

Ferintus®

Ferric Carboxymaltose

IV Injection/Infusion

Presentation

Ferintus® 100 mg/2 ml: Each 2 ml solution contains Ferric carboxymaltose INN equivalent to elemental Iron 100 mg.

Ferintus® 500 mg/10 ml: Each 10 ml solution contains Ferric carboxymaltose INN equivalent to elemental Iron 500 mg.

Description

Ferric carboxymaltose is a colloidal iron (III) hydroxide solution in complex with carboxymaltose, a carbohydrate polymer that releases iron. Ferric carboxymaltose solution is a dark brown, non-transparent and aqueous solution.

Indication and Usage

Ferric carboxymaltose is indicated for the treatment of iron deficiency Anaemia 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.

Dosage and Administration

The cumulative dose for repletion of iron using Ferric carboxymaltose is determined based on the patient's body weight and haemoglobin (Hb) level and must not be exceeded. The following table (Table 1) should be used to determine the cumulative iron dose:

Table 1: Determination of the cumulative iron dose

| Hb (g/dL) | Patients with body weight 35 kg to <70 kg | Patients with body weight ≥70 kg |
|-----------|---|----------------------------------|
| <10 | 1,500 mg | 2,000 mg |
| ≥10 | 1,000 mg | 1,500mg |

Note: A cumulative iron dose of 500 mg should not be exceeded for patients with a body weight <36 kg.

For overweight patients, a normal body weight/blood volume relationship should be assumed when determining the iron requirement.

For patients with a Hb value, >14 g/dL, an initial dose of 500 mg iron should be given and iron parameters should be checked prior to repeat dosing.

Post repletion, regular assessments should be completed to ensure that iron levels are corrected and maintained.

Maximum tolerated single dose

A single dose Ferric carboxymaltose should not exceed 1,000 mg of iron per day. Do not administer 1,000 mg of iron more than once a week.

Intravenous injection

Ferric carboxymaltose may be administered by intravenous injection using undiluted solution up to 1,000 mg iron (up to a maximum of 15 mg/kg body weight). For doses up to 200 mg iron, there is no prescribed administration time. For doses greater than 200 and up to 500 mg iron, Ferintus® should be administered at a rate of 100 mg/min. For doses greater than 500 and up to 1,000 mg iron Ferintus® should be administered over 15 minutes.

Intravenous infusion

Ferric carboxymaltose may be administered by intravenous infusion up to a maximum single dose of 1,000 mg of iron (up to a maximum of 20 mg/kg body weight).

Method of administration

Ferric carboxymaltose must be administered only by the intravenous route: by bolus injection, or during a haemodialysis session undiluted directly into the venous limb of the dialyser, or by infusion. In case of infusion. Ferintus® must be diluted only in sterile 0.9% m/v sodium

chloride solution as shown in Table to below.

Table 2: Dilution plan of Ferintus® for intravenous infusion

| Ferintus® | Iron | Maximum amount of sterile 0.9% m/v 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 |

Note: For stability reasons, dilutions to concentrations less than 2 mg iron/ml are not permissible. Ferintus® must not be administered by the subcutaneous or intramuscular route.

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.

Use in paediatric population

The use of Ferric carboxymaltose has not been studied in children and therefore is not recommended in children under 14 years.

Use in Pregnancy and Lactation

Pregnant women

There are no data for the use of Ferric carboxymaltose in pregnant women. A careful risk/benefit evolution is required before use during pregnancy and Ferric carboxymaltose should not be used during pregnancy unless clearly necessary. 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.

If the benefit of Ferric carboxymaltose treatment is judged to outweigh the potential risk to the fetus, it is recommended that treatment should be confined to the second and third trimester.

Lactating mothers

Ferric carboxymaltose is excreted in human milk which unlikely to affect the baby.

Precautions

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 adverse reactions associated with hypersensitivity which included, pruritus, rash, urticarial, wheezing or hypertension 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.

Laboratory Test Alterations

In the 24 hours following administration of Ferric carboxymaltose,

laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in Ferric carboxymaltose.

Contraindications

The use of Ferintus® is contraindicated in cases of:

- hypersensitivity to the active substance, to Ferintus® 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.

Overdose

Excessive dosages of Ferintus® may lead to accumulation of iron in storage sites potentially leading to hemosiderosis. 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.

Drug Interaction

Formal drug interaction studies have not been performed with Ferric carboxymaltose.

Side Effects

The side effects of Ferric carboxymaltose are infrequent, usually mild and generally do not cause patients to stop treatment. The most common side effects are nausea, injection site reactions (including pain or bruising at the injection site), and asymptomatic reductions in blood phosphorus, flushing, headache, hypertension, dizziness, and increased alanine aminotransferase. Potentially long lasting brown staining of skin near injection site may occur. Uncommon side effects are hypersensitivity, paraesthesia, dyspepsia, tachycardia, hypotension, flushing, dyspnoea, vomiting, dyspepsia, abdominal pain, constipation, diarrhea, pruritus, urticaria, erythema, rash, myalgia, back pain, arthralgia, muscle spasm, pyrexia, fatigue, chest pain, oedema peripheral, chills, aspartate aminotransferase increased, gamma-glutamyltransferase increased, blood lactate dehydrogenase increased and blood alkaline phosphatase increased. Very side effects are anaphylactoid reactions, loss of consciousness, anxiety, phlebitis, syncope, presyncope, bronchospasm, flatulence, angioedema, pallor face oedema, Rigors, malaise and influenza like illness.

Storage

Do not store above 30°C prior to opening. Protect from moisture and light. Do not freeze.

Commercial Pack

Ferintus® 100 mg/2 ml: Each box contains one vial of 2 ml Ferric carboxymaltose solution with one 50 ml normal saline, one infusion set, one alcohol pad, one first aid band & one 3 ml disposable syringe.

Ferintus® 500 mg/10 ml: 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 band & one 10 ml disposable syringe.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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