Iron Sucrose (Ferogen): Indications, Dosage, Administration and Side effects

Iron sucrose is a parenteral form of iron that is used in the correction and treatment of iron deficiency anemia. It is a brown sterile, aqueous, complex polynuclear iron (III)hydroxide in sucrose (iron sucrose) for intravenous use.

Iron sucrose injection has a molecular weight of approximately 34,000 -60,000 Daltons.

Each ml contains 20mg of elemental iron as iron sucrose in water for injection. The product contains approximately 30% sucrose w/v (300mg/ml) and has a pH of 10.5-11.1 at 20 degrees Celsius. The product contains no preservatives.

The osmolarity is not less than 1150 and not more than 1350mosm/L when tested by diluting the injection 1 in 10.

Clinical pharmacology

Pharmacodynamics

Following intravenous injection, iron sucrose is dissociated by the reticuloendothelial system into iron and sucrose.

Pharmacokinetics

Following intravenous doses of iron sucrose, the iron component exhibits first-order kinetics with an elimination half-life of 6 hours. Total clearance of 1.2L/hour, non-steady-state apparent volume of distribution of 10.0L, and a steady-state of distribution of 7.9 L. Since iron disappearance from serum depends on the need for iron in the iron stores and iron utilizing tissues of the body.

Serum clearance of iron is expected to be more rapid in iron deficiency anemic patients treated with iron sucrose compared with healthy individuals. The effects of age and gender on the pharmacokinetics of iron sucrose have not been studied.

Distribution

Following intravenous administration of iron sucrose, the iron component appears to distribute mainly in the blood and to some extent in the extravascular fluid. A significant amount of administered iron is distributed in the liver, spleen, and bone marrow.

Metabolism and elimination

Following intravenous administration, iron sucrose dissociates into iron and sucrose by the reticuloendothelial system. The sucrose component is eliminated mainly by binary excretion.

Indications and usage

This drug is indicated for the management and treatment of iron deficiency anemia in cases where a rapid and reliable substitute of iron is required.

Dosage and administration

The dosage of iron sucrose is expressed in terms of mg of elemental iron. Each ml contains 20mg of elemental iron.

Dosages in hemodialysis patients

The recommended dosage of iron sucrose for repletion of iron deficiency in patients undergoing hemodialysis is 5ml of iron sucrose (100mg of elemental iron) delivered intravenously during the dialysis session.

Most patients will require a minimum cumulative dose of 1000mg over 10 sequential dialysis sessions.

Frequency of dosing should not be more than 3 times weekly patients may continue to require therapy with iron sucrose at the lowest dose necessary to maintain target levels of hemoglobin, hematocrit, and laboratory parameters of iron storage within acceptable limits.

Calculation of dosage

The total cumulative dose of iron sucrose, equivalent to the total iron deficit (mg) is determined by the hemoglobin level and body weight. The dose of iron sucrose must be individually determined for each patient according to the total iron deficit calculated using the following formula.

> ***Total iron deficit (mg) = body weight (kg) x (target Hb-Actual Hb)[g/dl] x2.4 + depot iron (mg)***

Total number of ampoules of iron sucrose to be administered (1 ampoule of iron sucrose corresponds with 5ml)

Below 35kg body weight: Target Hb = 13g/dl and depot iron = 15mg/kg body weight

35 kg body weight and above: Target Hb =15g/dl and depot iron = 500mg

The factor 2.4 comes about from the calculation that the total iron content of hemoglobin is 0.34%, the blood volume accounts for 7% of the total body weight, and conversion from g/dl to mg/L = factor 1000.

Therefore factor 2.4 = 0.0034 X 0.07 X 10000

The total amount of iron sucrose to be administered in mls is =total iron deficit (mg)/20mg/ml

Administration

Iron sucrose must only be administered intravenously either by slow injection or by infusion

Slow intravenous injection

Iron sucrose may be administered undiluted by slow intravenous injection at the rate of 1ml (20 mg iron) solution per minute i.e. 5 minutes per ampule not exceeding one ampoule of 100mg per injection. You will then discard the unused portion.

Infusion

Iron sucrose may be administered by infusion (into dialysis line for hemodialysis patients) as every 5ml iron sucrose diluted exclusively in a maximum of 100ml of 0.9% sodium chloride, immediately prior to infusion. The solution must be infused at a rate of 100mg of iron over a period of at least 15 minutes. Unused diluted solution must be discarded.

Note: Do not mix iron sucrose injection solution with any other medications or add to parenteral nutrition solutions for intravenous infusion. Parenteral drug products should be inspected visually for any particulate matter and discoloration prior to administration, whenever the solution and container permit.

Side effects.

Side effects of this drug include hypotension, chest pain, hypertension, hypervolemia, CHF, cramps, musculoskeletal pain, nausea, diarrhea, vomiting, abdominal pain elevated liver enzymes, skin irritation, pruritus', application site infection, dizziness, dyspnea, pneumonia, cough, headache, fever, asthenia, and malaise.

Drug interactions

Iron sucrose should not be administered concomitantly with oral preparations since the absorption of oral iron is reduced.

Warnings

Hypersensitivity reactions have been reported with injectable iron products.

Precautions

General precautions

Because the body iron excretion is limited and excess iron in tissues is dangerous, caution should be exercised to withhold iron administration in the presence of evidence of tissue iron overload.

Patients receiving iron sucrose require periodic monitoring of hematologic and hematinic parameters. Iron therapy should be withheld in these patients who have evidence features of iron overload.

Transferrin saturation value increases rapidly after intravenous administration of iron sucrose thus serum levels may be reliably be taken after 48 hours from the start of the dosing.

Hypersensitivity reactions; serious hypersensitivity reactions have rarely been reported in patients receiving the therapy.

Hypotension

Hypotension has been reported in patients who have chronic kidney disease receiving parenteral iron. Hypotension following iron sucrose may be related to the rate of administration and total dose administered.

Carcinogenesis, mutagenesis, and impairment of fertility;

No long-term studies in animals have been performed to evaluate the carcinogenic potential of iron sucrose.

Pregnancy category B

No adequate and well-controlled studies in pregnant women have been reported. Because animal reproduction studies are not always predictive of human response, this drug should be used in pregnancy only if clearly indicated.

Nursing mothers; it is not known whether the drug gets excreted into breast milk. Because many drugs are excreted in human milk, caution should be taken when iron sucrose is administered to a nursing woman.

Pediatric use; safety and effectiveness of iron sucrose in pediatric patients have not been established.

Geniaric use; there are no identified differences in responses between elderly and younger patients, but greater sensitivity of some of the older individuals cannot be ruled out.

Overdose

Dosages of iron sucrose in excess of iron needs may lead to accumulation of iron in storage sites leading to hemosiderosis. Periodic monitoring of iron parameters such as ferritin and serum transferrin saturation may assist in recognizing iron accumulation.

Iron sucrose should not be administered in patients with iron overload and should be discontinued if serum ferritin levels equal or exceed established guidelines particular caution should be exercised to avoid iron overload where anemia unresponsive to treatment has been incorrectly diagnosed as iron deficiency anemia.

Symptoms associated with overdose or rapid infusion of iron sucrose are hypotension, headache, dyspnea, vomiting, nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain, edema, and cardiovascular collapse.

Most symptoms have been successfully treated with intravenous fluids, hydrocortisone and/or antihistamines infusing the solution as recommended or at a slower rate may also alleviate symptoms.

Contraindications

The use of iron sucrose is contraindicated in patients with evidence of iron overload, in patients with known hypersensitivity to iron and any of its inactive components, and in patients with anemia not caused by iron deficiency.