FCM Injection

(Ferric Carboxymaltose) 500mg/10mL

For Intravenous use only.

ایف سی ایم انجکشن

(فیرک کاربوکسی مالٹوز)

۵۰۰ ملی گرام/ ۱۰ ملی لیٹر

صرف وریدی استعمال کیلئے

COMPOSITION

Each 10mL contains:
Iron as Ferric Carboxymaltose.....500mg
Innovator's Specs.

DESCRIPTION

FCM (Ferric Carboxymaltose) injection is an iron replacement product. It is a dark brown, sterile, aqueous, isotonic colloidal solution for intravenous injection.

CLINICAL PHARMACOLOGY

Mechanism of Action: Ferric Carboxymaltose is a colloidal iron (III) hydroxide in complex with carboxymaltose, a carbohydrate polymer that releases iron.

Pharmacodynamics: Using positron emission tomography (PET) it was demonstrated that red cell uptake of $_{59}$Fe and $_{52}$Fe from Ferric Carboxymaltose ranged from 61% to 99%. In patients with iron deficiency, red cell uptake of radio-labelled iron ranged from 91% to 99% at 24 days after Ferric Carboxymaltose dose. In patients with renal anemia red cell uptake of radio labelled iron ranged from 61% to 84% after 24 days Ferric Carboxymaltose dose.

Pharmacokinetics: Absorption and Distribution: After administration of a single dose of Ferric Carboxymaltose of 100 to 1000 mg of iron in iron deficient patients, maximum iron levels of 37 μg/mL to 333μg/mL were obtained respectively after 15 minutes to 1.21 hours post dose. The volume of distribution was estimated to be 3L.

Metabolism and Excretion: 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.

INDICATIONS AND USAGE

FCM (Ferric Carboxymaltose) Injection is indicated for the treatment of iron deficiency anemia in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron & who have non-dialysis dependent chronic kidney disease.

CONTRAINDICATIONS

Known hypersensitivity to the active substance, or any of its excipients or serious hypersensitivity to other parenteral iron products, anemia not attributed to iron deficiency, e.g. other microcytic anemia and evidence of iron overload or disturbances in the utilisation of iron.

INTERACTIONS

The absorption of oral iron is reduced when administered concomitantly with parenteral iron preparations. Therefore, if required, oral iron therapy should not be started for at least 5 days after the last injection of Ferric Carboxymaltose.

USE IN SPECIFIC POPULATION

Pregnancy: Category C: A careful benefit/risk evaluation is required before use during pregnancy and Ferric Carboxymaltose should not be used during pregnancy unless clearly necessary.
Iron deficiency occurring in the first trimester of pregnancy can in many cases be treated with oral iron. Treatment with Ferric Carboxymaltose should be confined to the second and third trimester if the benefit is judged to outweigh the potential risk for both the mother and the foetus.

Nursing Mothers: Lactating women receiving Ferric Carboxymaltose are found to have higher breast milk iron levels than those lactating women receiving oral ferrous sulfate.

Breast-feeding: It is unlikely that Ferric Carboxymaltose represents a risk to the breast-fed child.

Paediatric Use: Safety and effectiveness have not been established in paediatric patients.

Geriatric Use: Greater sensitivity of some older individuals cannot be ruled out.

PRECAUTIONS

Hypersensitivity reactions: Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic/anaphylactoid reactions. Hypersensitivity reactions have also been reported after previously uneventful doses of parenteral iron complexes. The risk is enhanced for patients with known allergies including drug allergies, including patients with a history of severe asthma, eczema or other atopic allergy. There is also an increased risk of hypersensitivity reactions to parenteral iron complexes in patients with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis).

Hepatic or renal impairment: In patients with liver dysfunction, parenteral iron should only be administered after careful benefit/risk assessment. Parenteral iron administration should be avoided in patients with hepatic dysfunction where iron overload is a precipitating factor, in particular Porphyria Cutanea Tarda (PCT). Careful monitoring of iron status is recommended to avoid iron overload.
No safety data on haemodialysis dependent chronic kidney disease patients receiving single doses of more than 200 mg iron are available.

Infection: Parenteral iron must be used with caution in case of acute or chronic infection, asthma, eczema or atopic allergies. It is recommended that the treatment with Ferric Carboxymaltose is stopped in patients with ongoing bacteremia. Therefore, in patients with chronic infection a benefit/risk evaluation has to be performed, taking into account the suppression of erythropoiesis.

