HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use FERRLECIT® safely and effectively. See full prescribing information for FERRLECIT.
FERRLECIT (sodium ferric gluconate complex in sucrrose), injection, for intravenous use

INDICATIONS AND USAGE
Ferrlecit is an iron replacement product for treatment of iron deficiency anemia in adult patients and in pediatric patients age 6 years and older with chronic kidney disease receiving hemodialysis who are receiving supplemental epoetin therapy.

DOSE AND ADMINISTRATION

• Adult Patients - The recommended adult dosage is 10 mL (125 mg of elemental iron) diluted in 100 mL of 0.9% sodium chloride administered by intravenous infusion over 1 hour per dialysis session or undiluted as a slow intravenous injection (at a rate of up to 12.5 mg/min) per dialysis session.

• Pediatric Patients - The recommended pediatric dosage is 0.12 mL/kg Ferrlecit (1.5 mg/kg of elemental iron) diluted in 25 mL 0.9% sodium chloride and administered by intravenous infusion over 1 hour per dialysis session.

• Do not mix Ferrlecit with other medications or add to parenteral nutrition solutions for intravenous infusion.

• Administer in 0.9% saline.

CONTRAINDICATIONS
Known hypersensitivity to sodium ferric gluconate or any of its inactive components.

WARNINGS AND PRECAUTIONS

• Hypersensitivity Reactions: Monitor patients for signs and symptoms of hypersensitivity during and after Ferrlecit administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Ferrlecit when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.

• Hypotension: Ferrlecit may cause hypotension. Monitor patients for signs and symptoms of hypotension during and following each Ferrlecit dose.

• Iron Overload: Regularly monitor hematologic responses during Ferrlecit therapy.

• Do not administer Ferrlecit to patients with iron overload.

• Benzyl Alcohol Toxicity: Premature and low-birth-weight infants may be more likely to develop toxicity.

ADVERSE REACTIONS
The most commonly reported adverse reactions (≥10%) in adult patients were nausea, vomiting and/or diarrhea, injection site reaction, hypotension, cramps, hypertension, dizziness, dyspnea, chest pain, leg cramps, and pain. In patients 6 to 15 years of age the most common adverse reactions (≥10%) were hypotension, headache, hypertension, tachycardia and vomiting.

To report SUSPECTED ADVERSE REACTIONS, contact sanofi-aventis U.S. LLC at 1-800-633-1610 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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Full Prescribing Information
1 INDICATIONS AND USAGE
Ferrlecit is indicated for the treatment of iron deficiency anemia in adult patients and in pediatric patients age 6 years and older with chronic kidney disease receiving hemodialysis who are receiving supplemental epoetin therapy.

2 DOSAGE AND ADMINISTRATION
2.1 Important Administration Instructions
The dosage of Ferrlecit is expressed in terms of mg of elemental iron. Each 5 mL sterile, single-dose vial contains 62.5 mg of elemental iron (12.5 mg/mL). Do not mix Ferrlecit with other medications or add to parenteral nutrition solutions for intravenous infusion. The compatibility of Ferrlecit with intravenous infusion vehicles other than 0.9% sodium chloride has not been evaluated.

2.2 Adult Dosage and Administration
The recommended dosage of Ferrlecit for the repletion treatment of iron deficiency in hemodialysis patients is 10 mL of Ferrlecit (125 mg of elemental iron). Ferrlecit may be diluted in 100 mL of 0.9% sodium chloride administered by intravenous infusion over 1 hour per dialysis session. Ferrlecit may also be administered undiluted as a slow intravenous injection (at a rate of up to 12.5 mg/min) per dialysis session. For repletion treatment most patients may require a cumulative dose of 1000 mg of elemental iron administered over 8 dialysis sessions. Ferrlecit has been administered at sequential dialysis sessions by infusion or by slow intravenous injection during the dialysis session itself.
received Ferrlecit in this study, there were 9 patients (0.8%) who had an adverse reaction that, in the view of the investigator, precluded further Ferrlecit administration. These included one life-threatening reaction, six allergic reactions (including pruritus, facial swelling, chills, dyspnea/cheek pain, and rash), and two other reactions (hypotension and nausea). Another 2 patients experienced (0.2%) allergic reactions not deemed to represent drug intolerance (e.g., erythema/malaise and nausea/dizziness) following Ferrlecit administration.

