MORE THAN 30 MILLION REASONS TO BELIEVE®

VENOFER OFFERS

EFFICIENCY, FLEXIBILITY, AND RELIABILITY

Venofer®
iron sucrose injection, USP

The Most Prescribed IV Iron in the US[1]

More than 30 million patient years of exposure with over 685 million units[2*†]

*Patient years are calculated based on an estimated annual cumulative dose of 2,000 mg administered. †A unit is a 100 mg iron equivalent sold.

For Intravenous Use Only

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).

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Venofer is contraindicated in patients with known hypersensitivity to Venofer.

REFERENCES:
1. IQVIA. NSP Audit from January 2020 to January 2025. **2.** Data on file. Iron Sucrose Periodic Safety Update Report, 2023. American Regent, Inc.®

Venofer® efficiency

7-DAY STABILITY AFTER DILUTION

Venofer® (iron sucrose) injection, USP offers 7-day stability in both plastic syringes and IV admixtures.

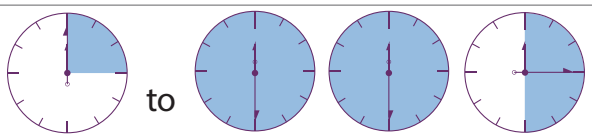
IV iron products	Stability after dilution*
Venofer® (iron sucrose) injection, USP	Syringes: Stable for 7 days at controlled room temperature and when refrigerated[3] Admixture: Stable for 7 days at controlled room temperature[3]
Injectafer® (ferric carboxymaltose injection)	Stable for 72 hours at room temperature[4]
Ferrlecit®/generic available (sodium ferric gluconate complex in sucrose injection)	Use immediately after dilution[5]
INFeD® (iron dextran injection, USP)	Not listed in Prescribing Information[6]
Feraheme® (ferumoxytol injection)	Stable for up to 4 hours at room temperature or 48 hours when refrigerated[7]
Monoferric® (ferric derisomaltose) injection	Stable for up to 8 hours at room temperature[8]

*Information obtained from Prescribing Information for respective treatments. Please consult their Full Prescribing Information. Trademarks are the property of their respective owners.

Venofer® flexibility

FLEXIBILITY IN PATIENT TREATMENT[3]

- Venofer comes in single-dose vials that can be made into syringes and IV bags
- 7-day stability allows for storage on hospital floors
- Venofer can be administered by IV push to adult patients with HDD- and NDD-CKD over 2 to 5 minutes†

IV push	Venofer can be administered by IV push to adult HDD- and NDD-CKD patients over 2 to 5 minutes.†
IV infusion	Venofer offers several infusion times for Adult HDD-, NDD-, and PDD-CKD patients ranging from 15 minutes to 2.5 hours, depending on the dose.† 

†Please see the Venofer Full Prescribing Information for complete dosage and administration information.
CKD=chronic kidney disease; HDD=hemodialysis-dependent; IV=intravenous; NDD=non–dialysis-dependent; PDD=peritoneal dialysis–dependent.

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.

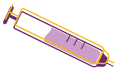
Venofer® compatibility

IV IRON COMPATIBILITY WITH VIAL CONNECTOR SYSTEMS

Venofer® (iron sucrose) injection, USP is compatible with vial connector systems that accommodate a 13 mm vial opening.

IV iron	Venofer® (iron sucrose) injection, USP
Vial size	13 mm
Usual infusion volume	100 mL
Connector compatibility	Yes

POTENTIAL SAVINGS



The ability to IV push Venofer may reduce pharmacy preparation time and material costs

Unopened vials can be stored in automated medication systems, which may reduce pharmacy compounding time

Venofer is compatible with vial connector systems that accommodate a 13 mm vial opening, which may save preparation time

