140mm

210mm

Feroject

100mg / **5**ml
Injection

(IRON SUCROSE)

فیروجیکٹ

۱۰۰ ملی گرام/۵ ملی لیٹر
انجیکشن

(آئرن سکروز)

COMPOSITION
Each 5ml contains:
Iron sucrose eq. to Elemental Iron.....100mg
(BP Specifications)

DESCRIPTION
Iron sucrose injection, is a brown, sterile, aqueous, complex of polynuclear iron (III) - hydroxide in sucrose for intravenous use. Iron sucrose injection has a molecular weight of approximately 34,000 – 60,000 daltons.
Each mL contains 20 mg elemental iron as iron sucrose in water for injection. The product contains no preservatives.
Therapeutic class: Hematinic

INDICATIONS
Iron sucrose is indicated in the treatment of iron deficiency anemia in the following patients:
- 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

MECHANISM OF ACTION
Iron sucrose is composed of a polynuclear iron (III)-hydroxide core surrounded by a large number of non-covalently bound sucrose molecules. The complex has a weight average molecular weight (Mw) of approximately 43 kDa. The polynuclear iron core has a structure similar to that of the core of the physiological iron storage protein ferritin. The complex is designed to provide, in a controlled manner, utilisable iron for the iron transport and storage proteins in the body (i.e., transferrin and ferritin, respectively).
Following intravenous administration, the polynuclear iron core from the complex is taken up predominantly by the reticuloendothelial system in the liver, spleen, and bone marrow. In a second step, the iron is used for the synthesis of Hb, myoglobin and other iron-containing enzymes, or stored primarily in the liver in the form of ferritin.

DOSAGE & ADMINISTRATION
Mode of Administration
Iron sucrose must only be administered intravenously either by slow injection or by infusion. The dosage of Iron sucrose is expressed in mg of elemental iron. Each mL contains 20 mg of elemental iron.
Adult Patients with Hemodialysis Dependent-Chronic Kidney Disease (HDD-CKD) Administer Iron sucrose 100 mg undiluted as a 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 session. Administer Iron sucrose early during the dialysis session (generally within the first hour). The usual total treatment course of Iron sucrose is 1000 mg. Iron sucrose treatment may be repeated if iron deficiency reoccurs.
Adult Patients with Non-Dialysis Dependent-Chronic Kidney Disease (NDD-CKD) Administer Iron sucrose 200 mg undiluted as a slow intravenous injection over 2 to 5 minutes or as an infusion of 200 mg in a maximum of 100 mL of 0.9% NaCl over a period of 15 minutes. Administer on 5 different occasions over a 14 day period. There is limited experience with administration of an infusion of 500 mg of Iron sucrose, diluted in a maximum of 250 mL of 0.9% NaCl, over a period of 3.5 to 4 hours on Day 1 and Day 14.Iron sucrose treatment may be repeated if iron deficiency reoccurs.
Adult Patients with Peritoneal Dialysis Dependent-Chronic Kidney Disease (PDD-CKD) Administer Iron sucrose in 3 divided doses, given by slow intravenous infusion, within a 28 day period: 2 infusions each of 300 mg over 1.5 hours 14 days apart followed by one 400 mg infusion over 2.5 hours 14 days later. Dilute Iron sucrose in a maximum of 250 mL of 0.9% NaCl. Iron sucrose treatment may be repeated if iron deficiency reoccurs.
Pediatric Patients (2 years of age and older) with HDD-CKD for iron maintenance treatment.
The dosing for iron replacement treatment in pediatric patients with HDD-CKD has not been established.
For iron maintenance treatment: Administer Iron sucrose at a dose of 0.5 mg/kg, not to exceed 100 mg per dose, every two weeks for 12 weeks given undiluted by slow intravenous injection over 5 minutes or diluted in 0.9% NaCl at a concentration of 1 to 2 mg/mL and administered over 5 to 60 minutes. Do not dilute to concentrations below 1 mg/mL
Pediatric Patients (2 years of age and older) with NDD-CKD or PDD-CKD who are on erythropoietin therapy for iron maintenance maintenance treatment
The dosing for iron replacement treatment in pediatric patients with NDD-CKD or PDD-CKD has not been established.
For iron maintenance treatment: Administer Iron sucrose at a dose of 0.5 mg/kg, not to exceed 100 mg per dose, every four weeks for 12 weeks given undiluted by slow intravenous injection over 5 minutes or diluted in 0.9% NaCl at a concentration of 1 to 2 mg/mL and administered over 5 to 60 minutes. Do not dilute to concentrations below 1 mg/mL. Iron sucrose treatment may be repeated if necessary.

