***Venofer® (iron sucrose injection, USP) dosage and administration[1]:**

Population†	Indication†	Dose
Adult patients	Hemodialysis-dependent chronic kidney disease (HDD-CKD)	100 mg slow intravenous injection or infusion
	Non-dialysis-dependent chronic kidney disease (NDD-CKD)	200 mg slow intravenous injection or infusion
	Peritoneal dialysis-dependent chronic kidney disease (PDD-CKD)	2 doses of 300 mg plus 1 dose of 400 mg intravenous infusion
Pediatric patients	HDD-CKD, PDD-CKD, or NDD-CKD	0.5 mg/kg slow intravenous injection or infusion

†Please see Venofer PI for complete dosage and administration information.

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‡Injectafer® (ferric carboxymaltose) recommended dosage in patients with iron deficiency with heart failure[4]:

	Weight less than 70 kg			Weight 70 kg or more		
	Hb (g/dL)			Hb (g/dL)		
	<10	10 to 14	>14 to <15	<10	10 to 14	>14 to <15
Day 1	1,000 mg	1,000 mg	500 mg	1,000 mg	1,000 mg	500 mg
Week 6	500 mg	No dose	No dose	1,000 mg	500 mg	No dose

Administer a maintenance dose of 500 mg at 12, 24, and 36 weeks if serum ferritin <100 ng/mL or serum ferritin 100-300 ng/mL with transferrin saturation <20%. There are no data available to guide dosing beyond 36 weeks or with Hb ≥15 g/dL.

‡Please see Injectafer PI for complete dosage and administration information.

¶The total amount of INFeD required for the treatment of iron deficiency anemia is determined based on the table and formula in the INFeD Full Prescribing Information.

#INFeD can also be given by intramuscular injection.

Venofer (iron sucrose) injection, USP

For Intravenous Use Only

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Known hypersensitivity to Venofer.

WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions: 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.

Hypotension: 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.

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 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.

ADVERSE REACTIONS
Adult Patients: The most common adverse reactions in clinical trials (≥2% and greater than comparator) included 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 in clinical trials (≥2%) were 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 hemodialysis-dependent chronic kidney disease (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
- *Cardiovascular system:* bradycardia, shock, acute myocardial ischemia with or without myocardial infarction or with in-stent thrombosis in the context of a hypersensitivity reaction
- *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.

USE IN SPECIFIC POPULATIONS
Pregnancy
Untreated iron deficiency anemia (IDA) in pregnancy is associated with adverse maternal outcomes such as post-partum anemia. Adverse pregnancy outcomes associated with IDA include increased risk for preterm delivery and low birth weight.

Severe adverse reactions including circulatory failure (severe hypotension, shock including in the context of anaphylactic reaction) may occur in pregnant women with parenteral iron products (such as Venofer), which may cause fetal bradycardia, especially during the second and third trimester.

Pediatric Use
Safety and effectiveness of Venofer for iron replacement treatment in pediatric patients with dialysis-dependent or non-dialysis-dependent chronic kidney disease (CKD) have not been established.

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.

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

For additional Safety Information, please see 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.

REF-0262 6/2022

Injectafer (ferric carboxymaltose injection)

INDICATIONS
Injectafer® (ferric carboxymaltose injection) is indicated for the treatment of iron deficiency anemia (IDA) in adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron, and in adult patients who have non-dialysis dependent chronic kidney disease. Injectafer is also indicated for iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Injectafer is contraindicated in patients with hypersensitivity to Injectafer or any of its inactive components.

WARNINGS AND PRECAUTIONS
Symptomatic Hypophosphatemia
Symptomatic hypophosphatemia with serious outcomes including osteomalacia and fractures requiring clinical intervention has been reported in patients treated with Injectafer in the post-marketing setting. These cases have occurred mostly after repeated exposure to Injectafer in patients with no reported history of renal impairment. However, symptomatic hypophosphatemia has been reported after one dose. Possible risk factors for hypophosphatemia include a history of gastrointestinal disorders associated with malabsorption of fat-soluble vitamins or phosphate, inflammatory bowel disease, concurrent or prior use of medications that affect proximal renal tubular function, hyperparathyroidism, vitamin D deficiency, malnutrition, and hereditary hemorrhagic telangiectasia (HHT or Osler-Weber-Rendu syndrome). In most cases, hypophosphatemia resolved within three months.

Correct pre-existing hypophosphatemia prior to initiating therapy with Injectafer. Monitor serum phosphate levels in patients at risk for chronic low serum phosphate. Check serum phosphate levels prior to a repeat course of treatment in patients at risk for low serum phosphate and in any patient who receives a second course of therapy within three months. Treat hypophosphatemia as medically indicated.

Hypersensitivity Reactions
Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life- threatening and fatal, have been reported in patients receiving Injectafer. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after Injectafer administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Injectafer when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. In clinical trials, serious anaphylactic/anaphylactoid reactions were reported in 0.1% (2/1775) of subjects receiving Injectafer. Other serious or severe adverse reactions potentially associated with hypersensitivity which included, but were not limited to, pruritus, rash, urticaria, wheezing, or hypotension were reported in 1.5% (26/1775) of these subjects.

