Oxyfer

Ferric Carboxymaltose

Composition:

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.

Therapeutic indications:

Ferric carboxymaltose is an iron replacement product 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

The diagnosis of iron deficiency must be based on laboratory tests.

Posology and method of administration:

Posology

The posology of ferric carboxymaltose follows a stepwise approach:

a) Determination of the individual iron need
b) Calculation and administration of the iron dose(s)
c) Post-iron repletion assessments.

These steps are outlined below-

Step 1: Determination of the iron need

The individual iron need for repletion using ferric carboxymaltose is determined based on the patient's body weight and haemoglobin (Hb) level. Refer to Table 1 for determination of the iron need:

Table 1: Determination of the iron need

Hb		**Patient body weight**		
g/dL	mmol/L	below 35 kg	35 kg to <70 kg	70 kg and over
<10	<6.2	500 mg	1,500 mg	2,000 mg
10 to 14	6.2 to 8.7	500 mg	1,000 mg	1,500 mg
>14	>8.7	500 mg	500 mg	500 mg

Step 2: Calculation and administration of the maximum individual iron dose(s)

Based on the iron need determined above the appropriate dose(s) of ferric carboxymaltose should be administered taking into consideration the following:

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)

The maximum recommended cumulative dose of ferric carboxymaltose is 1,000 mg of iron (20 ml ferric carboxymaltose) per week.

Step 3: Post-iron repletion assessments

Re-assessment should be performed by the clinician based on the individual patient's condition. The Hb level should be re-assessed no earlier than 4 weeks post final ferric carboxymaltose administration to allow adequate time for erythropoiesis and iron utilization. In the event the patient requires further iron repletion, the iron need should be recalculated using Table 1 above.

Special Population –

a. Patients with haemodialysis-dependent chronic kidney disease: A single maximum daily injection dose of 200 mg iron should not be exceeded in haemodialysis-dependent chronic kidney disease patients.
b. Paediatric population: The use of ferric carboxymaltose has not been studied in children, and therefore is not recommended in children under 14 years.

Method of administration:
Ferric carboxymaltose must only be administered by the intravenous route:

- by injection or
- by infusion or
- during a haemodialysis session undiluted directly into the venous limb of the dialyzer.

Ferric carboxymaltose must not be administered by the subcutaneous or intramuscular route.

a) Intravenous injection
Ferric carboxymaltose may be administered by intravenous injection using undiluted solution. The maximum single dose is 15 mg iron/kg body weight but should not exceed 1,000 mg iron. The administration rates are as shown in Table 2:

Table 2: Administration rates for intravenous injection of Ferric carboxymaltose

Volume of Ferric Carboxymaltose required			**Equivalent iron dose**			**Administration rate/Minimum administration time**
2	to	4 ml	100	to	200 mg	No minimal prescribed time
>4	to	10 ml	>200	to	500 mg	100 mg iron / min
>10	to	20 ml	>500	to	1,000 mg	15 minutes

b) Intravenous infusion
Ferric carboxymaltose may be administered by intravenous infusion, in which case it must be diluted. The maximum single dose is 20 mg iron/kg body weight, but should not exceed 1,000 mg iron.

For infusion, ferric carboxymaltose must only be diluted in sterile 0.9% sodium chloride solution as shown in Table 3. Note: for stability reasons, ferric carboxymaltose should not be diluted to concentrations less than 2 mg iron/ml (not including the volume of the ferric carboxymaltose solution).

Table 3: Dilution plan of Ferric carboxymaltose for intravenous infusion

Volume of Ferric Carboxymaltose required			Equivalent iron dose			Maximum amount of sterile 0.9% sodium chloride solution	Minimum Administration time
2	to	4 ml	100	to	200 mg	50 ml	-
>4	to	10 ml	>200	to	500 mg	100 ml	6 minutes
>10	to	20 ml	>500	to	1,000 mg	250 ml	15 minutes

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.

Adverse reactions:

The most common adverse reactions (≥2%) are nausea, hypertension, flushing, hypophosphatemia, and dizziness.

Fertility, 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.

Overdose:

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.

Presentation:
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.

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Manufactured By:
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