5.2 Hypotension
Ferrlecit may cause clinically significant hypotension. Hypotension associated with lightheadedness, malaise, fatigue, weakness or severe pain in the chest, back, flanks, or groin has been reported. Hypotensive reactions may or may not be associated with signs and symptoms of hypersensitivity reactions and usually resolve within one to two hours. In the single-dose safety study, postadministration hypotensive events were observed in 221,097 patients (2%) following Ferrlecit administration. Transient hypotension may occur during infusion. Administration of Ferrlecit may augment hypotension caused by dialysis. Monitor patients for signs and symptoms of hypotension during and following Ferrlecit administration [see Adverse Reactions (6.1)].

5.3 Iron Overload
Excessive therapy with parenteral iron can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. Patients receiving Ferrlecit require periodic monitoring of hematologic and iron parameters (hemoglobin, hematocrit, serum ferritin, and transferrin saturation).

5.4 Risk of Serious Adverse Reactions in Infants Due to Benzyl Alcohol Preservative
Ferrlecit is not approved for use in neonates or infants. Serious and fatal adverse reactions including “gasping syndrome” can occur in neonates and low-birth-weight infants treated with benzyl alcohol–preserved drugs, including Ferrlecit. The “gasping syndrome” is characterized by central nervous system depression, metabolic acidosis, and gasping respirations. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known (Ferrlecit contains 9 mg of benzyl alcohol per mL) [see Use in Specific Populations (8.1)].

6 ADVERSE REACTIONS
The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling:
- Hypersensitivity or Drug Contraindications (4) and Warnings and Precautions (5.1)
- Hypotension [see Warnings and Precautions (5.2)]

6.1 Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. The most commonly reported adverse reactions (≥10%) in adult patients were nausea, vomiting and/or diarrhea, injection site reaction, hypotension, cramps, hypertension, dizziness, abnormal erythrocytes (e.g., changes in morphology, color, or number of red blood cells), dyspnea, chest pain, leg cramps and pain. In patients 6 to 15 years of age the most common adverse reactions (≥10%) were hypotension, headache, hypertension, tachycardia and vomiting.

In multiple dose Studies A and B (total 126 adult patients), the most frequent treatment emergent adverse reactions following Ferrlecit were:
- Body as a Whole: injection site reaction (33%), chest pain (10%), pain (10%), asthma (7%), headache (7%), fatigue (6%), fever (5%), malaise, infection, abscess, chills, rashes, pruritus, conjunctivitis, rolling of eyes, watery eyes, puffy eye lids, arcus lipius.
- Nervous System: cramps (25%), dizziness (13%), paresthesias (6%), agitation, somnolence, decreased level of consciousness.
- Respiratory System: dyspnea (11%), coughing (6%), upper respiratory infections (6%), rhinitis, pneumonia.
- Cardiovascular System: hypotension (29%), hypertension (13%), syncope (6%), tachycardia (5%), bradycardia, vasodilatation, angina pectoris, myocardial infarction, pulmonary edema.
- Gastrointestinal System: nausea, vomiting and/or diarrhea (35%), anorexia, abdominal pain (6%), rectal disorder, dyspepsia, eructation, flatulence, gastrointestinal disorder, melela.
- Musculoskeletal System: leg cramps (10%), myalgia, arthralgia, back pain, arm pain.
- Skin and Appendages: pruritus (6%), rash, increased sweating.
- Genitourinary System: urinary tract infection, and menstruation.
- Special Senses: conjunctivitis, rolling of the eyes, watery eyes, puffy eye lids, eosin senilis, redness of the eye, diplopia, and deafness.
- Metabolic and Nutritional Disorders: hyperkalemia (6%), generalized edema (5%), leg edema, peripheral edema, hypoglycemia, edema, hypervolemia, hypokalemia.
- Hematologic System: abnormal erythrocytes (11%) (changes in morphology, color, or number of red blood cells), anemia, leucocytosis, lymphoadenopathy.