Hypertension
In clinical studies, hypertension was reported in 4% (67/1775) of subjects in clinical trials 1 and 2. Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed in 6% (106/1775) of subjects in these two clinical trials. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each Injectafer administration.

Laboratory Test Alterations
In the 24 hours following administration of Injectafer, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in Injectafer.

ADVERSE REACTIONS
Adults
In two randomized clinical studies [Studies 1 and 2], a total of 1775 patients were exposed to Injectafer, 15 mg/kg of body weight, up to a maximum single dose of 750 mg of iron on two occasions, separated by at least 7 days, up to a cumulative dose of 1500 mg of iron. Adverse reactions reported by >2% of Injectafer-treated patients were nausea (7.2%); hypertension (4%); flushing (4%); injection site reactions (3%); erythema (3%); hypophosphatemia (2.1%); and dizziness (2.1%).

Pediatric
The safety of Injectafer in pediatric patients was evaluated in Study 3. Study 3 was a randomized, active- controlled study in which 40 patients (1 to 12 years of age: 10 patients, 12 to 17 years of age: 30 patients) received Injectafer 15 mg/kg to a maximum single dose of 750 mg (whichever was smaller) on Days 0 and 7 for a maximum total dose of 1500 mg; 38 patients evaluable for safety in the control arm received an age- dependent formulation of oral ferrous sulfate for 28 days. The median age of patients who received Injectafer was 14.5 years (range, 1-17); 83% were female; 88% White and 13% Black. The most common adverse reactions (≥4%) were hypophosphatemia (13%), injection site reactions (8%), rash (8%), headache (5%), and vomiting (5%).

Patients with Iron Deficiency and Heart Failure
The safety of Injectafer was evaluated in adult patients with iron deficiency and heart failure in randomized controlled trials FAIR-HF (NCT00520780), CONFIRM-HF (NCT01453608) and AFFIRM-AHF (NCT02937454) in which 1016 patients received Injectafer versus 857 received placebo. The overall safety profile of Injectafer was consistent across the studied indications.

Post-Marketing Experience
The following adverse reactions have been identified during post approval use of Injectafer. 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.

The following adverse reactions have been reported from the post-marketing spontaneous reports with Injectafer: *cardiac disorders:* tachycardia; *general disorders and administration site conditions:* chest discomfort, chills, pyrexia; *metabolism and nutrition disorders:* hypophosphatemia; *musculoskeletal and connective tissue disorders:* arthralgia, back pain, hypophosphatemic osteomalacia; *nervous system disorders:* syncope; *respiratory, thoracic and mediastinal disorders:* dyspnea; *skin and subcutaneous tissue disorders:* angioedema, erythema, pruritus, urticaria; *pregnancy:* fetal bradycardia.

CLINICAL CONSIDERATIONS IN PREGNANCY
Untreated IDA in pregnancy is associated with adverse maternal outcomes such as postpartum anemia. Adverse pregnancy outcomes associated with IDA include increased risk for preterm delivery and low birth weight.

Severe adverse reactions including circulatory failure (severe hypotension, shock including in the context of anaphylactic reaction) may occur in pregnant women with parenteral iron products (such as Injectafer) which may cause fetal bradycardia, especially during the second and third trimester.

For additional Safety Information, please see 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.

REF-2471 1/2025

REFERENCES:
1. Ferrlecit® (sodium ferric gluconate complex injection). Package insert. Sanofi-Aventis US LLC. **2.** Monoferric (ferric derisomaltose) injection. Package Insert. Pharmacosmos Therapeutics, Inc. **3.** Venofer® (iron sucrose injection, USP). Package insert. American Regent, Inc. **4.** Injectafer® (ferric carboxymaltose injection). Package insert. American Regent, Inc. **5.** INFeD® (iron dextran injection, USP). Package insert. Actavis Pharma, Inc. **6.** Feraheme® (ferumoxytol injection). Package insert. AMAG Pharmaceuticals, Inc.

AMERICAN REGENT®
5 Ramsey Road \ Shirley, NY 11767 \ 1.800.645.1706
F 631.924.1731 \ www.americanregent.com

Learning About
IV Iron Therapies

The following table is provided as a quick reference guide. It contains select information from the prescribing information of the drugs listed.

The table should not be used to draw conclusions about the relative efficacy or safety of one product to another.

Please see Full Prescribing Information for each product.

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The following table is provided as a quick reference guide. It contains select information from the prescribing information of the drugs listed. The table should not be used to draw conclusions about the relative efficacy or safety of one product to another. Please see Full Prescribing Information for each product.

