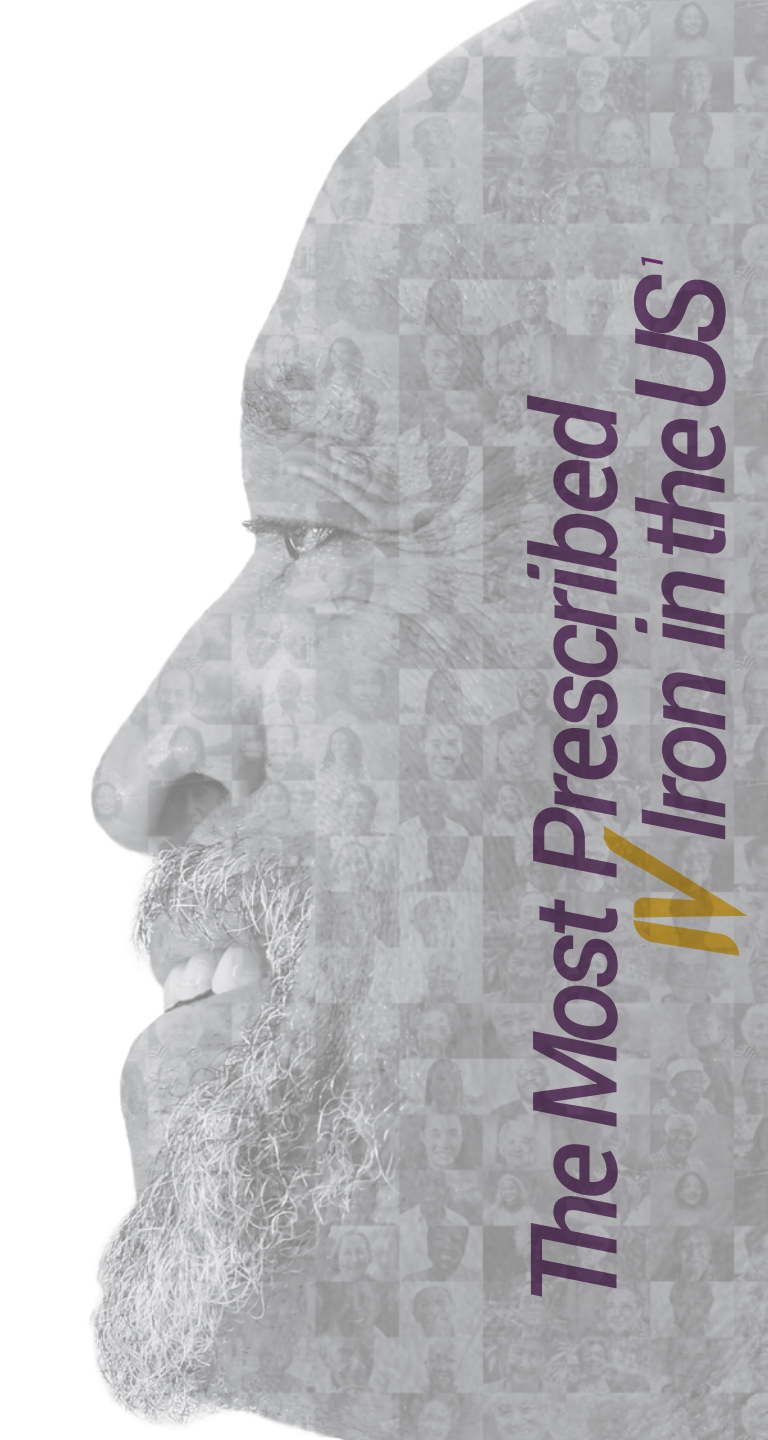


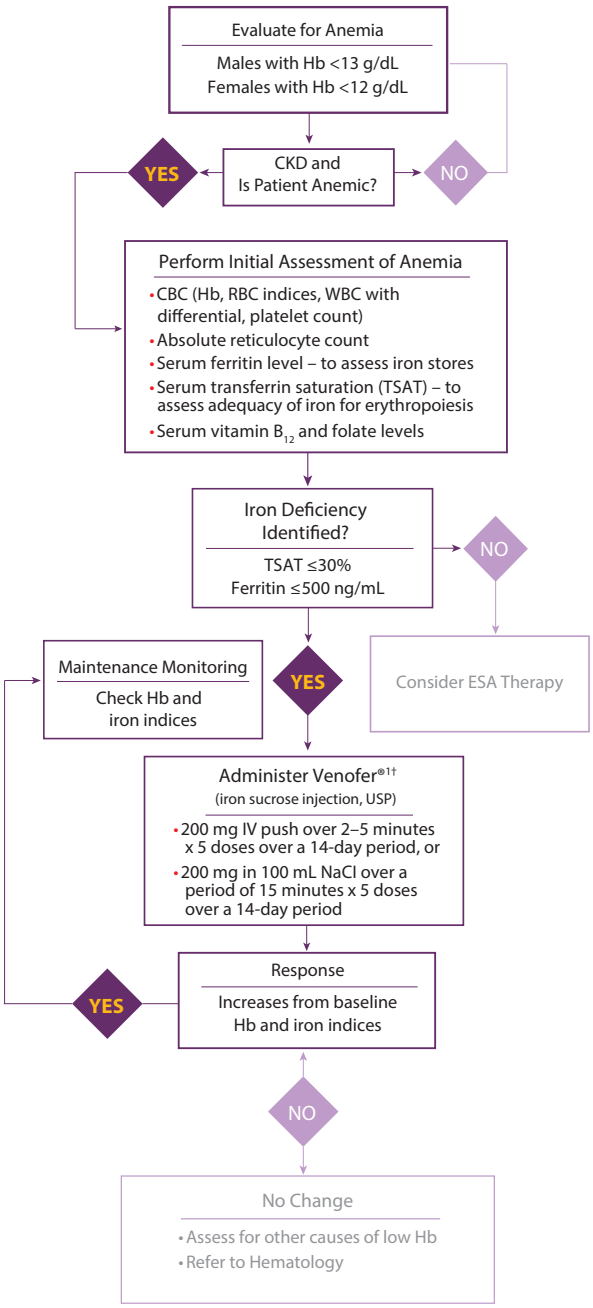
The Most Prescribed IV Iron in the US[1]

Venofer™
iron sucrose injection, USP

Venofer® must only be administered intravenously either by slow injection or infusion.

Dosing & Administration Guide

Non-dialysis-dependent CKD adult IV iron dosing algorithm*



*Adapted from the KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Official Journal of the International Society of Nephrology. *Kidney Int*. 2012;2(4):288-335.

†For adult CKD patients on ESA therapy who are not receiving iron supplementation, the guideline suggests a trial of IV iron (or in CKD ND patients alternatively a 1–3 month trial of oral iron therapy) if:

- An increase in Hb concentration or a decrease in ESA dose is desired, and
- TSAT is ≤30% and ferritin is ≤500 ng/mL (≤500 µg/L)

7-Day stability after dilution

Venofer® (iron sucrose injection, USP) offers 7-day stability in both plastic syringes and IV admixtures diluted with 0.9% sodium chloride (NaCl) injection, avoiding potential waste.

	Concentration	Controlled Room Temperature (25°C ± 2°C)	Refrigerated (4°C ± 2°C)
Plastic Syringe	• 2 mg–10 mg elemental iron per mL • 20 mg of elemental iron per mL (undiluted)	✓	✓
IV Admixture (PVC and non-PVC)	• 1 mg–2 mg elemental iron per mL	✓	⊘

- **Do not dilute in concentrations below 1 mg/mL**
- Do not mix Venofer with other medications
- Do not add Venofer to parenteral nutrition solutions for intravenous infusion

INDICATION AND USAGE

