1 Ferinject® (ferric carboxymaltose) checklist

(Prescribing information is available on the last page)

CSL Vifor

Ferinject is indicated for treatment of iron deficiency when oral iron preparations are ineffective or cannot be used or when there is a clinical need to deliver iron rapidly. The diagnosis of iron deficiency must be based on laboratory tests.

Patient Name:	
Date of infusion:	
Patient age:	Please refer to the SmPC for correct dosing according to age.
Patient weight:	
Patient haemoglobin level:	
Patient results for Ferritin, TSAT or other iron status marker:	
Total iron need:	The individual iron need for repletion using Ferinject is determined based on the patient's body weight and haemoglobin (Hb) level. Refer to Table 1 [from the SPC] for determination of the total iron need. Two doses may be required to replenish the total iron need, see below for the maximum individual iron doses.
Amount of Ferinject to be given today:	**Note:** For stability reasons, dilutions to concentrations less than 2 mg iron/ml are not permissible. Do not administer 20 ml (1,000 mg of iron) as an injection or infusion more than once a week. **In adults and adolescents aged 14y and above, a single Ferinject administration should not exceed:** • 15 mg iron/kg body weight (for administration by intravenous injection) or 20 mg iron/kg body weight (for administration by intravenous infusion). • 1,000 mg of iron **For dosing requirements for children aged 1-13y please refer to the SmPC.**

For information on adverse drug reactions, please refer to the Ferinject summary of product characteristics

Are facilities for cardio-pulmonary resuscitation available?	**Yes**	**No**	If **No**, seek advice as cardio-pulmonary resuscitation facilities and staff trained to use them must be available: • Staff trained to evaluate and manage anaphylactic reactions • Full resuscitation facilities can be assured • Including an injectable 1:1,000 adrenaline solution • Each patient should be observed for adverse effects for at least 30 minutes
Method of administration: Refer to dosing and administration card for administration times and dilution information.	Intravenous infusion.		Intravenous injection.
	Ferinject **must not** be administered by the subcutaneous or intramuscular route.		

Duration of today's infusion: _____ **minutes**

Ferinject equivalent iron dose 100 to 200mg; there is no minimum administration time
Ferinject equivalent iron dose >200 to 500 mg; minimum administration time 6 minutes
Ferinject equivalent iron dose >500 to 1,000 mg; minimum administration time 15 minutes

Duration of today's injection: _____ **minutes**

Ferinject equivalent iron dose 100 to 200mg; there is no minimum administration time
Ferinject equivalent iron dose >200 to 500mg; adminstration rate is 100mg iron / min
Ferinject equivalent iron dose >500 to 1,000mg; minimum administration time is 15 minutes

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2 Ferinject contraindications and special precautions

Does the patient have any of the following?	Tick if YES	Additional information
Known hypersensitivity to the active substance, to Ferinject or to any of its excipients.		**Seek advice** – Ferinject is contraindicated.
Known serious hypersensitivity to other parenteral iron products.		
Anaemia not attributed to iron deficiency. e.g. other microcytic anaemia.		
Evidence of iron overload or disturbances in utilisation of iron.		
Liver dysfunction.		Ensure risk/benefit assessment has been completed.
Hepatic dysfunction where iron overload is a precipitating factor, in particular Porphyria Cutanea Tarda (PCT).		Parenteral iron should be avoided in patients with hepatic dysfunction where iron overload is a precipitating factor, in particular Porphyria Cutanea Tarda (PCT). Careful monitoring of iron status is recommended to avoid iron overload.
Hypophosphataemia (low serum phosphate levels) and hypophosphataemic osteomalacia.		Hypophosphataemia is a common (≥1/100 to <1/10) adverse drug reaction. Symptomatic hypophosphataemia leading to osteomalacia and fractures requiring clinical intervention including surgery has been reported in the post marketing setting. Frequency of hypophosphataemic osteomalacia is not known, it was exclusively reported in the post-marketing setting; estimated as rare. Patients should be asked to seek medical advice if they experience worsening fatigue with myalgias or bone pain. **Serum phosphate should be monitored in patients who receive multiple administrations at higher doses or long-term treatment, and those with existing risk factors for hypophosphataemia. In case of persisting hypophosphataemia, treatment with ferric carboxymaltose should be re-evaluated.**
Extravasation.		Caution should be exercised to avoid paravenous leakage when administering Ferinject. Paravenous leakage of Ferinject at the administration site may lead to irritation of the skin and potentially long lasting brown discolouration at the site of administration. **In case of paravenous leakage, the administration of Ferinject must be stopped immediately.**
Acute or chronic infection asthma, eczema or atopic allergies.		Use with caution. In patients with chronic infection a benefit/risk evaluation has to be performed, taking into account the suppression of erythropoiesis.
Hypersensitivity reactions.		Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic reactions. **Hypersensitivity reactions have also been reported after previously uneventful doses of parenteral iron complexes.** There have been reports of hypersensitivity reactions which progressed to Kounis syndrome (acute allergic coronary arteriospasm that can result in myocardial infarction). The risk is enhanced for patients with known allergies including drug allergies, including patients with a history of severe asthma, eczema or other atopic allergy, and in patients with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis).
Ongoing bacteraemia.		**It is recommended that the administration of Ferinject is stopped.**
Is the patient on a sodium controlled diet?		One ml of undiluted Ferinject contains up to 5.5 mg (0.24 mmol) of sodium. This has to be taken into account in patients on a sodium-controlled diet.
Does the patient have Haemodialysis-dependent chronic kidney disease?		A single maximum daily injection dose of 200 mg iron should not be exceeded in adults or adolescents aged 14 and above. Ferinject is not recommended for HD-CKD patients under 14 years of age.
Is the patient taking oral iron?		As with all parenteral iron preparations the absorption of oral iron is reduced when administered concomitantly. Therefore, if required, oral iron therapy should not be started for at least 5 days after the last injection of Ferinject.