		Ferrlecit® / generic available *(sodium ferric gluconate complex in sucrose injection)*[1]	**Monoferric®** *(ferric derisomaltose) injection*[2]	**Venofer®** *(iron sucrose injection, USP)*[3]	**Injectafer®** *(ferric carboxymaltose injection)*[4]	**INFeD®** *(iron dextran injection, USP)*[5]	**Feraheme®** *(ferumoxytol injection)*[6]
Indications	**Indications**	Treatment of iron deficiency anemia (IDA) in adult patients and in pediatric patients age 6 years and older with chronic kidney disease receiving hemodialysis who are receiving supplemental epoetin therapy	Treatment of IDA in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron; who have non-dialysis-dependent chronic kidney disease	An iron replacement product indicated for the treatment of iron deficiency anemia (IDA) in patients with chronic kidney disease (CKD)	Injectafer is an iron replacement product indicated for the treatment of IDA in adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron, adult patients who have non-dialysis dependent chronic kidney disease, or iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity.	Treatment of adult and pediatric patients of age 4 months and older with documented iron deficiency who have intolerance to oral iron or have had an unsatisfactory response to oral iron	Treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron or who have chronic kidney disease (CKD)
Dosing	**Dose per administration**	• For adult patients, the recommended dose is 10 mL (125 mg of elemental iron) • For pediatric patients, the recommended pediatric dose is 0.12 mL/kg (1.5 mg/kg of elemental iron)	• For patients weighing 50 kg or more, administer 1,000 mg • For patients weighing less than 50 kg, administer 20 mg/kg actual body weight	100 mg to 400 mg for adults, depending upon the indication* *(For specific dosing for HDD-CKD, PDD-CKD, and NDD-CKD, see page 5 and Full Prescribing Information)	• For IDA patients weighing 50 kg or more: the recommended dose is 750 mg (2 doses separated by at least 7 days) • For IDA patients weighing less than 50 kg, the recommended dosage is 15 mg/kg (2 doses separated by at least 7 days) • For adult IDA patients weighing 50 kg or more, an alternative dose of 15 mg/kg body weight up to a maximum of 1,000 mg (a single-dose treatment) ‡For specific dosing for adult patients with iron deficiency and heart failure, please see page 6 and Full Prescribing Information	Administer daily doses of no more than 2 mL (100 mg of elemental iron) Recommended dosage is calculated based on actual patient weight utilizing a volume table and formulas provided in the Full Prescribing Information¶	The recommended dose is an initial 510 mg dose, followed by a second 510 mg dose 3 to 8 days later
	Recommended cumulative dose	• Adult patients: Most patients may require a cumulative dose of 1,000 mg of elemental iron • Pediatric patients: The maximum dosage should not exceed 125 mg per dose	• For patients weighing 50 kg or more, treatment is 1,000 mg per course • For patients weighing less than 50 kg, treatment is 20 mg/kg actual body weight	Usual total treatment course is 1,000 mg	Total cumulative dose for IDA not to exceed 1,500 mg of iron per course	Daily doses of no more than 2 mL until the total required dose is administered¶	Usual treatment course is 1,020 mg
	Number of administrations for recommended cumulative dose	8	1	5† ***(for IDA patients with NDD-CKD)***	2‡ ***(maximum doses per course for IDA)*** *For more information regarding ID in heart failure, see Full Prescribing Information*	Number of administrations is determined by the total required dose needed for each individual patient based on their weight and hemoglobin¶ 1 to 10	2
Administration	**IV push**	Adult patients: Yes Pediatric patients: No	No	Yes†	Yes§	Yes# #INFeD may also be given by intramuscular injection	No
	IV infusion	Yes, over 1 hour	Yes, over at least 20 minutes	Yes, over a period of 15 minutes (for IDA patients with NDD-CKD)*†	Yes, over at least 15 minutes§	No	Yes, over at least 15 minutes
	Test dose required	No	No	No	No	Yes	No
	Boxed Warning	No	No	No	No	Yes	Yes
Pharmacy Specifications	**Stability when mixed with 0.9% NaCl**	Use immediately after dilution	Stable for up to 8 hours at room temperature	Stable for 7 days • Admixture: concentrations of 1 mg to 2 mg of iron per mL at controlled room temperature • Syringe: concentrations of 2 mg to 10 mg of iron per mL (or undiluted) at controlled room temperature or under refrigeration	Admixture: stable for 72 hours at controlled room temperature at concentrations of 2 mg to 4 mg of iron per mL	Given undiluted	Use immediately or store at controlled room temperature for up to 4 hours or refrigerated for up to 48 hours
	Preservative	Benzyl alcohol	None	None	None	None	None
	How supplied	62.5 mg/5 mL single-dose vial	1,000 mg/10 mL single-dose vial, 500 mg/5 mL single-dose vial, 100 mg/mL single-dose vial	50 mg/2.5 mL single-dose vial,100 mg/5 mL single-dose vial, 200 mg/10 mL single-dose vial	100 mg/2 mL single-dose vial, 750 mg/15 mL single-dose vial	100 mg/2 mL single-dose vial	510 mg/17 mL single-dose vial