

Ferric Carboxymaltose INN

Composition

Hemojet 100: Each 2 ml ampoule contains 322.58 mg of Ferric Carboxymaltose INN equivalent to 100 mg of Iron.

Hemojet 500: Each 10 ml vial contains 1612.90 mg of Ferric Carboxymaltose INN equivalent to 500 mg of Iron.

Hemojet 1000: Each 20 ml vial contains 3225.80 mg of Ferric Carboxymaltose INN equivalent to 1000 mg of Iron.

Pharmacology

Ferric Carboxymaltose is a colloidal iron (iii) hydroxide complex with Carboxymaltose, a carbohydrate polymer that releases iron. Ferric Carboxymaltose solution is a dark brown, non-transparent and aqueous solution.

Indications

Ferric Carboxymaltose is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients:

- who have intolerance to oral iron or have unsatisfactory response to oral iron;
- who have non-dialysis-dependent chronic kidney disease.

Dosage and Administration

Route of administration: IV

Determination of the iron need

The individual iron need for repletion using Ferric Carboxymaltose is determined based on the patient's body weight and hemoglobin (Hb) level.

Determination of the iron need

Hb		Patient body weight		
g/dL	mmol/L	<35 kg	35 kg to <70 kg	≥70 kg
<10	<6.2	500 mg	1500 mg	2000 mg
10 to 14	6.2 to 8.7	500 mg	1000 mg	1500 mg
≥14	≥8.7	500 mg	500 mg	500 mg

Tolerated single dose

A single Ferric Carboxymaltose administration should not exceed:

- 15 mg iron/kg body weight (for administration by intravenous injection)
- 20 mg iron/kg body weight (for administration by intravenous infusion).
- The maximum recommended cumulative dose of Ferric Carboxymaltose is 1,000 mg of iron.

Post-iron repletion assessments

Re-assessment should be performed by the clinician based on the individual patient's condition. The Hb level should be re-assessed no earlier than 4 weeks post final Ferric Carboxymaltose administration. In the event the patient requires further iron repletion, the iron need should be recalculated.

Method of administration

Ferric Carboxymaltose must only be administered by the intravenous route:

- by injection or
- by infusion or
- during a hemodialysis session undiluted directly into the venous limb of the dialyzer.

Ferric Carboxymaltose must not be administered by the subcutaneous or intramuscular route.

Administration of Intravenous Injection

Ferric Carboxymaltose may be administered by intravenous injection using undiluted solution.

Administration rates for intravenous injection of Ferric Carboxymaltose

Volume of Ferric Carboxymaltose required	Equivalent iron dose	Administration rate/ Minimum administration time
2 ml	100 mg	No minimal prescribed time
10 ml	500 mg	100 mg iron/min
20 ml	1000 mg	15 minutes

Administration of Intravenous infusion

Ferric Carboxymaltose may be administered by intravenous infusion for which it must be diluted.

For infusion, Ferric Carboxymaltose must only be diluted in sterile 0.9% w/v sodium chloride solution as shown.

Note: For stability reasons, Ferric Carboxymaltose should not be diluted to concentrations less than 2 mg iron/ml (not including the volume of the Ferric Carboxymaltose solution).

Dilution plan of Ferric Carboxymaltose for intravenous infusion

Volume of Ferric Carboxymaltose required	Maximum amount of sterile 0.9% sodium chloride solution	Minimum administration time
2 ml	50 ml	6 minutes
10 ml	100 ml	15 minutes
20 ml	250 ml	15 minutes

Contraindications

The use of Ferric Carboxymaltose is contraindicated in cases of-

- Hypersensitivity to the active substance to Ferric Carboxymaltose or any of its excipients.
- Known serious hypersensitivity to other parenteral iron products.
- Evidence of iron overload or disturbances in the utilization of iron.

Warning and Precaution

Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Ferric Carboxymaltose. Monitor patients for signs and symptoms of hypersensitivity during and after Ferric Carboxymaltose administration for at least 30 minutes and until clinically stable following completion of the infusion.

Hypertension: Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness or nausea were observed.

Side effects

Common side effects: The most common side effects are nausea, injection site reactions (including pain or bruising at the injection site), asymptomatic reductions in blood phosphorus, flushing, headache, hypertension, dizziness, and increased alanine aminotransferase.

Rare side effects: Hypersensitivity, paraesthesia, dysgeusia, tachycardia, hypotension, flushing, dyspnea, vomiting, dyspepsia, abdominal pain etc.

Use in Pregnancy and Lactation

Pregnancy: Pregnancy Category C.

There is no data for the use of Ferric Carboxymaltose in pregnant women. A careful risk/benefit evaluation is required before use during pregnancy and Ferric Carboxymaltose should not be used during pregnancy unless clearly necessary.

Lactation: Ferric Carboxymaltose is excreted in human milk which is unlikely to affect the baby.

Use in children & adolescents

The use of Ferric Carboxymaltose has not been studied in children and therefore is not recommended in children under 14 years.

Drug Interactions

Formal drug interaction studies have not been performed with Ferric Carboxymaltose.

Overdose

Excessive dosages of Ferric Carboxymaltose may lead to accumulation of iron in storage sites potentially leading to hemosiderosis. Monitoring of iron parameters such as serum ferritin and transferrin saturation may assist in recognizing iron accumulation. If iron accumulation has occurred, treat according to standard medical practice, e.g. consider the use of an iron Chelator.

Storage

Store below 30° C & dry place, protected from light.

Keep all medicines out of reach of children.

Do not freeze.

Packing

Hemojet 100 IV Injection: Each commercial box contains 1 ampoule of Hemojet 100 IV injection with 100 ml normal saline, 1 ampoule breaker and a complementary pouch pack including 1 infusion set, 1 alcohol pad, 3 ml sterile disposable syringe with needle and 1 first aid bandage.

Hemojet 500 IV Injection: Each commercial box contains 1 vial of Hemojet 500 IV injection with 100 ml normal saline and a complementary pouch pack including 1 infusion set, 1 alcohol pad, 10 ml sterile disposable syringe with needle and 1 first aid bandage.

Hemojet 1000 IV Injection: Each commercial box contains 1 vial of Hemojet 1000 IV injection with 250 ml normal saline and a complementary pouch pack including 1 infusion set, 1 alcohol pad, 20 ml sterile disposable syringe with needle and 1 first aid bandage.

* Further information is available on request.