IMPORTANT SAFETY INFORMATION *(Continued)*

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

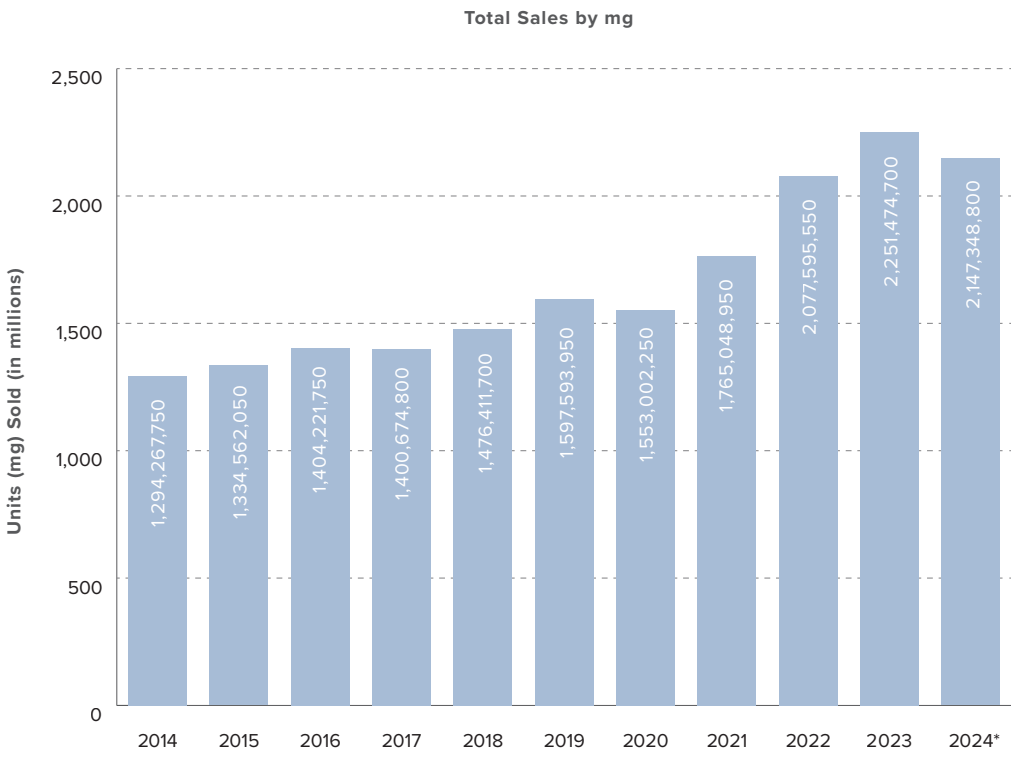
Adult Patients: The most common adverse reactions in clinical trials (≥2% and greater than comparator) included diarrhea, nausea, vomiting, headache, dizziness, hypotension, pruritus, pain in extremity, arthralgia, back pain, muscle cramp, injection site reactions, chest pain, and peripheral edema.

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.

Venofer® reliability



*From June 2024 through November 2024, product was on allocation but shipping weekly.

- **Consistent supply since 2014[9]**
- **More than 100 million milligrams supplied monthly, on average, since 2014[9]**
- **Supplied in 50 mg, 100 mg, and 200 mg single-dose vials**

IMPORTANT SAFETY INFORMATION *(Continued)*

Post-Marketing Experience *(Continued)*
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 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 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.

Venofer® safety profile

#1 The most prescribed IV iron in the US[1]

30 More than 30 million patient years of exposure globally with over 685 million units[2*†]

*Patient years are calculated based on an estimated annual cumulative dose of 2,000 mg administered. †A unit is a 100 mg iron equivalent sold.

69 Venofer® (iron sucrose) injection, USP has been studied in more than 69 clinical trials globally with more than 16,500 patients enrolled[2]

Approved for use in 82 countries[2]

DEMONSTRATED SAFETY AND TOLERABILITY

- NO BOXED WARNING
- DEXTRAN-FREE
- NO TEST DOSE REQUIRED
- PRESERVATIVE-FREE
- USE IN PEDIATRIC PATIENTS*

*2 years of age and older.

SELECTED IMPORTANT SAFETY INFORMATION

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).

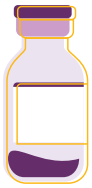
ADVERSE REACTIONS

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.

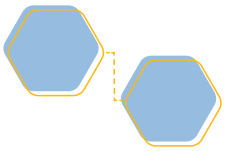
Pediatric Patients: The most common adverse reactions (≥2%) are headache, respiratory tract viral infection, peritonitis, vomiting, pyrexia, dizziness, cough, nausea, arteriovenous fistula thrombosis, hypotension, and hypertension.

More than 30 million reasons to believe

No boxed warning*



No test dose or premedication required



100% dextran-free IV iron

Approved for use in pediatric patients (2 years of age and older)†

*Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Venofer.

†The dosing for iron replacement treatment in pediatric patients with Hemodialysis Dependent-Chronic Kidney Disease (HDD-CKD), Non-Dialysis Dependent-Chronic Kidney Disease (NDD-CKD), or Peritoneal Dialysis Dependent-Chronic Kidney Disease (PDD-CKD) has not been established.