Venofer® (iron sucrose injection, USP) is indicated for the treatment of iron deficiency anemia in patients with chronic kidney disease (CKD).

IMPORTANT SAFETY INFORMATION

DOSAGE AND ADMINISTRATION

Pediatric Patients (2 Years of Age and Older)
The dosing for iron replacement treatment in pediatric patients with Peritoneal or Hemodialysis-Dependent - CKD or Non-Dialysis Dependent CKD have not been established.

CONTRAINDICATIONS

Known hypersensitivity to Venofer.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information.

Venofer™
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Dosing and administration for adult CKD patients[2]

The usual adult total treatment course of Venofer® (iron sucrose injection, USP) is 1000 mg. Venofer treatment may be repeated if iron deficiency reoccurs.

IV Push	100 mg over 2–5 min	• Hemodialysis-dependent chronic kidney disease (HDD-CKD) • Consecutive dialysis sessions
	200 mg over 2–5 min	• Non-dialysis-dependent chronic kidney disease (NDD-CKD) • Five occasions over 14 days
Infusion* Diluted with 0.9% sodium chloride injection at concentrations of 1–2 mg/mL	100 mg/100 mL over 15 min	• Hemodialysis-dependent chronic kidney disease (HDD-CKD) • Consecutive dialysis sessions
	200 mg/100 mL over 15 min	• Non-dialysis-dependent chronic kidney disease (NDD-CKD) • Five occasions over 14 days
	2 doses of 300 mg/250 mL over 1.5 hrs **plus** 1 dose of 400 mg/250 mL over 2.5 hrs	• Peritoneal-dialysis-dependent chronic kidney disease (PDD-CKD) • 14 days apart

*Administer early during the dialysis session.

