

**University Health System
Pharmacy & Therapeutics Committee
Iron sucrose (Venofer®)
Guidelines for Use
October 2010**

OVERVIEW

- Iron sucrose (Venofer®) is an intravenous iron supplement used to replete iron stores in patients with chronic kidney disease (CKD)
- It has been shown to be effective in hemodialysis-dependent (HDD), nonhemodialysis-dependent (NDD), and peritoneal dialysis (PDD) patients
- Intravenous (IV) administration overcomes issues related to oral iron supplementation
 - Multiple daily dosing
 - Inadequate absorption
 - Gastrointestinal side effects (nausea, constipation)
- Its use is favored to other IV formulations such as iron dextran due to a decreased incidence of hypersensitivity reaction
 - Administration of a test dose of iron sucrose is not required¹
- Not indicated for total dose infusions
- ALL PATIENTS ON ERYTHROPOIETIN THERAPY SHOULD BE GIVEN SUPPLEMENTAL IRON

FDA-APPROVED USES

- Iron deficiency anemia
 - All NDD-CKD patients
 - HDD-CKD patients receiving concurrent erythropoietin therapy
 - PDD-CKD patients receiving concurrent erythropoietin therapy

FDA-APPROVED DOSING

- Total cumulative iron dose of 1,000 mg is generally sufficient to replete iron stores in patients with CKD
- HDD-CKD¹
 - 100 mg undiluted injection, given over 2-5 minutes **OR**
 - 100 mg in 100 mL of normal saline, given over 15 minutes
 - *Give with each hemodialysis session until total cumulative iron dose is met*
- NDD-CKD¹
 - 200 mg undiluted injection, given over 2-5 minutes
 - *Give total cumulative iron dose in 5 separate administrations within 14 day period*

ALTERNATIVE USAGE AND DOSING

- Use in chemotherapy-related anemia: The use of intravenous iron supplementation may decrease red blood cell (RBC) transfusion requirements greater than oral iron therapy in patients with anemia related to chemotherapy.²
- Higher doses of iron sucrose: Doses of 300 mg given over 2 hours appear to be safe and well-tolerated.³ Doses of 400- 500 mg diluted in 250 mL of normal saline given in a single infusion over 2-3 hours on days 1 and 14 has been studied for iron-repletion in HDD-CKD and NDD-CKD patients.^{4,5} Adverse events were more common at higher doses. Hypotension may be more frequent in patients receiving larger doses during hemodialysis. Higher doses of iron sucrose may be better tolerated in patients not on hemodialysis.^{4,5}

CONTRAINDICATIONS

- Iron overload
- Known hypersensitivity to any component of the formulation
- Anemia not caused by iron deficiency

WARNINGS

- Hypersensitivity reaction
 - Monitor for signs and symptoms of an allergic reaction during infusion
 - Patients with pre-existing immune-mediated diseases may be at increased risk
- Hypotension
 - May be related to the rate of administration and total amount of drug administered

P&T GUIDELINES FOR USE

- Iron sucrose should only be used in the following patient populations:
 - Patients with iron deficiency anemia due to CKD
 - Patients with chemotherapy-induced anemia
 - Patients with active bleeding who refuse blood transfusion

P&T RESTRICTIONS

As of October 2010, the use of iron sucrose is no longer restricted.

Table 1: Comparison of IV iron products

Formulation	Concentration of elemental iron	Advantages	Disadvantages	Incidence of adverse events ⁶	Reported hypersensitivity (per 1 million doses) ⁶	In-patient cost
Iron sucrose (Venofer®)	20 mg/mL	Can be administered to iron dextran-sensitive patients ⁶ Decreased risk of free iron remaining in circulation Larger doses (200-300 mg) given over 2 hours appear to be well tolerated ^{3,5}	Free-iron toxicity: nausea, vomiting, flushing, and hypotension with rapid or large dose administration No total dose iron replacement- must be given 1-3 times per week	Up to 36%	2.6	\$40.57/100 mg
Sodium ferric gluconate (Ferrlecit®)	12.5 mg/mL	Can be administered to iron dextran-sensitive patients ⁶	Free-iron toxicity: nausea, vomiting, flushing, and hypotension with rapid or large dose administration Increased free iron in circulation due to rapid release of iron from gluconate complex ⁶ No total dose iron replacement- given over 8 separate dialysis sessions	Up to 35%	3.3	\$43.52/125 mg
Iron dextran (Dexferrum®, Infed®)	50 mg/mL	Only IV iron product approved for total dose infusion Can be given IM Adverse events are not related to the <i>rate</i> of administration- iron dextran complex dissociates slowly	Highest rate of adverse events, including hypersensitivity reactions Hypersensitivity reaction caused by antigenicity of dextran component Requires administration of a 25 mg test dose	Up to 50%	8.7* *Adverse events are more common with high-molecular weight iron dextran (Dexferrum®)	Dexferrum®: \$21.50/100 mg INFeD®: \$23.02/100 mg

References

1. Venofer® package insert. American regent; last revision 10/08.
2. Danguwan P, Manchana T. Blood transfusion reduction with intravenous iron in gynecologic cancer patients receiving chemotherapy. *Gynecologic Oncology* 2010; 116: 522-525.
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4. Chandler G, Harchowel J, Macdougall I. Intravenous iron sucrose: establishing a safe dose. *Am J Kid Dis* 2001; 38 988-991.
5. Blaustein D et al. The safety and efficacy of an accelerated iron sucrose dosing regimen in patients with chronic kidney disease. *Kid Inter* 2003;64:S72-S77.
6. Silverstein S, Rodgers G. Parenteral iron therapy options. *Am J Hematol* 2004;76:74-78.
7. Sinha S, Chiu D, Kolakkat S. Comparison of intravenous iron sucrose versus low-molecular-weight iron dextran in chronic kidney disease. *J Renal Care* 2009;35:67-73.