Extravasation: Caution should be exercised to avoid paravenous leakage when administering Ferric Carboxymaltose. Paravenous leakage of Ferric Carboxymaltose at the injection site may lead to irritation of the skin and potentially long lasting brown discoloration at the site of injection. In case of paravenous leakage, the administration of Ferric Carboxymaltose must be stopped immediately.

Excipients: One mL of undiluted Ferric Carboxymaltose contains up to 5.5 mg (0.24 mmol) of sodium. This has to be taken into account in patients on a sodium-controlled diet.

ADVERSE REACTIONS

Common: Nausea, dizziness, gastrointestinal disturbances, headache, injection site reactions, rash, hypophosphatemia, hypertension.

Uncommon: Anaphylaxis, arthralgia, back pain, chest pain, fatigue, flushing, hypotension, malaise, tachycardia, myalgia, paraesthesia, dysgeusia, peripheral oedema, chills, pruritus, pyrexia, rigors, urticaria.

Rare: Dyspnoea, loss of consciousness, anxiety, phlebitis, syncope, flatulence, pallor.

DOSAGE AND ADMINISTRATION

For patients weighing 50kg (110lb) or more: Give Ferric Carboxymaltose in two doses separated by at least 7 days. Give each dose as 750mg for a total cumulative dose not to exceed 1500 mg of iron per course.

For patients weighing less than 50kg (110 lb): Give Ferric Carboxymaltose in two doses separated by at least 7 days. Give each dose as 15mg/kg body weight for a total cumulative dose not to exceed 1500mg of iron per course.
Administer Ferric Carboxymaltose intravenously, either as an undiluted slow intravenous push or by infusion.

Administration as Slow IV Push: When administering as a slow intravenous push, give at the rate of approximately 100mg (2mL) per minute.

Administration Via Infusion: When administered via infusion, dilute up to 750mg of iron in no more than 250mL of sterile 0.9% sodium chloride injection, U.S.P. such that the concentration of the infusion is not less than 2 mg of iron per mL and administer over at least 15 minutes.

OVERDOSAGE

Administration of Ferric Carboxymaltose 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 recognizing iron accumulation. If iron accumulation has occurred, treat according to standard medical practice, e.g. consider the use of an iron chelator.

INSTRUCTIONS

Dosage as directed by the physician.
Store at 25°C, excursions permitted to 15°C-30°C.
To be sold on the prescription of a registered medical practitioner only.
Protect from heat and sunlight. Do not freeze.

Storage After Reconstitution: When added to an infusion bag containing 0.9% Sodium Chloride Injection, U.S.P. at concentrations ranging from 2mg to 4mg of iron per mL, FCM (Ferric Carboxymaltose) solution is physically and chemically stable for 72 hours when stored at room temperature. To maintain stability, do not dilute to concentrations less than 2mg iron/mL.

PRESENTATION

FCM (Ferric Carboxymaltose) Injection 500mg/10mL is available in glass vial along with insert.

طریقہ استعمال:

ایف سی ایم انجکشن اُن مریضوں میں آئرن کی کمی کو دور کرتا ہے جو اورل تھراپی سے مستفید نہ ہو سکتے ہوں اس کے علاوہ گردوں کے امراض میں مبتلا اُن مریضوں کے لئے ہے جن کو ڈائلسز کی ضرورت نہیں ہے۔

مضر اثرات:

متلی، غنودگی، معدے کی خرابی، سر درد، خون میں فاسفیٹ کی کمی، ہائی بلڈ پریشر، خارش، انجکشن کی جگہ پر سوزش، کمر درد، سینے میں درد، تھکن وغیرہ۔

احتیاطی تدابیر:

علاج سے پہلے حساس مریضوں کی تشخیص ضروری ہے۔
حاملہ خواتین، جگر اور گردے کے مریض احتیاط سے استعمال کریں۔
سوڈیم کی موجودگی کے پیش نظر سوڈیم کنٹرولڈ ڈائیٹ والے مریض احتیاط سے استعمال کریں۔

ہدایات:

خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔ ۲۵ ڈگری سینٹی گریڈ پر رکھیں،
محفوظ رکھنے کی حد ۱۵ سے ۳۰ ڈگری سینٹی گریڈ ہے۔ گرمی اور سورج کی روشنی سے محفوظ رکھیں۔ منجمد نہ کریں۔
تیار کردہ انفیوژن سلوشن کمرے کے درجہ حرارت پر ۲۴ گھنٹے تک استعمال کیا جا سکتا ہے۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ صرف رجسٹرڈ ڈاکٹر کے نسخہ پر فروخت کریں۔

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