IV Drug Monograph

IRON SUCROSE (Venofer®)

For information on **OUTPATIENT IV iron therapy** use link to Sunnynet below

IV Iron Therapy: http://sunnynet.ca/Default.aspx?cid=112737

THERAPEUTIC CLASSIFICATION: Hematinic for Iron Deficiency Anemia

AVAILABILITY: 5 mL vial containing 100 mg (20 mg/mL) of elemental iron

PREPARATION: Doses >100 mg must be diluted in NS prior to infusion. See table, page 2.

STABILITY: Use infusion solution as soon as possible after preparation.

INDICATIONS & CRITERIA for USE:
- See Appendix, page 4

USUAL DOSAGE:

Hemodialysis Patients
- Initially: 100 mg IV at each dialysis session 3 times per week for a total of 10 doses. Dose is given into dialysis line by either direct injection over 5 min or by infusion in 100 mL NS over 15-30 min.
- Maintenance therapy: 100 mg IV into dialysis line according to individual patient requirements (usual range: once weekly to once monthly).

Other Patients
- Dosage varies according to the extent of anemia and iron deficiency.
- **The recommended usual maximum dose for routine use is 300 mg added to NS 100 mL** (total infusion volume of approximately 125 mL) **and infused over a period of 2 hours.**
- **For smaller patients (< 50 kg or 110 lb), consider limiting the dose to 200 mg.**
- If patient is deemed to require > 300 mg of iron sucrose, consider the option of administering two doses of up to 300 mg on two separate days rather than giving a single larger dose (400-500 mg.)
- The usual interval between successive infusions is 3-7 days; however, when a larger dose of iron is urgently required, doses can be infused on consecutive days at physician's discretion

ADMINISTRATION:

Authorized methods of administration by nurses (click anywhere in box).

A. Direct Injection: Hemodialysis RNs may give ≤ 100 mg by direct injection slowly over 5 minutes.

B. Intermittent Infusion: Add dose to NS and infuse according to table (see page 2).

C. Continuous Infusion: Not applicable.

INFUSION VOLUME, RATE AND DURATION :

Dose (volume)	**Volume of NS Infusion**	**Total Volume: Drug + Solution** (includes overfill)	**Final Concentration¶**	**Infusion Rate**	**Infusion Duration**
< 100 mg	100 mL	Depends on dose	Depends on dose	N/A	15-30 min
100 mg (5 mL)	100 mL	115 mL	0.87 mg/mL	230 mL/h	30 min
200 mg * (10 mL)	250 mL *	290 mL	0.69 mg/mL	290 mL/h	1 hour
300 mg (15 mL)	**100 mL**	**125 mL**	**2.4 mg/mL**	**65 mL/h**	**2 hours**
400 mg ** (20 mL)	500 mL	568 mL	0.70 mg/mL	200 mL/h	3 hours
500 mg ** (25 mL)	500 mL	573 mL	0.87 mg/mL	150 mL/h	4 hours

¶The optimal concentrations for infusion with a Sapphire pump are less than 1 mg/mL OR 2.4-2.5 mg/mL as they appear to avoid false pump alarms.
*FLUID RESTRICTED patients – the preferred treatment is 300 mg in 100 mL NS (total volume of 125 mL) as doses of 200 mg cannot be added to 100 mL (may cause false pump alarms).
**** Doses of 400 mg or 500 mg are not recommended for routine use (see "Usual Dosage")**

ADVERSE EFFECTS:

Common adverse effects (> 5%) include:

- ***Hyperglycemia is not a concern with iron sucrose***
- Hypotension – associated with larger doses, and/or more rapid infusion rates
- Chest pain, tightness, discomfort
- Nausea, vomiting, diarrhea
- Abdominal or lower back pain
- Muscle cramps, particularly in the legs
- Acute tenosynovitis, usually involving the hands
- Headache
- Infusion site reactions (swelling, erythema, pruritus, phlebitis)

Serious hypersensitivity (anaphylactoid) reactions are rare:

- Signs and symptoms include flushing, hypotension, urticaria, pruritus, bronchospasm, angioedema

NURSING IMPLICATIONS:

