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FERRIC CARBOXYMALTOSE NEW ARMAMENTARIUM IN PARENTERAL IRON

Gynecology

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KEYWORDS

This is a non-dextran iron agent that can be given in large doses by rapid IV injection over a few minutes. It is approved for use in postpartum women, by both the US FDA and DCGI.

Feric Carboxymaltose (FCM) contains iron in a stable ferric state as a complex, tightly bound within a carbohydrate polymer. Due to the stability of the complex, it does not release ionic iron under physiological conditions. The iron hydroxide core, with its carbohydrate shell, is taken up by macrophages and enters the lysosomes where Fe3+ can be converted into Fe2+ as required. The Fe2+ is released by a divalent metal transporter (DMTI), then by ferroportin and taken up by transferrin afte oxidation by ceruloplasmin.

Properties :

1. Type I - robust iron
2. Not associated with dextran-induced hypersensitivity.
3. Can be administered in much higher doses than others.
4. Shorter infusion time.
5. Test does not required.
6. Stable complex-does not release non-transferrin bound iron.
7. Low rate of injection site reactions.
8. Latest parenteral iron-closest to the ideal iron.

Mechanism of Action :

Parenteral iron-iron carbohydrate complex is separated by reticulo-endotheliam system. Iron is gradually released into the circulation, it combines with transferrin and transported to the liver, spleen and bone marrow. Iron binds to bone marrow receptor sited for haemoglobin synthesis.

Red Cell Utilization :

Iron from FCM is distributed in the liver and spleen and taken up predominatly by the bone marrow within 60 minutes of administration. Within 2-3 weeks of FCM administration, iron utilization rates are 91-99% in the iron-deficient patients, and 61-84% in the patients with functional iron deficiency.

Ferric Carboxymaltose Injection

Composition :

Each ml contains Ferric Carboxymaltose equivalent to elemental Iron : 50mg

Water for Injection IP : q.s.

Presentation :

Vials of 10 ml (500 mg)

Storage :

It should be stored in the original package.

Not to be stored above 30^0C.

Not to be refrigerator or frozen.

Dosage :

For IV use only the dose of FCM required may be derived from the table given below. FCM can be administered as an infusion of 500 mg in 100ml of Normal Saline over 15 minutes or a slow IV push at the rate of 100mg per minute. A maximum dose of 1000mg may be given in one week. The advantage with FCM is that much higher single dose can be given and fewer injections are required to correct the iron deficiency. This should be the treatment of choice if intravenous iron therapy is indicated in postpartum anaemia. I a study to evaluate the superiority, safety and tolerability of FCM to oral iron in postpartum women with iron deficiency anaemia, it was found that FCM was safe and well-tolerated FCM was superior to oral iron in increasing Hb to 12g/dL earlier with greater sustained success. FCM was more effective in raising Transferrin saturation and Ferritin. Drug-related adverse events were lower with FCM (11%) that oral iron (22%). Urticaria (2%) was the only drug related adverse event occurring in about 2% of the FCM group. Response to therapy is noticed as early as Day 7 of treatment. Patients report a feeling of wellness, and blood test shows reticulocytosis, rise in haemoglobin % and improvement in red cell indices.

Simpler regimen as used in FERGIcor study/Gastroenterology 2011.

Hb (g/dl)	Body wt 35 kg to < 70 kg	Body wt > 70kg
> 10	1000 mg	1500 mg
< 10	1500 mg	2000 mg

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

METHOD OF ADMINISTRATION :

Iron	Maximum volume of normal saline for dilution	Minimum time for administration
200 to < 500 mg	100 ml	6 mins
500 to 1000 mg	250 ml	15 mins

Indications :

1. Intolerance to oral iron.
2. Poor compliance to oral iron.
3. Gastrointestinal disorders.
4. Rapid blood loss.
5. Severe anaemia.

Contraindications :

1. Known hypersensitivity to FCM.
2. Anaemia not due to iron deficiency.
3. Evidence of iron overload or disturbances in utilization of iron.
4. Pregnancy (?)
5. Children below 14 years.

Benefits :

1. Few Clinic visits.
2. Improved patient compliance.
3. Reduction of blood transfusions.
4. Saves : cost of disposables, monitoring cost, true hospital cost, travelling cost.