Study C – Pediatric

Pediatric Patients: In a clinical trial of 66 iron-deficient pediatric hemodialysis patients, 6 to 15 years of age, inclusive, who were receiving a stable erythropoiesis stimulating regimen, the most commonly reported adverse reactions, occurring in ≥25%, regardless of treatment dosage were: hypotension (35%), headache (24%), hypertension (23%), tachycardia (17%), vomiting (11%), fever (9%), nausea (9%), abdominal pain (9%), pharyngitis (9%), diarrhea (8%), infection (8%), rhinitis (6%), and thrombocytopenia (6%). More patients in the higher dose group (3.0 mg/kg) than in the lower dose group (1.5 mg/kg) experienced the following adverse events: hypotension (41% vs. 28%), tachycardia (21% vs. 13%), fever (15% vs. 3%), headache (29% vs. 19%), abdominal pain (15% vs. 3%), nausea (12% vs. 6%), vomiting (12% vs. 9%), pharyngitis (12% vs. 6%), and rhinitis (9% vs. 3%).

6.2 Postmarketing Experience
In the single-dose, postmarketing, safety study, 11 patients who received Ferrlecit and 9.4% of patients who received placebo reported adverse reactions. The most frequent adverse reactions following Ferrlecit administration were hypotension (2%), nausea, vomiting and/or diarrhea (2%), pain (0.7%), hypertension (0.6%), allergic reactions (0.5%), chest pain (0.5%), pruritus (0.5%), and back pain (0.4%). The following additional events were reported in two or more patients: hypertonia, dry mouth, and hemorrhage.

In the multiple-dose, open-label surveillance study, 28% of the patients received concomitant angiotension-converting enzyme inhibitor (ACEI) therapy. The incidence of both drug intolerance and suspected allergic events following first dose Ferrlecit administration were 1.6% in patients with concomitant ACEI use compared to 0.7% in patients without concomitant ACEI use. The patient with a life-threatening event was not on ACEI therapy. One patient had facial flushing immediately on Ferrlecit exposure. No hypotension occurred and the event resolved rapidly and spontaneously without intervention other than drug withdrawal.

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 additional adverse reactions have been identified with the use of Ferrlecit from postmarketing spontaneous reports:
- Cardiovascular System: shock, fetal bradycardia, injection site superficial thrombophlebitis, phlebitis, acute myocardial ischemia with or without myocardial infarction or in-stent thrombosis in the context of a hypersensitivity reaction.
- Gastrointestinal System: dyspepsia.
- Immune system: anaphylactic reactions.
- Nervous System: loss of consciousness, generalized convulsion, hyposthesia.
- Skin and Appendages: skin discoloration, pallor.

Individual doses exceeding 125 mg may be associated with a higher incidence and/or severity of adverse events based on information from postmarketing spontaneous reports. These adverse events included hypotension, nausea, vomiting, abdominal pain, diarrhea, dizziness, dyspnea, urticaria, chest pain, paresthesia, and peripheral swelling.

DRUG INTERACTIONS
Drug–drug interactions involving Ferrlecit have not been studied. Ferrlecit may reduce the absorption of concomitantly administered oral iron preparations.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Parenteral administration of Ferrlecit has not been studied in pregnant women. Available data from postmarketing spontaneous reports with Ferrlecit use in pregnancy are insufficient to assess the risk of major birth defects and miscarriage.

Ferrlecit contains benzyl alcohol as a preservative. Benzyl alcohol is rapidly metabolized by a pregnant woman, benzyl alcohol exposure in the fetus is unlikely. However, an adverse event has occurred in a pregnant woman and a low-birth-weight infant who received intravenously administered benzyl alcohol–containing drugs [see Warnings and Precautions (5.4) and Use in Specific Populations (8.4)]. Consider alternative iron replacement therapies without benzyl alcohol.

There are risks to the mother and fetus associated with untreated iron deficiency anemia in pregnancy [see Clinical Considerations].

In the absence of maternal toxicity, Ferrlecit was not teratogenic to offspring of pregnant mice or rats at clinically relevant exposures (see Data).

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defects, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%–4% and 15%–20%, respectively.

Clinical Considerations

Disease-associated maternal and/or embryo/fetal risk

Intended iron deficiency anemia 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.

Fetal/Neonatal adverse reactions

Serious adverse reactions include circulatory failure (severe hypotension, shock resulting in the context of an anaphylactic reaction) may occur in pregnant women with intravenous iron administration, which may have serious consequences on the fetus such as fetal bronchopulmonary dysplasia, especially during the second and third trimesters.

