FEGOLD
(Iron Sucrose Injection 5ml (20mg/ml))

For the use of a Registered Medical Practitioner or Hospital or a Laboratory Only
Abbreviated Prescribing information for FEGOLD (Iron Sucrose Injection USP) [Please refer the complete prescribing information for details]
PHARMACOLOGICAL PROPERTIES: Iron sucrose injection is an aqueous complex of poly-nuclear iron (III)-hydroxide in sucrose. Following intravenous (IV) administration, it dissociated into iron and sucrose, the iron is transported as a complex with transferrin to target cells including erythroid precursor cells where it is incorporated to Hemoglobin as cells mature to RBCs.
INDICATIONS: Iron deficiency anemia in which rapid and reliable substitution of iron is required.
DOSAGE AND ADMINISTRATION: Fegold injection must be administered by the IV route (MUST NOT by intramuscular). This may be by a slow IV injection or by an IV drip infusion. Test dose should be administered to new patient prior injection. The total cumulative dose (equivalent to total iron deficit in mg) determined by Hb level and body weight of each individual based on formula: [Total Iron deficit (mg) = body weight (kg)x(target Hb-Actual Hb)x0.24 + Depot iron (mg)]. [The amount of Fegold injection volume required can be determined by: Volume required = Total Iron deficit (mg)/20mg per ml]. The total single dose must not exceed 200 mg of iron given not more than three times per week. [for further details see PI]. C**ONTRAINDICATIONS**: Hypersensitivity to iron/its preparation/inactive ingredients of formulation/iron overload or anemia not caused by iron deficiency. Patients with history of asthma, eczema, atopic allergy. Pregnancy first trimester (Falling under pregnancy category B).
WARNINGS AND PRECAUTIONS: Use cautiously by considering hypersensitivity, hypotension, liver dysfunction, acute or chronic infection with injectable iron preparation and use in nursing mother. Iron overload may leads to iatrogenic hemosiderosis. Pediatric population experience unknown. **DRUG INTERACTION**: Iron Sucrose should not be administered concomitantly with oral Iron preparations since the absorption of oral Iron is reduced.
ADVERSE REACTIONS: The most frequently reported AEs (0.5-1.5%) with Injectable iron transient taste perversion (metallic taste), hypotension, fever and shivering, injection site reactions and nausea. Anaphylactoid/anaphylactic reaction. Isolated cases: reduced level of consciousness, light-headed feeling, confusion, angio-oedema, swelling of joints, hyperhidrosis, back pain, bradycardia, chromaturia, conjunctivitis, fluid overload, gout, hyperglycemia, hypoglycemia, hypertension, shock, convulsion. Nasopharyngitis, sinusitis, upper respiratory tract infections, pharyngitis, graft complications.
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 IV fluids, hydrocortisone, and/or antihistamines. Slowing the infusion rate may alleviate symptoms.