COMPATIBILITY AND EFFICIENCY

- **7-day stability in both plastic syringes and IV admixtures[3]**
- **Allows syringes and IV admixtures to be kept on hospital floors[3]**
- **Compatible with vial connector systems that accommodate a 13 mm vial opening and may be used in certain automated medication dispensing systems**
- **May save pharmacy preparation time and material costs**

CONSISTENT SUPPLY VOLUME AND RELIABILITY

- **Consistent supply since 2014[9‡]**
- **More than 100 million milligrams supplied monthly, on average, since 2014[9]**
- **Supplied in 50 mg, 100 mg, and 200 mg single-dose vials[3]**

‡From June 2024 through November 2024, product was on allocation but shipping weekly.

REFERENCES:
1. IQVIA. NSP Audit from January 2020 to February 2025. **2.** Data on file. Iron Sucrose Periodic Safety Update Report, 2023. American Regent, Inc.® **3.** Venofer® (iron sucrose) injection, USP. Package insert. American Regent, Inc. **4.** Injectafer® (ferric carboxymaltose injection). Package insert. American Regent, Inc.® **5.** Ferrlecit® (sodium ferric gluconate complex injection). Package insert. Sanofi-Aventis US LLC. **6.** INFeD® (iron dextran injection, USP). Package insert. Actavis Pharma, Inc. **7.** Feraheme® (ferumoxytol injection). Package insert. AMAG Pharmaceuticals, Inc. **8.** Monoferric® (ferric derisomaltose) Injection. Package insert. Pharmacosmos Therapeutics, Inc. **9.** IQVIA NSP Audit Data on File. [January 2014 to January 2025].

Venofer®
iron sucrose injection, USP

The Most Prescribed IV Iron in the US

More than 30 million reasons to believe

MORE THAN 30 MILLION PATIENT YEARS OF EXPOSURE WITH OVER 685 MILLION UNITS[1]*

Venofer® (iron sucrose) injection, USP is an established and effective treatment for CKD patients experiencing iron deficiency anemia.[2]

*Patient years are calculated based on an estimated annual cumulative dose of 2,000 mg administered. A unit is a 100 mg iron equivalent sold.[1]

VENOFER OFFERS 7-DAY STABILITY AFTER DILUTION[2]

Venofer offers 7-day stability in both plastic syringes and IV admixtures

Delivery device	Concentration	Storage conditions	Stability
Syringe (plastic)	2 mg to 10 mg elemental iron/mL† 20 mg elemental iron/mL (undiluted)	Room temperature (25°C ± 2°C) or Refrigerated (4°C ± 2°C)	7 days
IV admixture (PVC and non-PVC)	1 mg to 2 mg elemental iron/mL†	Room temperature (25°C ± 2°C)	7 days

†Diluted with 0.9% Sodium Chloride Injection, USP. Do not dilute in concentrations below 1 mg/mL. Do not add Venofer to other medications or parenteral nutrition solutions. Parenteral drugs should be inspected visually for particulate matter and discoloration before infusion.

DOSING INFORMATION

Adult CKD patients[2]

The usual adult total treatment course of Venofer is 1,000 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, USP at concentrations of 1-2 mg/mL	100 mg in a maximum of 100 mL over at least 15 min	• Hemodialysis-dependent chronic kidney disease (HDD-CKD)‡ • Consecutive dialysis sessions
	200 mg in a maximum of 100 mL over 15 min	• Non-dialysis-dependent chronic kidney disease (NDD-CKD) • Five occasions over 14 days
	2 infusions each of 300 mg in a maximum of 250 mL over 1.5 hrs followed by 1 infusion of 400 mg in a maximum of 250 mL over 2.5 hrs	• Peritoneal dialysis–dependent chronic kidney disease (PDD-CKD) • 3 divided infusions each within a 28-day period • 14 days apart

‡Administer early during the dialysis session.

Pediatric CKD patients[2]

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

Pediatric patients (2 years of age or older) **with HDD-CKD**	For iron maintenance treatment, administer Venofer: • At a dose of 0.5 mg/kg, not to exceed 100 mg per dose • Every 2 weeks for 12 weeks • 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 to 60 minutes Do not dilute to concentrations below 1 mg/mL
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 • 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 to 60 minutes Do not dilute to concentrations below 1 mg/mL

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

Please see Important Safety Information on reverse side and accompanying Full Prescribing Information.

Venofer® iron sucrose injection, USP

The Most Prescribed IV Iron in the US[3]

REFERENCES:
1. Data on file. Iron Sucrose Periodic Safety Update Report, 2023. American Regent, Inc.® **2.** Venofer® (iron sucrose) injection, USP. Package insert. American Regent, Inc. **3.** IQVIA. NSP Audit from January 2020 to January 2025.

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 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 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 or visit www.venofer.com. 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