Dosing and administration for pediatric patients[2]

Pediatric Patients (2 years of age or older) with HDD-CKD	For iron maintenance treatment, administer Venofer® (iron sucrose injection, USP) • At a dose of 0.5 mg/kg, not to exceed 100 mg per dose • Every 2 weeks for 12 weeks • Given undiluted by slow intravenous injection over 5 minutes or diluted in 0.9% NaCl at concentrations of 1–2 mg/mL and administered over 5–60 minutes
Pediatric Patients (2 years of age or older) with NDD-CKD or PDD-CKD who are on erythropoietin therapy for iron maintenance treatment	For iron maintenance treatment, administer Venofer • At a dose of 0.5 mg/kg, not to exceed 100 mg per dose • Every 4 weeks for 12 weeks • Given undiluted by slow intravenous injection over 5 minutes or diluted in 0.9% NaCl at concentrations of 1–2 mg/mL and administered over 5–60 minutes

Venofer treatment may be repeated if necessary. The dosing for iron replacement treatment in pediatric patients with HDD-CKD, NDD-CKD, or PDD-CKD has not been established.

Venofer has not been studied in patients younger than 2 years old.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Venofer. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. If hypersensitivity reactions or signs of intolerance occur during administration, stop Venofer immediately. Monitor patients for signs and symptoms of hypersensitivity during and after Venofer administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Venofer when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. Most reactions associated with intravenous iron preparations occur within 30 minutes of the completion of the infusion.

Venofer may cause clinically significant hypotension. Monitor for signs and symptoms of hypotension following each administration of Venofer. Hypotension following administration of Venofer may be related to rate of administration and/or total dose delivered.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Excessive therapy with parenteral iron can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. All adult and pediatric patients receiving Venofer require periodic monitoring of hematologic and iron parameters (hemoglobin, hematocrit, serum ferritin and transferrin saturation). Do not administer Venofer 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.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information.

Venofer™
iron sucrose injection, USP

For Intravenous Use Only

INDICATION AND USAGE

Venofer® (iron sucrose injection, USP) is indicated for the treatment of iron deficiency anemia in patients with chronic kidney disease (CKD).

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ADVERSE REACTIONS

Adult Patients: The most common adverse reactions (≥2%) include diarrhea, nausea, vomiting, headache, dizziness, hypotension, pruritus, pain in extremity, arthralgia, back pain, muscle cramp, injection site reactions, chest pain and peripheral edema.
Pediatric Patients: The most common adverse reactions (≥2%) are headache, respiratory tract viral infection, peritonitis, vomiting, pyrexia, dizziness, cough, nausea, arteriovenous fistula thrombosis, hypotension and hypertension.

Post-Marketing Experience
Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. In post-marketing safety studies of Venofer in 1,051 patients with HDD-CKD, adverse reactions reported by > 1% were cardiac failure congestive, sepsis and dysgeusia.

- *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 Venofer 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 Venofer injection. Reactions have occurred following the first dose or subsequent doses of Venofer. Slowing the infusion rate may alleviate symptoms.

Injection site discoloration has been reported following extravasation. Assure stable intravenous access to avoid extravasation.

DRUG INTERACTIONS

Venofer may reduce the absorption of concomitantly administered oral iron preparations.

Geriatric Use
Dose administration to an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

OVERDOSAGE

No data are available regarding overdosage of Venofer in humans. Excessive dosages of Venofer may lead to accumulation of iron in storage sites potentially leading to hemosiderosis. Do not administer Venofer to patients with iron overload.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information.

You are encouraged to report Adverse Drug Events to American Regent, Inc. at 1-800-734-9236 or to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

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The Most Prescribed IV Iron in the US[1]

Available in the Following Sizes

NDC#	Strength (Each mL contains 20 mg of Elemental Iron)	Supplied As
0517-2310-05	200 mg	10 mL Single-Dose Vial
0517-2325-10	50 mg	2.5 mL Single-Dose Vial
0517-2340-10	100 mg	5 mL Single-Dose Vial
0517-2340-25	100 mg	5 mL Single-Dose Vial

Venofer™
iron sucrose injection, USP

You are encouraged to report Adverse Drug Events to American Regent, Inc:
Email: pv@americanregent.com; Fax: 1-610-650-0170
Phone: 1-800-734-9236

ADEs may also be reported to the FDA
at 1-800-FDA-1088 or **www.fda.gov/medwatch**

Drug Information:
1-888-354-4855 (9:00 am–5:00 pm Eastern Time, Monday–Friday)
For urgent drug information outside of normal business hours, assistance is available at 1-877-845-6371

1-800-645-1706 \\ AMERICANREGENT.COM

AMERICAN REGENT™

REFERENCES
1. IQVIA [NSP Audit from MAT November 2013 to November 2018].
2. Venofer® [package insert]. Shirley, NY: American Regent, Inc.; 2019.