- ***Before preparing dose for administration:***
  - Ask if the patient has had a previous allergic reaction to IV iron. Patients with a history of adverse reaction to IV iron can be given subsequent doses depending on the severity of the reaction. It is preferable in such patients to consider using a lower dose and a longer infusion time. Premedication with steroids and/or antihistamines may also be considered. Consult with physician.
  - Use of a test dose of iron sucrose is NOT recommended since the predictive value is low.
  - Epinephrine, diphenhydramine, and corticosteroid injections should be available in the treatment area since iron sucrose may rarely cause serious anaphylactoid reactions, even in patients who have tolerated previous infusions.

- ***Monitoring***
  - Monitor BP prior to administration, at completion of infusion, at 30 min after completion of the infusion, and whenever patient exhibits signs of hypotension (dizziness).
  - Outpatients must be observed for any signs of an adverse reaction for a minimum of 30 min after completion of the infusion; check BP 30 min after completion of infusion.
  - Adverse effects usually occur toward the end of the infusion and generally resolve within 5 minutes to 2 hours after stopping the infusion.
  - If the patient experiences an acute adverse reaction:
    - Stop the infusion
    - Notify the attending physician
    - Perform vital signs (HR, RR, BP, temperature)
    - Continue intravenous fluids
    - Institute management as directed by physician
- Avoid extravasation. If infiltration is suspected, stop infusion immediately and apply ice.
- **Note: Iron sucrose <u>does not alter MRI</u> (magnetic resonance imaging)**

Continued on page 4

APPENDIX

INDICATIONS, CRITERIA for USE, and TREATMENT REGIMENS:

- Iron deficiency anemia in patients who cannot be managed using oral iron therapy
- Venofer infusions may be used to treat iron deficiency defined as:
  1. Hb < 110 **AND** either of #2 or #3 below:
  2. Ferritin < 30; **OR**
  3. Ferritin < 200 AND iron saturation < 20%
- Recommended dose is 300 mg in 100 mL of NS by IV infusion over 2 hours.
- If patient < 50 kg (110 lb), consider a 200 mg dose to reduce infusion-related side effects.

Indications & Criteria for Use	**Treatment Regimen**
Inadequate response to an adequate trial of oral iron*	1 infusion and reassess in 4 weeks
Nephrology (non-hemodialysis patients)**:** Inadequate response to an adequate trial of oral iron*	300 mg weekly x 3 infusions (Hemodialysis patients usually receive 100 mg doses at each session 3 x / week)
Inability to absorb oral iron resulting in severe iron deficiency (ferritin < 30) caused by GI disease (celiac) or surgery (gastrectomy) Goal: maintain ferritin > 50 with IV iron	Typically 1 infusion per month
Severe intolerance to oral iron (vomiting and/or diarrhea)	1 infusion and reassess in 4 weeks
Chronic GI bleeding with inadequate response to an adequate trial of oral iron* and GI interventions Goal: maintain hemoglobin > 110 g/L	Typically 1 infusion per month. Titrate to lowest possible frequency.
Rapid correction of anemia in patients with severe symptomatic iron deficiency anemia (Hb < 90 g/L) in whom avoidance of RBC transfusion is important	2-3 infusions given 3-7 days apart. Depending on urgency, doses can be infused on consecutive days at physician's discretion.
During chemotherapy or radiation therapy for cancer	Hb 90-109 g/L – 1 infusion Hb < 90 g/L – 2-3 infusions usually given once weekly
Preoperative iron deficiency anemia before elective **high blood loss surgery**	Hb < 130 g/L – 1 infusion Hb < 110 g/L – 2-3 infusions usually given 3-7 days apart

* An adequate trial of oral iron therapy consists of the following:
- Adequate dose – 200 mg/day of elemental iron given as ferrous fumarate 300 mg po BID; if not tolerated, consider Proferrin (heme iron polypeptide) 11 mg po BID
- Vitamin C to enhance iron absorption – 500 mg with each dose of iron
- Optimal timing – to be taken on an empty stomach (1 hr before breakfast and at bedtime)
- Appropriate duration – 3 months