AmFerro™

Ferric Carboxymaltose Injection 50 mg/ml

Presentation: Each ml contains: Ferric Carboxymaltose equivalent to Elemental Iron 50 mg, Water for Injection I.P. q.s.

Pharmaceutical form: Injections

Indications: Ferric carboxymaltose Injection is indicated for the treatment of iron deficiency anemia (IDA) in Adults and pediatric patients.

Dosage and administration: Recommended Dosage: For patients weighing 50 kg or more, the recommended dosage is Ferric carboxymaltose Injection 750 mg intravenously in two doses separated by at least 7 days for a total cumulative dose of 1,500 mg of iron per course. Preparation and Administration: Administer Ferric carboxymaltose Injection intravenously, either as an undiluted slow intravenous push or by infusion. Each vial of Ferric carboxymaltose Injection is intended for single dose only.

Contraindications: Ferric carboxymaltose Injection is contraindicated in patients with a history of hypersensitivity to Ferric carboxymaltose Injection or any of its components.

Warnings & precautions: Serious hypersensitivity reactions, including anaphylactic-type reactions have been reported. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse.

Pregnancy & lactation: Pregnancy: Parenteral iron administration may be associated with hypersensitivity reactions which may have serious consequences, such as fetal bradycardia. Breastfeeding: The available published data on the use of ferric carboxymaltose in lactating women demonstrate that iron is present in breast milk. Among the breastfed infants, adverse reactions included constipation and diarrhea but none of the adverse reactions reported were considered related to ferric carboxymaltose exposure through breast milk. There is no information on the effects of ferric carboxymaltose on milk production.

Symptoms and treatment of overdosage: Excessive dosages of ferric carboxymaltose injection may lead to accumulation of iron in storage sites potentially leading to hemosiderosis. Hypophosphatemic osteomalacia has been reported in patients who have received repeated high-cumulative courses of ferric carboxymaltose injection.

Storage: Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). Do not freeze.

Pack size: Ferric carboxymaltose injection is a dark brown, non-transparent, sterile, aqueous solution. 500 mg iron/10 ml Single-Dose Vial Individually Boxed. 1000 mg iron/20 ml Single-Dose Vial Individually Boxed.

Before prescribing, please consult full prescribing information available from Amneal Healthcare Private Limited Regd. Office: 9th Floor, 901 to 905, Iscon Elegance, Circle P, S.G. Highway, Ahmedabad – 380015.

To be sold by retail on the prescription of an Oncologist only.