Front

130.00 mm

150.00 mm

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

Rx Ferric Carboxymaltose Injection

FAROSUCK™ FCM

Composition :

Each ml contains :		**500 mg/10ml**
Ferric Carboxymaltose Eq. to elemental iron	50 mg	For IV Injection/Infusion Single Dose Vial
Water for Injections IP	q.s.	

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: There are no adequate and well-controlled trials of Ferric carboxymaltose in pregnant women. A careful benefit/risk evaluation is required before use during pregnancy and Ferric carboxymaltose should not be used during pregnancy unless clearly necessary. 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. Animal data suggest that iron released from Ferric carboxymaltose can cross the placental barrier and that its use during pregnancy may influence skeletal development in the fetus.

Lactation

Clinical studies showed that transfer of iron from Ferric carboxymaltose to human milk was negligible (≤1%). Based on limited data on breast-feeding women 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.

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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.

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:

Monitor carefully patients for signs and symptoms of hypersensitivity reactions during and following each administration of ferric carboxymallose.

Ferric Carboxymaltose Injection should only be administered when staff trained to evaluate and manage anaphylactic reactions is immediately available, in an environment where full resuscitation facilities can be assured. The patient should be observed for adverse effects for at least 30 minutes following each Ferric Carboxymaltose Injection.

Calculation of the cumulative iron dose

The cumulative dose for repletion of iron using ferric carboxymaltose is determined based on the patient's body weight and haemoglobin level and must not be exceeded. The following table should be used to determine the cumulative iron dose:

Hb	Patient body weight		
g/dL	below 35 kg	35 kg to <70 kg	70 kg and above
<10	500 mg	1,500 mg	2,000 mg
10 to <14	500 mg	1,000 mg	1,500 mg
≥14	500 mg	500 mg	500 mg

Note: A cumulative iron dose of 500 mg should not be exceeded for patients with body weight <35 kg.

Maximum tolerated single dose a single Ferric Carboxymaltose administration should not exceed:

- 15 mg iron/kg body weight (for administration by intravenous injection) or 20 mg iron/kg body weight (for administration by intravenous infusion)
- 1,000 mg of iron (20 mL Ferric Carboxymaltose)

Do not administer 1000 mg of iron (20 ml) more than once a week.

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

Note : For stability reasons, Ferric Carboxymaltose should not be diluted to concentrations less than 2 mg iron/ml : Minimum administration time should be 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.
Do not freeze. Do not store above 30°C.
To be sold on the prescription of a registered medical practitioner only.
Protect from heat and sunlight.

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 type-I amber glass vial along with insert.

Storage : Store in the original Carton in order to protect from light.
Do not freeze.
Do not store above 30°C.

Keep medicine out of reach of children.

Manufactured in India by :
Penam Biosciences Pvt. Ltd.
Mauza Sarawan, Sadhaura, Yamunanagar,
Haryana. INDIA - 133206

Marketed by:
windlas
Windlas Biotech Limited
(A WHO GMP Certified Company)
40/1, Mohabewala Industrial Area,
Dehradun-248110, Uttarakhand