Solution will appear dark to light brown.
Rate of Administration For IV push, administer at maximum rate of 100 mg/min. For IV infusion, administer over at least 15 min. Monitor for extravasation.
ADULTS/ELDERLY(WEIGHING 50 KG OR MORE): 750 mg times 2 doses, separated by at least 7 days. **Maximum dose:** 1500mg/treatment course. **(WEIGHING LESS THAN 50 KG):** 15 mg/kg times 2 doses,separated by at least 7 days. **Maximum dose:** 1500 mg/treatment course.
Side effects:-
Rare or very rare Face oedema .flatulence
Occasional (7%–2%): Nausea, hypertension, flushing, dizziness.
Rare (less than 2%): Vomiting, headache, dysgeusia, hypotension, constipation.
PREGNANCY:-
Avoid in first trimester; crosses the placenta in animal studies. May influence skeletal development.
Distributed in breast milk.
Pregnancy Category C.
Children : Safety and efficacy not established.
Elderly : No age-related precautions noted.
IMPORTANT SAFETY INFORMATION
Ferric carboxymaltose is associated with hypophosphataemia, resulting in hypophosphataemic osteomalacia and fractures, particularly in patients with existing risk factors and following prolonged exposure to high doses—some cases required clinical intervention, including surgery. The risk of persistent hypophosphatemia and osteomalacia may be higher with ferric carboxymaltose than with other intravenous iron formulations. Healthcare professionals are advised to monitor serum phosphate levels in patients requiring multiple high dose administrations, on long-term treatment, or with pre-existing risk factors for hypophosphataemia.
Patients experiencing symptoms of hypophosphataemia (including new musculoskeletal symptoms or worsening tiredness) should seek medical advice—be aware that these symptoms may be confused with those of iron deficiency anaemia. If hypophosphataemia persists, ferric carboxymaltose treatment should be re-evaluated.
ADVERSE EFFECTS
Hypersensitivity reaction including angioedema, chills, erythema, hypotension, pruritus, syncope, urticaria,wheezing reported in 1.5% of pts.
Anaphylaxis was noted is less than 1%of pts. Transient hypertension reportedin 4% of pts.
Hemosiderosis (ironoverload) may present with joint disorder, gait disturbance, asthenia.
Extravasation may cause injection site discoloration.
OVERDOSAGE
Excessive dosages of Ferric Carboxymaltose may lead to accumulation of iron in storage sites potentially leading to hemosiderosis. A patient who received Ferric Carboxymaltose 18,000 mg over 6 months developed hemosiderosis with multiple joint disorder, walking disability, and asthenia. Hypophosphatemico steomalacia was reported in a patient who received Ferric Carboxymaltose 4,000 mg over 4 months. Partial recovery followed discontinuation of Ferric Carboxymaltose.
Storage: - Store protect from light, at a temperature between 8°C to 25°C .
Do not freeze. Improper Storage may deteriorate the product
Medicine : Keep out of reach of children.
Presentation: -Each vial contains 1000 mg/20 ml of Solution, a vial pack in a monocarton.

Manufactured by:
AMERICAN REMEDIES
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA
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E-mail: info@americanremedies.in

For the use only of a Registered Medical Practitioner of a Hospital or a Laboratory

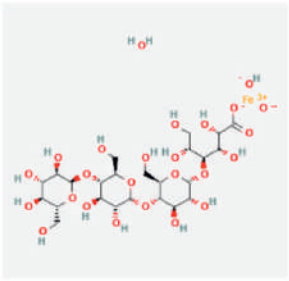
℞ Ferric Carboxymaltose Injection

AMERICAN
Fortose FCM 1000 mg
Injection

FOR I.V. USE ONLY
Composition:
Each ml Contains:

Ferric Carboxymaltose		
Eq. to Elemental Iron	IP	50 mg
Water for Injection	IP	qs

Description:-
Ferric carboxymaltose injection is a dark brown, sterile, aqueous, isotonic colloidal solution for intravenous injection. Each mL contains 50 mg iron as ferric carboxymaltose in water for injection.
Ferric carboxymaltose, an iron replacement product, is an iron carbohydrate complex with the chemical name of polynuclear iron (III)-hydroxide 4(R)-(poly-(1→4)-O-α-Dglucopyranosyl)-oxy-2(R),3(R),5(R),6-tetrahydroxy-hexanoate. It has a relative molecular weight of approximately 150,000 Da corresponding to the following empirical formula:$C_{24}H_{44}FeO_{25}$-



Ferric carboxymaltose

PHARMACOLOGY
Pharmacokinetics
After administration of a single dose of Ferric Carboxymaltose of 100 to 1,000 mg of iron in iron deficient adult patients, maximun iron concentration of 37 µg/mL to 333 µg/mL were obtained respectively after 15 minutes to 1.21 hours post dose. The volume of distribution was estimated to be 3 L. The iron injected or infused was rapidly cleared from the plasma, the terminal half-life ranged from 7 to 12 hours. Renal elimination of iron was negligible. After administration of a single dose of Ferric Carboxymaltose 15 mg/kg in pediatric patients 1-17 years of age, the maximum concentrations ranged between 124 and 418.1 µg/mL and the median time to maximum concentration was 7 minutes. The elimination half-life of Ferric Carboxymaltose in pediatric patients was approximately 9.7 hours. The total median 72-hourexposure (AUC0-72h) after a single dose of Ferric Carboxymaltose15 mg/kg in pediatric patients was 4529.7 µg·h/ml while the median exposure after a single dose of 1000 mg in adults was 5875.3 µg·h/ml.
Iron is protein-bound to form hemosiderin, ferritin, or transferrin. No physiologic system of elimination. Small amounts are lost in daily shedding of skin, hair, nails, with trace elimination in feces, urine. **Half-life:-** 7–12 hrs.
Direction for Administration
For intravenous infusion, give intermittently in Sodium chloride 0.9%, dilute 200–500mg in up to 100mL infusion fluid and give over at least 6 minutes; dilute 0.5–1 g in up to 250mL infusion fluid and give over at least 15 minutes.
ADMINISTRATION
Reconstitution May give either as undiluted slow IV push or IV infusion.
• When administering as IV infusion, dilute 750 mg dose in maximum of 250 ml 0.9% NaCl for concentration of 2–4 mg/ml. Inspect for particulate matter.