SUMMARY OF PRODUCT CHARACTERISTICS
Ferric Carboxymaltose 500 mg/10 mL Solution for Injection/Infusion

1. NAME OF THE MEDICINAL PRODUCT

FERCARI INJECTION 500MG/10ML (Ferric Carboxymaltose 500 mg/10 mL Solution for Injection/Infusion)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 mL vial contains ferric carboxymaltose equivalent to 500 mg iron (50 mg/mL).

Ferric carboxymaltose is a colloidal iron(III) hydroxide complex with carboxymaltose, a carbohydrate polymer.

Excipients with known effect:

Each mL of undiluted solution contains up to 5.5 mg (0.24 mmol) sodium, equivalent to 0.3% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection/infusion (concentrate).

Dark brown, non-transparent aqueous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ferric carboxymaltose is indicated for the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used, in adults and adolescents aged 14 years and above. Also indicated for the treatment of iron deficiency in patients with heart failure (New York Heart Association class II/III) to improve exercise capacity. ATC code: B03AC.

4.2 Posology and method of administration

Step 1: Determination of total iron need

For iron deficiency anaemia in adults, use the Ganzoni formula: Total iron need (mg) = body weight (kg) × [target Hb − actual Hb (g/dL)] × 2.4 + iron stores (mg). Iron stores for patients with body weight ≥35 kg: 500 mg.

Simplified table for iron deficit repletion in IDA based on Hb and body weight:

Hb (g/dL)	Body weight <70 kg — Single dose	Body weight ≥70 kg — Single dose
<10	1,500 mg	2,000 mg
10 to <14	1,000 mg	1,500 mg
≥14	500 mg	500 mg

Step 2: Administration

Maximum single dose: 20 mg iron/kg body weight, not to exceed 1,000 mg iron (20 mL). Maximum recommended cumulative dose: 1,000 mg/week. If total iron need exceeds 1,000 mg, the second dose must be administered at least 7 days after the first. For haemodialysis-dependent CKD: maximum single daily dose 200 mg.

Heart failure (NYHA class II/III)

Dosing based on body weight and Hb (as shown in the heart failure dosing table from EMA reference). Maintenance dose: 500 mg at 12, 24 and 36 weeks if serum ferritin <100 ng/mL or ferritin 100–300 ng/mL with TSAT <20%.

Method of administration

By intravenous route only — by injection, by infusion, or during haemodialysis into the venous limb of the dialyzer. Must not be administered subcutaneously or intramuscularly. As IV injection: administer undiluted using a maximum rate of 1 mL (50 mg iron)/minute and a minimum injection time of 10 minutes for doses up

to 500 mg. For 500 mg doses, administer as IV infusion diluted in 100 mL 0.9% sodium chloride over a minimum of 6 minutes; for 1,000 mg doses, dilute in 250 mL 0.9% sodium chloride over a minimum of 15 minutes.

4.3 Contraindications

- Hypersensitivity to ferric carboxymaltose, any of its excipients, or other parenteral iron products.
- Known serious hypersensitivity to other parenteral iron products.
- Anaemia not attributable to iron deficiency.
- Iron overload or disturbances of iron utilisation.

4.4 Special warnings and precautions for use

Hypersensitivity reactions

Anaphylactic/anaphylactoid reactions — which may be fatal — have been reported with parenteral iron preparations. In case of a hypersensitivity reaction, discontinue the injection/infusion immediately and institute appropriate emergency measures. Resuscitative facilities must be available. Administer only when staff trained to evaluate and manage anaphylaxis is present.

Infections

Parenteral iron must be used with caution in case of acute or chronic infection, asthma, eczema or atopic allergies. Discontinue in patients with ongoing bacteremia. In patients with chronic infection, perform benefit/risk evaluation.

Hypophosphataemia

Symptomatic hypophosphataemia has been reported, most often in patients receiving higher doses and in those at risk (e.g. patients with vitamin D deficiency). Monitor serum phosphate after treatment in at-risk patients.

Blood pressure

Monitor blood pressure following each administration as transient hypotension may occur.

Extravasation

Extravasation of ferric carboxymaltose causes brown skin discolouration. If extravasation occurs, stop the infusion immediately at that site. After parenteral iron, skin discolouration may be permanent.

Concomitant use with oral iron

Do not administer oral iron preparations within 5 days of a ferric carboxymaltose injection.

