Peel sticker on reverse of this strip to adhere to a place where you can easily refer to this information

Ferinject® (ferric carboxymaltose) Dosing and Administration Summary[1]

Ferinject® does not require the Ganzoni formula to determine required dose

Ferinject® only requires patient's current weight and current haemoglobin (Hb) level to calculate the required dose of iron*

Hb (g/dL)	Body weight 35 kg to <70 kg	Body weight ≥70 kg
<10	1500 mg	2000 mg
≥10	1000 mg	1500 mg

* For overweight patients, a normal body weight / blood volume relationship should be assumed when determining the iron requirement.

A cumulative iron dose of 500 mg should not be exceeded for patients with a body weight <35 kg. For patients with an Hb≥14g/dL, an initial dose of 500 mg should be given and iron parameters checked prior to repeat dosing. 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 injection.

- A maximum single dose of 20 mg/kg body weight up to 1000 mg of iron can be administered by **intravenous drip infusion**
- A maximum single dose of 15 mg/kg body weight up to 1000 mg of iron can be administered by **intravenous injection**
- Do not administer 1000 mg of iron more than once per week

Ferinject® can be administered up to 1000 mg as an IV infusion or IV injection

IV Infusion[1]

Dose	Maximum dilution†	Minimum administration time
100 to 200 mg	50 ml	-
≥200 to 500 mg	100 ml	6 minutes
≥500 to 1000 mg	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
0-200 mg	-
>200-≤500 mg	100 mg/min
>500 mg-≤1000 mg	15 minutes

Administer undiluted Ferinject® by the intravenous injection route.

No test dose requirement

Prescribing information

ferinject®
ferric carboxymaltose

Vifor Pharma

ferinject®
ferric carboxymaltose

Ferinject® (ferric carboxymaltose)
Prescribing Information - UK

Active ingredient: Ferric carboxymaltose (50mg/mL) Presentation: Solution 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. The diagnosis must be based on laboratory tests. **Dosage and Administration:** The cumulative dose for repletion of iron using Ferinject is determined based on the patient's body weight and haemoglobin level and must not be exceeded. The table in the SmPC should be used to determine the cumulative iron dose. Intravenous injection: A maximum single dose of up to 15mg/kg bodyweight. For doses <200mg there is no prescribed administration time. For doses >200mg to ≤500mg, Ferinject should be administered at a rate of 100mg/min. For doses >500mg Ferinject should be administered over ≥15mins. Intravenous drip: A maximum single dose of up to 20mg/kg bodyweight. Ferinject must be diluted in 0.9% m/V NaCl. Do not administer 1000mg of iron (20ml) more than once a week. **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/anaphylactoid 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. 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. 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-dependant 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. **Special populations:** The use of Ferinject has not been studied in children. A careful risk/benefit evaluation is required before use during pregnancy. Ferinject should not be used during pregnancy unless clearly necessary. **Undesirable effects:** Common (≥1/100 to <1/10): Headache, dizziness, hypertension, nausea, injection site reaction, alanine aminotransferase increased, hypophosphataemia. 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 = £181.45 **MA Number:** 15240/0002 **Date of Authorisation:** 19.07.2007 **MA Holder:** Vifor France S.A. 7-13 Boulevard Paul-Emile victor, 92200 Neuilly-sur-Seine, France. **Date of revision:** 10/13

Reference:

1. Vifor Pharma. Ferinject® Summary of Product Characteristics. Available at http://www.medicines.org.uk/emc/medicine/24167/SPC Date of revision of the text October 2013.

For full prescribing information refer to the Summary of Product Characteristics. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Vifor Pharma UK Ltd. Tel: +44 1276 853633. Ferinject® is a registered trademark.

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