutes

For stability reasons, dilution to concentrations less than 2 mg iron/mL are not permissible.

*** Maximum amount of sterile 0.9% m/V sodium chloride solution.**

IV Injection[1]

Dose	Administration time/rate
100 to 200 mg	No time limit
>200 to 500 mg	100 mg/min
>500 to 1000 mg	15 minutes

Administer undiluted Ferinject® by the intravenous injection route.

No test dose requirement.[2]

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Prescribing Information - Ireland

For full prescribing information refer to the Summary of Product Characteristics (SmPC)

Active Ingredient: Ferric carboxymaltose (50mg/mL)
Presentation: Dispersion for injection/infusion. Available as a 2mL vial (as 100mg of iron), 10mL vial (as 500mg of iron) and 20mL vial (as 1000mg of iron).
Indication: Treatment of iron deficiency when oral iron preparations are ineffective or cannot be used or if there is a clinical need to deliver iron rapidly. The diagnosis must be based on laboratory tests.
Dosage and Administration: The posology of Ferinject follows a stepwise approach:
Step 1: Determination of the iron need:
The individual iron need for repletion using Ferinject is determined based on the patient's body weight and haemoglobin (Hb) level, using the simplified table in the SmPC. Two doses may be required to replenish the total iron need.
Step 2: Calculation and administration of the maximum individual iron dose(s): Based on the total iron need determined, the appropriate dose(s) of Ferinject should be administered:
In adults and adolescents aged 14 years and older, the maximum single dose is 15 mg iron/kg body weight (for administration by intravenous injection) or 20 mg iron/kg body weight (for administration by intravenous infusion) and the maximum recommended cumulative dose of Ferinject is 1,000 mg of iron (20 mL Ferinject) per week. In children and adolescents aged 1 to 13 years, the maximum single dose is 15 mg iron/kg body weight, and the maximum recommended cumulative dose of Ferinject is 750 mg of iron (15 mL Ferinject) per week.
In all cases, if the total iron need is higher, then the administration of an additional dose should be a minimum of 7 days apart from the first dose. Administration rates for intravenous injection using undiluted dispersion: For iron doses of 100mg to 200mg, there is no prescribed administration time. For doses >200mg to 500mg, Ferinject should be administered at a rate of 100mg iron/min. For doses >500mg to 1,000mg, the minimum administration time is 15 min. Administration of intravenous drip infusion:
For iron doses of 100mg to 200mg, there is no prescribed administration time. For doses >200mg to 500mg, Ferinject should be administered in a minimum of 6 mins. For doses >500mg to 1,000mg, the minimum administration time is 15 mins. Ferinject must only be diluted in 0.9% m/V NaCl but should not be diluted to concentrations less than 2 mg iron/mL.
Step 3: Post-iron repletion assessments
Contraindications: Hypersensitivity to Ferinject or any of its excipients.Known serious hypersensitivity to other parenteral iron products. Anaemia not attributed to iron deficiency.Iron overload or disturbances in utilisation of iron.
Special warnings and precautions: Parenterally administered iron preparations can cause potentially fatal anaphylactic reactions. The risk is enhanced for patients with known allergies, a history of severe asthma, eczema or other atopic allergy, and in patients with immune or inflammatory conditions. There have been reports of hypersensitivity reactions which progressed to Kounis syndrome (acute allergic coronary arteriospasm that can result in myocardial infarction). Ferinject should only be administered in the presence of staff trained to manage anaphylactic reactions where full resuscitation facilities are available (including 1:1000 adrenaline solution). Each patient should be observed for 30 minutes following administration. If hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately. Symptomatic hypophosphataemia leading to osteomalacia and fractures requiring clinical intervention has been reported. Patients should be asked to seek medical advice if they experience symptoms. Serum phosphate should be monitored in patients who receive multiple administrations at higher doses or long-term treatment, and those with existing risk factors. In case of persisting hypophosphataemia, treatment with ferric carboxymaltose should be re-evaluated. In patients with liver dysfunction, parenteral iron should only be administered after careful risk/benefit assessment. Careful monitoring of iron status is recommended to avoid iron overload. There is no safety data on the use of single doses of more than 200mg iron in haemodialysis-dependent chronic kidney disease patients. Parenteral iron must be used with caution in case of acute or chronic infection, asthma, eczema or atopic allergies. It is recommended that treatment with Ferinject is stopped in patients with ongoing bacteraemia. In patients with chronic infection a benefit/risk evaluation has to be performed. Caution should be exercised to avoid paravenous leakage when administering Ferinject. The efficacy and safety of Ferinject has not been investigated in children below 1 year of age. Ferinject is therefore not recommended for use in children in this age group.
Special Populations: In adults and adolescents aged 14 years and older, a single maximum daily dose of 200 mg iron should not be exceeded in haemodialysis-dependent chronic kidney disease patients. In children aged 1 to 13 years with chronic kidney disease requiring haemodialysis, the efficacy and safety of Ferinject has not been investigated. Ferinject is therefore not recommended for use in children aged 1 to 13 years with chronic kidney disease requiring haemodialysis. A careful risk/benefit evaluation is required before use during pregnancy. Ferinject should not be used during pregnancy unless clearly necessary and should be confined to the second and third trimester. Foetal bradycardia may occur during administration of parenteral irons, as a consequence of hypersensitivity. The unborn baby should be carefully monitored during administration to pregnant women.
Undesirable effects: Common (≥1/100 to <1/10): Hypophosphataemia, headache, dizziness, flushing, hypertension, nausea, injection/infusion site reactions. Rare (≥1/10,000 to <1/1,000): Anaphylactic reactions. Frequency not known: Kounis syndrome, hypophosphataemic osteomalacia. Please consult the SmPC in relation to other undesirable effects
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Additional information is available on request

Adverse events should be reported.
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Tel: +44 1276 853633
Email: medicalinfo_UK@viforpharma.com

1. Ferinject® Summary of Product Characteristics. 2. EMA. *Assessment report for: Iron containing Intravenous medicinal products.* Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/IV_iron_31/WC500150771.pdf. (Accessed April 2023).

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