PHARMACOKINETICS
In healthy adults administered intravenous doses of Iron sucrose, its iron component exhibited first order kinetics with an elimination half-life of 6 h, total clearance of 1.2 L/h, and steady state apparent volume of distribution of 7.9 L. The iron component appeared to distribute mainly in blood and to some extent in extravascular fluid. A study evaluating Iron sucrose containing 100 mg of iron labeled with $^{52}Fe/^{59}Fe$ in patients with iron deficiency showed that a significant amount of the administered iron is distributed to the liver, spleen and bone marrow and that the bone marrow is an irreversible iron trapping compartment.
Following intravenous administration of Iron sucrose, iron sucrose is dissociated into iron and sucrose. The sucrose component is eliminated mainly by urinary excretion. In a study evaluating a single intravenous dose of Iron sucrose containing 1,510 mg of sucrose and 100 mg of iron in 12 healthy adults (9 female, 3 male: age range 32 to 52), 68.3% of the sucrose was eliminated in urine in 4 h and 75.4% in 24 h. Some iron was also eliminated in the urine. Neither transferrin nor transferrin receptor levels changed immediately after the dose administration. In this study and another study evaluating a single intravenous dose of iron sucrose containing 500 to 700 mg of iron in 26 patients with anemia on erythropoietin therapy (23 female, 3 male; age range 16 to 60), approximately 5% of the iron was eliminated in urine in 24 h at each dose level. The effects of age and gender on the pharmacokinetics of Iron sucrose have not been studied.

WARNINGS & PRECAUTIONS
General
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.
Hypersensitivity Reactions
Serious hypersensitivity reactions have been reported in patients receiving Iron sucrose. No life threatening hypersensitivity reactions were observed in the clinical studies. Several cases of mild or moderate hypersensitivity reactions were observed in these studies. There are post-marketing spontaneous reports of life-threatening hypersensitivity reactions in patients receiving Iron sucrose.
Hypotension
Hypotension has been reported frequently in hemodialysis dependent-chronic kidney disease patients receiving intravenous iron. Hypotension also has been reported in non-dialysis dependent and peritoneal dialysis dependent-chronic kidney disease patients receiving intravenous iron. Hypotension following administration of Iron sucrose may be related to rate of administration and total dose administered. Caution should be taken to administer Iron sucrose according to recommended guidelines.
Pregnancy
Pregnancy Category B
Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.
Nursing Mothers
Iron sucrose is excreted in milk of rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Iron sucrose is administered to a nursing woman.
Iron Overload
Excessive therapy with parenteral iron can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. All adult and pediatric patients receiving Iron sucrose require periodic monitoring of hematologic and iron parameters (hemoglobin, hematocrit, serum ferritin and transferrin saturation). Do not administer Iron sucrose to patients with evidence of iron overload. Transferrin saturation (TSAT) values increase rapidly after intravenous administration of iron sucrose; do not perform serum iron measurements for at least 48 hours after intravenous dosing.

DRUG INTERACTIONS
Drug interactions involving Iron sucrose have not been studied. However, Iron sucrose may reduce the absorption of concomitantly administered oral iron preparations. Therefore, oral iron therapy should be started at least 5 days after the last injection of Iron sucrose.

SIDE EFFECTS
Immune system disorders: anaphylactic-type reactions, angioedema
Psychiatric disorders: confusion
Nervous system disorders: convulsions, collapse, light-headedness, loss-of-consciousness
Cardiac disorders: bradycardia
Vascular disorders: shock
Respiratory, thoracic and mediastinal disorders: bronchospasm, dyspnea
Musculoskeletal and connective tissue disorders: back pain, swelling of the joints
Renal and urinary disorders: chromaturia
General disorders and administration site conditions: hyperhidrosis
Symptoms associated with Iron sucrose injection total dosage or infusing too rapidly included hypotension, dyspnea, headache, vomiting, nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain, edema, and cardiovascular collapse. These adverse reactions have occurred up to 30 minutes after the administration of Iron sucrose injection. Reactions have occurred following the first dose or subsequent doses of Iron sucrose injection. Symptoms may respond to intravenous fluids, hydrocortisone, and/or antihistamines. Slowing the infusion rate may alleviate symptoms. Injection site discoloration has been reported following extravasation. Assure stable intravenous access to avoid extravasation.

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.

OVERDOSE
Dosages of iron sucrose injection in excess of iron needs may lead to accumulation of iron in storage sites leading to hemosiderosis. Periodic monitoring of iron parameters such as serum ferritin and transferrin saturation may assist in recognizing iron accumulation.
It should not be administered to patients with iron overload and should be discontinued when 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 overdosage or infusing iron sucrose too rapidly included hypotension, dyspnea, headache, vomiting, nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain, edema, and cardiovascular collapse. 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 & INSTRUCTIONS
Store in original carton at 20-25°C.
Protect from heat and sunlight. Do not freeze.
Keep away from the reach of the children.
Before using check on the absence of sediments.
Do not use the injection if any particulate matter is present, container is leaking or solution is cloudy.
To be sold on the prescription of a registered medical practitioner only.
FOR INTRAVENOUS USE ONLY.

HOW SUPPLIED
5ml x 5's Ampoules

خوراک وطریقہ استعمال:
ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

ہدایات:
دوا کو اس کی اصل پیکنگ میں ۲۰-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں ۔ دھوپ، گرمی اور منجمد ہونے سے بچائیں ۔ بچوں کی پہنچ سے دور رکھیں استعمال سے پہلے انجیکشن کو اچھی طرح چیک کرلیں۔ انجیکشن کے لیک ہونے، دھندلا ہونے یا اس میں ذرات نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔ صرف وریدی استعمال کیلئے۔

Manufactured by:
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Lahore, Pakistan.