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Pregnancy and fertility questions	Tick if YES	Additional information
Is the patient pregnant?		There are limited data from the use of Ferinject in pregnant women. A careful benefit/risk evaluation is required before use during pregnancy and Ferinject should not be used during pregnancy unless clearly necessary. Iron deficiency occurring in the first trimester of pregnancy can in many cases be treated with oral iron. Treatment with Ferinject should be confined to the second and third trimester if the benefit is judged to outweigh the potential risk for both the mother and the foetus. Foetal bradycardia may occur following administration of parenteral irons. It is usually transient and a consequence of a hypersensitivity reaction in the mother. **The unborn baby should be carefully monitored during intravenous administration of parenteral irons to pregnant women.** Animal data suggest that iron released from Ferinject can cross the placental barrier and that its use during pregnancy may influence skeletal development in the foetus.
Is the patient breast feeding?		Clinical studies showed that transfer of iron from Ferinject to human milk was negligible (≤1%). Based on limited data on breast-feeding women it is unlikely that Ferinject represents a risk to the breast-fed child.
Does the patient have any questions about fertility?		There are no data on the effect of Ferinject on human fertility. Fertility was unaffected following Ferinject treatment in animal studies.

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Pre IV injection or IV infusion checks	Tick when completed
Ensure only containers containing polyethylene and glass are used as the compatibility with containers other than those is not known.	
Do not mix Ferinject with other medicinal products except sterile 0.9% m/V sodium chloride solution. No other intravenous dilution solutions and therapeutic agents should be used, as there is the potential for precipitation and/or interaction.	
Ensure the Ferinject vial is in date. (The shelf life for Ferinject as packaged for sale is 3 years).	
Ensure Ferinject has not been stored above 30 °C or frozen.	
Inspect vials visually for sediment and damage before use. Use **only** those containing sediment-free, homogeneous solution.	
If an intravenous **injection** is to be given then ensure it is given immediately after opening the vial. From a microbiological point of view, preparations for parenteral administration should be used immediately.	
If an intravenous **infusion** is to be given ensure the infusion takes place immediately after the vial is opened and the contents diluted with sterile 0.9% m/V sodium chloride. From a microbiological point of view, preparations for parenteral administration should be used immediately after dilution with sterile 0.9% m/V sodium chloride solution.	

5 Infusion/Injection information

Monitor the patient's vital signs throughout the administration.	If allergic reactions or signs of intolerance occur during administration, the treatment **must be stopped immediately**.
Monitor the patient for paravenous leakage.	Paravenous leakage may lead to brown discolouration and irritation of the skin. In case of paravenous leakage, the administration of Ferinject **must be stopped immediately**.
Observation period.	Each patient should be observed for adverse effects for at least 30 minutes following each Ferinject infusion/ injection.

6 Post infusion

Ferinject is unlikely to impair the ability to drive or operate machines.			
Has the patient received the full dose?	**Yes**	**No**	If **No**, enter remaining dose required and next appointment date: _____ **In adults or adolescents aged 14 years and above, do not administer more than 1,000mg of Ferinject per week (20ml of Ferinject). For children aged 1-13y please refer to the SmPC.**
Post repletion, regular assessments should be completed to ensure that iron levels are corrected and maintained. Enter suggested date for review of iron status: _____			

Has the patient been given a pathology form with haemoglobin and ferritin tests requested and asked to have a blood test in 4 weeks' time via their GP or hospital? (This is to review response).	**Yes**	**No**
Return this checklist to specialist nurse.		

7 Specialist nurse follow up

Is any further action required?		If **Yes**, enter details of further action required here:
Yes	**No**	☐ Blood test ☐ Outpatient appointment ☐ Follow up infusion/injection

Blood results:	**Haemoglobin**	**Ferritin**	**CRP**	Further action required?
Request follow up appointment to review iron status.	Suggested date:			

Threshold for treatment:		
Hb	**Ferritin**	**Symptoms**
Name:	**Date:**	**Signature:**

CSL Vifor

Ferinject® (ferric carboxymaltose)
Prescribing Information - UK

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 1,000mg 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 1:1,000 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.

Legal category: POM

Price: pack of 5 x 2ml = £95.50; pack of 5 x 10ml = £477.50; pack of 1 x 20ml = £154.23

MA Number: 15240/0002

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MA Holder: Vifor France, 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris La Défense Cedex, France

Ferinject® is a registered trademark

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Adverse events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk
Adverse events should also be reported to Vifor Pharma UK Ltd. Tel: +44 1276 853633.
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