4.5 Interaction with other medicinal products and other forms of interaction

Ferric carboxymaltose should not be mixed with other medicinal products. Concurrent use with oral iron preparations: oral iron may reduce the absorption of ferric carboxymaltose; avoid co-administration within 5 days. No known pharmacokinetic drug-drug interactions have been identified.

4.6 Fertility, pregnancy and lactation

Pregnancy

Limited clinical data. Animal studies show iron crosses the placenta and is excreted in milk in limited amounts. Minor skeletal abnormalities in rabbit foetuses at high IV doses. Ferric carboxymaltose should be used during pregnancy only if the expected benefit justifies the potential risk to the foetus. Use after the first trimester is preferable.

Breast-feeding

Iron released from ferric carboxymaltose may be excreted in breast milk in limited amounts. No harmful effects are expected on the breast-fed infant at therapeutic doses.

Fertility

No adverse effects on fertility in animal studies.

4.7 Effects on ability to drive and use machines

Ferric carboxymaltose may have a minor influence on the ability to drive and use machines due to dizziness, headache, nausea or hypotension occurring after administration.

4.8 Undesirable effects

Common: Hypophosphataemia, headache, dizziness, flushing, hypertension, nausea, injection/infusion site reactions (discolouration, irritation, phlebitis). Uncommon: Hypersensitivity reactions (urticaria, rash, pruritus, erythema); paraesthesia; tachycardia; hypotension; dyspnoea; vomiting, abdominal pain, dyspepsia; fatigue, pyrexia, chills, muscle cramps, arthralgia, myalgia. Rare: Anaphylactic/anaphylactoid shock. Frequency not known: Numbness, loss of consciousness; syncope; angioedema; bronchospasm; pallor; extravasation; temporary skin discolouration at injection site (may be permanent).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Overdose may result in iron overload with haemosiderosis. Follow standard methods for treating iron overload — iron chelation therapy may be required. Monitor iron stores (serum ferritin, transferrin saturation) to detect any accumulation.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antanaemic preparations; parenteral iron preparations. ATC code: B03AC.

Ferric carboxymaltose is a colloidal iron(III) hydroxide complex with carboxymaltose that releases iron in a controlled manner. The carbohydrate polymer coating prevents the release of large amounts of free iron ions into the bloodstream and provides a stable, biocompatible and physiological form of iron for uptake by the reticuloendothelial system. Iron is then incorporated into haemoglobin in erythrocytes and/or stored as ferritin. In clinical studies, ferric carboxymaltose effectively increased haemoglobin and serum ferritin concentrations in patients with iron deficiency anaemia.

5.2 Pharmacokinetic properties

Distribution: After IV administration, ferric carboxymaltose is rapidly distributed. Maximum total serum iron levels of 37–333 µg/mL are obtained 15 minutes to 1.21 hours after a single dose of 100–1,000 mg iron, respectively. Volume of the central compartment corresponds approximately to the plasma volume (approximately 3 litres). Elimination: Iron is rapidly cleared from the plasma; terminal half-life 7–12 hours. Renal elimination of iron is negligible.

5.3 Preclinical safety data

No special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity and genotoxicity. Iron crosses the placenta and is excreted in milk in limited, controlled amounts. Minor skeletal foetal abnormalities in iron-replete rabbits. No effects on fertility. No carcinogenicity data; no evidence of allergy or immunotoxic potential. No cross-reactivity with anti-dextran antibodies. No local irritation or intolerance after IV administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide BP, water for injections USP.

6.2 Incompatibilities

Ferric carboxymaltose must not be mixed with other medicinal products. It must not be added to blood or blood derivatives. Compatibility has only been established with 0.9% sodium chloride solution for dilution. Other diluents must not be used without prior compatibility assessment.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C. Protect from sunlight. Do not freeze. Keep out of the reach and sight of children. Do not administer if sedimentation is observed.

6.5 Nature and contents of container

10 mL Type I glass vials. Pack of 1 vial.

6.6 Special precautions for disposal and other handling

Inspect the vial visually before use. Ferric carboxymaltose must not be diluted in solutions other than 0.9% sodium chloride. Do not use if sedimentation is present. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

HILTON PHARMA (PVT) LTD.

8th & 9th Floor, Progressive Plaza, Beaumont Road,

Karachi, Pakistan.

Manufacturer: Hilton Pharma (Pvt) Ltd., Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

CTD10057

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

14.02.2026

10. DATE OF REVISION OF THE TEXT

14.02.2026