Anefer®

Iron sucrose

Description
Iron sucrose is used to replenish body iron stores in patients with iron deficiency anemia in non-dialysis dependent-CKD patients receiving or not receiving an erythropoietin, and in hemodialysis and peritoneal dialysis dependent-CKD patients receiving an erythropoietin. Iron is essential to the formation of hemoglobin and to the function and formation of other heme and nonheme compounds. Untreated depletion of iron stores leads to iron-deficient erythropoiesis and, in turn, to iron deficiency anemia. Administration of iron sucrose replenishes tissue iron stores, reverses iron depletion and iron-deficient erythropoiesis, and corrects or prevents iron deficiency anemia.

Mode of action
Following intravenous administration iron sucrose is dissociated into iron and sucrose by the reticuloendothelial system, and iron is transferred from the blood to a pool of iron in the liver and bone marrow. Ferritin, an iron storage protein, binds and sequesters iron in a nontoxic form, from which iron is easily available. Iron binds to plasma transferrin, which carries iron within the plasma and the extracellular fluid to supply the tissues. The transferrin receptor, located in the cell membrane, binds the transferrin iron complex, which is then internalized in vesicles. Iron is released within the cell, and the transferrin-receptor complex is returned to the cell membrane. Transferrin without iron (apotransferrin) is then released to the plasma. The intracellular iron becomes (mostly) hemoglobin in circulating red blood cells (RBCs). Transferrin synthesis is increased and ferritin production reduced in iron deficiency. The converse is true when iron is plentiful.

Pharmacokinetics
In healthy adults treated with intravenous doses of iron sucrose. Its iron component exhibits first-order kinetics:

Elimination: T1/2 6 hours
Total clearance: 1.2 Liters per hour
Non–steady–state apparent volume of distribution: 10.0 Liters
Steady–state apparent volume of distribution : 7.9 Liters

Since iron disappearance from the 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-deficient patients treated with iron sucrose as compared with healthy individuals.

Distribution
In healthy adults, the iron component of iron sucrose appears to distribute mainly in the blood and to some extent in extravascular fluid.
Metabolism iron sucrose is dissociated into iron and sucrose by the reticuloendothelial system.

Elimination
The sucrose component is eliminated mainly by urinary excretion. Some iron is also eliminated in the urine (approximately 5%).

Composition
Anefer® Injection: Each 5 ml ampoule contains Iron Sucrose USP equivalent to 100 mg Elemental Iron (20 mg/ml).

Indications
Where there is a clinical need for a rapid Iron supply, In patients who cannot tolerate oral Iron therapy or who are non-compliant,In active inflammatory bowel disease where oral Iron preparations are ineffective. Non-dialysis dependent-chronic kidney disease (NDD-CKD) patients receiving an erythropoietin, Non-dialysis dependent-chronic kidney disease (NDD-CKD) patients not receiving an erythropoietin, Hemodialysis dependent-chronic kidney disease (HDD-CKD) patients receiving an erythropoietin, Peritoneal dialysis dependent-chronic kidney disease (PDD-CKD) patients receiving an erythropoietin, Patients undergoing surgical procedures, Patients donating blood etc.

Dosage & administration
Most CKD patients will require a minimum cumulative repletion dose of 1,000 mg of elemental iron to achieve a favorable hemoglobin response and to replenish iron stores (ferritin,). Patients may continue to require therapy with iron sucrose injection at the lowest dose necessary to maintain target levels of hemoglobin, and laboratory parameters of iron storage within acceptable limits.

• Hemodialysis Dependent Chronic-Kidney Disease Patients (HDDCKD):
with iron sucrose may be administered undiluted as a 100 mg slow intravenous injection over 2 to 5 minutes or as an infusion of 100 mg, diluted in a maximum of 100 mL of 0.9% NaCl over a period of at least 15 minutes per consecutive hemodialysis sessions for a total cumulative dose of 1,000 mg.

• Non-Dialysis Dependent Chronic-Kidney Disease Patients (NDD-CKD):
with iron sucrose is administered as a total cumulative dose of 1,000 mg over a 14 day period as a 200 mg slow IV injection undiluted over 2 to 5 minutes on 5 different occasions within the 14 day period. There is limited experience with administration of an infusion of 500 mg of with iron sucrose, diluted in a maximum of 250 mL of 0.9% NaCl, over a period of 3.5-4 hours on day 1 and day 14; hypotension occurred in 2 of 30 patients treated.

• Peritoneal Dialysis Dependent-Chronic Kidney Disease Patients (PDDCKD):
iron sucrose is administered as a total cumulative dose of 1,000 mg in 3 divided doses, given by slow intravenous infusion, within a 28 day period: 2 infusions of 300 mg over 1.5 hours 14 days apart followed by one 400 mg infusion over 2.5 hours 14 days later. The iron sucrose dose should be diluted in a maximum of 250mL of 0.9% NaCl.

Contraindications
The use of Iron Sucrose is contraindicated in patients with evidence of Iron overload, in patients with known hypersensitivity to Iron Sucrose or any of its inactive components, and in patients with anemia not caused by iron deficiency. It is also contraindicated in patients with history of allergic disorders including asthma, eczema and anaphylaxis, liver disease and infections.

Side effects
Hypotension, cramps/leg cramps, nausea, headache, vomiting, and diarrhea, headache, fever, pain, asthenia, unwell, malaise, accidental injury, chest pain, hypertension, hypervolemia,nausea, vomiting, abdominal pain, elevated liver enzymes. Mild or moderate hypersensitivity reactions presenting with wheezing, dyspnea, hypotension, rashes, or pruritus. Anaphylactoid reactions (anaphylactic shock, loss of consciousness or collapse, bronchospasm with dyspnea, or convulsion) associated with Iron Sucrose administration can occur.

Use in pregnancy & lactation
Pregnancy Category-B. This drug should be used during pregnancy only if clearly needed. Use in Lactation: Caution should be exercised when Iron Sucrose is administered to a nursing woman.

Precautions
Because body iron excretion is limited and excess tissue iron can be hazardous, 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 (hemoglobin, hematocrit, serum ferritin and transferrin saturation). Iron therapy should be withheld in patients with evidence of iron overload. Transferrin saturation values increase rapidly after IV administration of iron sucrose; thus, serum iron values may be reliably obtained 48 hours after IV dosing.

Drug interactions
Drug-drug interactions involving Iron sucrose have not been studied. Iron sucrose injection should not be administered concomitantly with oral Iron preparations since the absorption of oral Iron is reduced. Even oral Iron therapy should not be given until 5 days after last injection. Do not mix Iron Sucrose with other medications or add to parenteral nutrition solutions for intravenous infusion. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit.

Over dosage
Overdosage can cause acute iron overloading wich may manifests itself as haemosiderosis. Symptoms associated with overdosage or infusing Iron Sucrose too rapidly included hypotension, headache, vomiting, nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain, edema, and cardiovascular collapse. Overdosage should be treated with supportive measures and, if required, an Iron chelating agent. Most symptoms have been successfully treated with IV fluids, hydrocortisone, and/or antihistamines. Infusing the solution as recommended or at a slower rate may also alleviate symptoms

Storage
Store in a cool and dry place (do not freeze), protected from light.

Packaging
Anefer® Injection: Each carton contains 1 ampoule of 5 ml Iron Sucrose USP equivalent to 100 mg Elemental Iron (20 mg/ml) and 5 ml disposable syringe.

Opsonin Pharma
Ideas for healthcare

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