Fercabin
(Ferric Carboxymaltose)

Solution for Injection / Infusion
500mg/10ml

فرکابن
(فیرک کاربوکسی مالٹوز)
سلوشن برائے انجکشن / انفیوژن
۵۰۰ ملی گرام/۱۰ ملی لیٹر

COMPOSITION: Each 10ml contains:
Iron as Ferric Carboxymaltose ... 500mg. [Innovator's Specs.]

DESCRIPTION: 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.

INDICATIONS: Fercabin is indicated for the treatment of iron deficiency when oral iron preparations are ineffective or oral iron preparations cannot be used.

DOSAGE AND ADMINISTRATION:
Step 1: Determination of the iron need: The individual iron need for repletion using **Fercabin** is determined based on the patient body weight and haemoglobin (Hb) level.

Step 2: Calculation and administration of the maximum individual iron dose: Based on the iron need determined above the appropriate dose of **Fercabin** should be administered taking into consideration the following:
A single Fercabin administration should not exceed:
• 15mg iron/kg body weight (for administration by intravenous injection) or 20mg iron/kg body weight (for administration by intravenous infusion)
• 1000mg of iron (20ml **Fercabin**). The maximum recommended cumulative dose of **Fercabin** is 1000mg of iron (20ml **Fercabin**) per week.

Step 3: Post-iron repletion assessments: Re-assessment should be performed by the clinician based on the individual patient condition. The Hb level should be re-assessed no earlier than 4 weeks post final **Fercabin** administration to allow adequate time for erythropoiesis and iron utilisation. In the event the patient requires further iron repletion, the iron need should be recalculated.
Special Population - patients with haemodialysis-dependent chronic kidney disease: A single maximum daily dose of 200mg iron should not be exceeded in haemodialysis-dependent chronic kidney disease patients.
Paediatric population: The use of **Fercabin** has not been studied in children and therefore is not recommended in children under 14 years.
Method of administration:
Fercabin must only be administered by the intravenous route:
• By injection
• By infusion
• During a haemodialysis session undiluted directly into the venous limb of the dialyser.
Fercabin must not be administered by the subcutaneous or intramuscular route.
Intravenous injection: Fercabin may be administered by intravenous injection using undiluted solution. The maximum single dose is 15mg iron/kg body weight but should not exceed 1000mg iron.
Intravenous Infusion: Fercabin may be administered by intravenous infusion, in which case it must be diluted. The maximum single dose is 20mg iron/kg body weight, but should not exceed 1,000mg iron.
Dilution Plan of Fercabin for Intravenous Infusion:

Volume of Fercabin Required	Equivalent Iron Dose	Maximum Amount of Sterile 0.9% m/v Sodium Chloride Solution	Minimum Administration Time
2 to 4ml	100 to 200mg	50ml	No minimal prescribed time
4 to 10ml	200 to 500mg	100ml	6 minutes
10 to 20ml	500 to 1000mg	250ml	15 minutes

CLINICAL PHARMACOLOGY:
Mechanism of Action: Ferric Carboxymaltose is a colloidal iron (III) hydroxide in complex with carboxymaltose, a carbohydrate polymer that release iron.
Pharmacokinetics: Absorption & Distribution:
After administration of a single dose of Ferric Carboxymaltose of 100 to 1000mg of iron in iron deficient patients, maximum iron concentration of 37μg/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.

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Metabolism & Elimination: 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.

CONTRAINDICATIONS:
The use of Ferric Carboxymaltose Injection is contraindicated in cases of:
• Hypersensitivity to the active substance, to Ferric Carboxymaltose Injection or any of its excipients.
• Known serious hypersensitivity to other parenteral iron products.
• Anaemia not attributed to iron deficiency, e.g. other microcytic anaemia.
• Evidence of iron overload or disturbances in the utilization of iron.

WARNINGS AND 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. **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. **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 Injection is stopped in patients with ongoing bacteraemia. 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 Injection. Paravenous leakage of Ferric Carboxymaltose Injection at the administration site may lead to irritation of the skin and potentially long lasting brown discolouration at the site of administration. In case of paravenous leakage, the administration of Ferric Carboxymaltose Injection must be stopped immediately.
Pregnancy and Lactation: There are limited data from the use of Ferric Carboxymaltose Injection in pregnant women. A careful benefit/risk evaluation is required before use during pregnancy and Ferric Carboxymaltose Injection 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 Injection 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. Clinical studies showed that transfer of iron from Ferric Carboxymaltose Injection to human milk was negligible (≤1%). Based on limited data on breast-feeding women it is unlikely that Ferric Carboxymaltose Injection represents a risk to the breast-fed child.

SIDE EFFECTS: The following are the side effects as described below:
• Itching
• Hives
• Wheezing
• Low Blood Pressure
• High Blood Pressure
• Dizziness
• Nausea
• Flushing
• Low Levels of Phosphorous In Your Blood

DRUG 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 administration of Ferric Carboxymaltose Injection.

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

INSTRUCTIONS: Store below 30° C. Protect from heat and light. Keep out of the reach of children.

PRESENTATION:
Fercabin 500mg/10ml Injection is available in pack size of 1's

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی اور روشنی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

PHARMA
Manufactured By:
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