The most commonly reported ADR is headache, occurring in 3.3% of the patients.

Undesirable Effects from Post-marketing Spontaneous Reporting

As part of the continuing post-marketing surveillance of ferric carboxymaltose, the following adverse reactions have been observed:

Post-marketing Spontaneous Reports

System Organ Class	Preferred Terms[(1)]
Nervous System Disorders	Loss of consciousness and vertigo
Psychiatric Disorders	Anxiety
Cardiovascular Disorders	Syncope, Pre-syncope
Skin and Subcutaneous Tissue Disorders	Angioedema, dermatitis, pallor, and face oedema
Respiratory, Thoracic and Mediastinal Disorders	Bronchospasm
General Disorders and Administration Site Conditions	Influenza like illness

1 Frequency not known.

DOSAGE AND ADMINISTRATION

Determination of the cumulative iron dose
The cumulative dose for repletion of iron using FERINJECT is determined based on the patient's body weight and Hb level and must not be exceeded. There are two methods for determining the cumulative dose, the Ganzoni Method and the Simplified Method. Caution is recommended with the Simplified Method since it is based on experience in a single trial in adults with median Hb 104 g/L (range 61-146 g/L) and body weight ≥35 kg – See Clinical Trials.

Patients should be closely monitored when large single doses of FERINJECT (> 200 mg iron) are administered since the safety data are limited.

Post repletion, regular assessments should be done to ensure that iron levels are corrected and maintained.

Ganzoni Method

Cumulative Iron Dose = Body Weight *kg* x (Target Hb – Actual Hb *g/L*) x 0.24 + Iron Stores *mg*

where

Target Hb = 130 g/L for body weight <35 kg and 150 g/L for body weight ≥35 kg

Iron Stores = 15 mg/kg body weight for body weight <35 kg and 500 mg for body weight ≥35 kg.

Round down to nearest 100 mg if body weight ≤66 kg and round up to nearest 100 mg if body weight > 66 kg.

Simplified Method (for patients of body weight ≥ 35 kg)

The cumulative iron dose is determined according to the following table:

Hb g/L	Body weight 35 to < 70 kg	Body weight ≥70 kg
<100	1500 mg	2000 mg
≥100	1000 mg	1500 mg

Intravenous injection:
FERINJECT may be administered by intravenous injection using undiluted solution up to a maximum single dose of 1,000 mg iron (up to a maximum of 20 mg iron/kg body weight). For doses greater than 200 and up to 500 mg iron, FERINJECT should be administered at a rate of 100 mg iron/min. For doses greater than 500 and up to 1,000 mg iron, FERINJECT should be administered over 15 minutes. Do not administer more than 1,000 mg of iron per week.

Intravenous infusion:
FERINJECT may be administered by intravenous infusion up to a maximum single dose of 1,000 mg iron (up to a maximum of 20 mg iron/kg body weight). Do not administer more than 1,000 mg iron per week.

Haemodialysis-dependent chronic kidney disease
In haemodialysis-dependent chronic kidney disease patients, a single daily injection of FERINJECT should not exceed 200 mg iron.

Method of administration
FERINJECT must be administered only by the intravenous route: by bolus injection, or during a haemodialysis session undiluted directly into the venous limb of the dialyser, or by infusion. In case of infusion FERINJECT must be diluted only in sterile 0.9% m/V sodium chloride solution as follows:

Dilution plan of FERINJECT for intravenous infusion

FERINJECT	Iron	Maximum amount of sterile 0.9% m/V sodium chloride solution	Minimum administration time
2 to 4 mL	100 to 200 mg	50 mL	3 minutes
>4 to 10 mL	>200 to 500 mg	100 mL	6 minutes
>10 to 20 mL	>500 to 1,000 mg	250 mL	15 minutes

Note: For stability reasons, dilutions to concentrations less than 2 mg iron/mL (not including the volume of the ferric carboxymaltose solution) are not permissible.

FERINJECT must not be administered by the subcutaneous or intramuscular route.

Inspect vials visually for sediment and damage before use. Use only those containing sediment-free, homogeneous solution.

Each vial of FERINJECT is intended for single use only. Any unused product or waste material should be disposed of in accordance with local requirements.

FERINJECT must only be mixed with 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. For dilution instructions, see above.

This medicinal product must not be mixed with other medicinal products than those mentioned above. The compatibility with containers other than polyethylene and glass is not known.

OVERDOSAGE

Administration of FERINJECT in quantities exceeding the amount needed to correct iron deficit at the time of administration may lead to accumulation of iron in storage sites eventually leading to haemosiderosis. Monitoring of iron parameters such as serum ferritin and transferrin saturation may assist in recognising iron accumulation. If iron accumulation has occurred, the use of an iron chelator may be considered.

PRESENTATION AND STORAGE CONDITIONS

Presentations
2 mL of solution in a vial (type I glass) with bromobutyl rubber stopper and aluminium cap in pack sizes of 1 and 5 vials. Each 2 mL vial contains 100 mg of iron as ferric carboxymaltose.

10 mL of solution in a vial (type I glass) with bromobutyl rubber stopper and aluminium cap in pack sizes of 1 and 5 vials. Each 10 mL vial contains 500 mg of iron as ferric carboxymaltose.

Storage conditions
Store in the original package. Do not store above 30 °C. Do not freeze, do not refrigerate.

Shelf-life
Shelf-life of the product as packaged for sale:
36 months.

Shelf-life after first opening of the container:
From a microbiological point of view, preparations for parenteral administration should be used immediately.

Shelf-life after dilution with sterile 0.9% m/V sodium chloride solution:
To reduce microbiological hazard, use as soon as practicable after dilution. If storage is necessary, hold at 2-8°C for not more than 12 hours.