OXYFER

FERRIC CARBOXYMALTOSE INN

Compositions:
Oxyfer-500: Each 10 ml solution contains Ferric carboxymaltose INN equivalent to elemental Iron 500 mg. Oxyfer-750: Each 15 ml solution contains Ferric carboxymaltose INN equivalent to elemental Iron 750 mg. Oxyfer-1G: Each 20 ml solution contains Ferric carboxymaltose INN equivalent to elemental Iron 1 G.

Pharmacology:
Non-dextran, IV is a colloidal iron hydroxide in complex with carboxymaltose, a carbohydrate polymer that releases iron; replaces iron stores found in hemoglobin, myoglobin, and enzymes; works to transport oxygen via hemoglobin Macrophage engulf FCM from blood and control iron release. Transferrin saturates and, Iron into the liver, spleen and Bone marrow.

Dosage And Administration:
For patients weighing 50 kg or more: Give Ferric Carboxymaltose in two doses separated by at least 7 days. Give each dose as 750 mg for a total cumulative dose not to exceed 1500 mg of iron per course. For patients weighing less than 50 kg: Give Ferric Carboxymaltose in two doses separated by at least 7 days. Give each dose as 15 mg/kg body weight for a total cumulative dose not to exceed 1500 mg of iron per course. The dosage of Ferric Carboxymaltose is expressed in mg of elemental iron. Each mL of Ferric Carboxymaltose contains 50 mg of elemental iron. Ferric Carboxymaltose treatment may be repeated if iron deficiency anemia reoccurs. Administer Ferric Carboxymaltose intravenously, either as an undiluted slow intravenous push or by infusion. When administering as a slow intravenous push, give at the rate of approximately 100 mg (2 mL) per minute. When administered via infusion, dilute up to 750 mg of iron in no more than 250 mL of sterile 0.9% sodium chloride injection, USP, such that the concentration of the infusion is not less than 2 mg of iron per mL and administer over at least 15 minutes. When added to an infusion bag containing 0.9% Sodium Chloride Injection, USP, at concentrations ranging from 2 mg to 4 mg of iron per mL, 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 2 mg iron/mL. Inspect parenteral drug products visually for the absence of particulate matter and discoloration prior to administration. The product contains no preservatives. Each vial of Ferric Carboxymaltose is intended for single use only. Any unused drug remaining after injection must be discarded. Avoid extravasation of Ferric Carboxymaltose since brown discoloration of the extravasation site may be long lasting. Monitor for extravasation. If extravasation occurs, discontinue the Ferric Carboxymaltose administration at that site.

Contraindications:
The use of ferric carboxymaltose is contraindicated in cases of- • hypersensitivity to the active substance, to ferric carboxymaltose 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. Special precautions for disposal and other handling • Inspect vial visually for sediment and damage before use. Use only those containing sediment-free, homogeneous solution. • Each vials of ferric carboxymaltose is intended for single use only. Any unused product or waste material should be disposed of in accordance with local requirements. • Ferric carboxymaltose must only be mixed with sterile 0.9% sodium chloride solution. No other intravenous dilution solutions and therapeutic agents should be used, as there is the potential for recipitation and/or interaction.

Warning And Precaution:
Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Ferric carboxymaltose. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after Ferric carboxymaltose administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Ferric carboxymaltose when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. Other serious or severe adverse reactions potentially associated with hypersensitivity which included, but not limited to, pruritus, rash, urticaria, wheezing, or hypotension may occur. Hypertension: Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each Ferric carboxymaltose administration.

Side Effects:
Nausea, Hypertension, Flushing, Decreased blood phosphorus, Dizziness, Vomiting, Pruritus, Rash, Urticaria, Wheezing, Injection site discoloration, Headache, Increased alanine aminotransferase), Dysgeusia, Hypotension, Constipation, Serious anaphylactic/anaphylactoid reactions

Use in Pregnancy and Lactation:
Pregnancy: Pregnancy category: C. 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. Breast-feeding: 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. Fertility: There are no data on the effect of ferric carboxymaltose on human fertility. Fertility was unaffected following ferric carboxymaltose treatment in animal studies.

Drug Interaction:
There are no known drug interactions and none well documented.

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.

Storage:
Store at temperature not exceeding 30°C in a dry place. Protect from light. Do not freeze.

Packing:
Oxyfer-500: Each box contains one vial of 10 ml Ferric carboxymaltose solution with one 100 ml normal saline, one infusion set, one alcohol pad, one first aid bandage, hanger & one 10 ml disposable syringe. Oxyfer-750: Each box contains one vial of 15 ml Ferric carboxymaltose solution with one 250 ml normal saline, one infusion set, one alcohol pad, one first aid bandage, hanger & one 20 ml disposable syringe. Oxyfer-1G: Each box contains one vial of 20 ml Ferric carboxymaltose solution with one 250 ml normal saline, one infusion set, one alcohol pad, one first aid bandage, hanger & one 20 ml disposable syringe.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
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