Data

Animal data

Ferrlecit was administered intravenously to pregnant mice during gestation days 6 to 15 at doses of 5, 30, and 100 mg Fe/kg/day to assess embryofetal development. No teratogenic effects were seen in offspring at the highest dose, representing maternal exposure of approximately 4 times maximum human exposure based on body surface area. There were increased fetal resorptions and decreased fetal weights at doses that caused maternal toxicity as evidenced by decreased body-weight gain and decreased food consumption.

Ferrlecit was administered intravenously to pregnant rats during gestation days 6 to 15 at doses of 4 and 20 mg Fe/kg/day to assess embryofetal development. No teratogenic effects were seen in offspring at the highest dose, representing maternal exposure of approximately 1.5 times maximum human exposure based on body surface area. There were decreases in gestation index and litter size, increased fetal resorptions, and decreased fetal weights at doses that caused maternal toxicity as evidenced by decreased body-weight gain and decreased food consumption.

Risk Summary

Ferrlecit contains benzyl alcohol. Because benzyl alcohol is rapidly metabolized by a lactating woman, benzyl alcohol exposure in the breastfed infant is unlikely. However, an adverse event has occurred in premature neonates and low-birth-weight infants who received intravenously administered benzyl alcohol–containing drugs [see Warnings and Precautions (5.4) and Use in Specific Populations (8.4)]. Consider alternative iron replacement therapies without benzyl alcohol for use during lactation.

There are no available data on the presence of Ferrlecit in human or animal milk, the effects on milk production, or the effects on the breastfed child.

8.4 Pediatric Use

The safety and effectiveness of Ferrlecit have been established in pediatric patients 6 to 15 years of age [see Dosage and Administration (2.3), Clinical Pharmacology (12.2), and
Clinical Studies [14]. Safety and effectiveness in pediatric patients younger than 6 years of age have not been established.

Benzyl Alcohol Toxicity and Pediatrics

Ferrlecit is not approved for use in neonates or infants. Serious adverse reactions including fatal reactions and the "gassing syndrome" occurred in premature neonates and low-birth-weight infants receiving undiluted benzyl alcohol at which serious adverse reactions may occur is not known (Ferrlecit). Experiments have shown that less than 1% of the iron species within Ferrlecit can be dialyzable.

10 OVERDOSAGE

The Ferrlecit iron complex is not dialyzable. No data is available regarding overdose of Ferrlecit in humans. Excessive dosages of Ferrlecit may lead to accumulation of iron in storage sites potentially leading to hemosiderosis. Do not administer Ferrlecit to patients with iron overload [See Warnings and Precautions (6.5)].

Individual doses exceeding 125 mg may be associated with a higher incidence and/or severity of adverse events [see Adverse Reactions (6.2)]. Ferrlecit at elemental iron doses of 125 mg/kg, 78.8 mg/kg, 62.5 mg/kg and 250 mg/kg caused deaths in mice, rats, rabbits, and dogs respectively. The major symptoms of acute toxicity were decreased activity, staggering, ataxia, increases in the respiratory rate, tremor, and convulsions.

11 DESCRIPTION

Ferrlecit® (sodium ferric gluconate complex in sucrrose injection), an iron replacement product, is a sterile, aqueous, macromolecular complex of sodium ferric gluconate produced by precipitation of ferric gluconate with sodium hydroxide and back titration with hydrochloric acid. The complex contains 221 mg (sodium ferric gluconate complex in sucrose injection) group (50% female, 50% male; 74% white, 18% black, 5% Hispanic, 3% Asian; mean age 54 years, range 22–83 years), 44 patients in the high-dose Ferrlecit group (50% female, 46% male, 2% unknown; mean age 65 years, range 50–80 years), and 29 control patients (50% male, 50% female; 86% white, 12% black, 4% Asian; 6% unknown; mean age 58 years, range 25–84 years).

The mean baseline hemoglobin and hematocrit were similar between treatment and historical control patients: 9.8 g/dL and 29% and 9.6 g/dL and 29% in low- and high-dose Ferrlecit-treated patients, respectively, and 9.4 g/dL and 29% in historical control patients. Baseline serum ferritin and hematocrit were similar between treatment and historical control patients: 106 mg/mL and 20% and 100 mg/mL and 24% in low- and high-dose Ferrlecit-treated patients, respectively, and 90 mg/mL and 20% in historical control patients. Patients in the high-dose Ferrlecit group achieved significantly higher increases in hemoglobin and hematocrit than patients in the low-dose Ferrlecit group. See Table 1.

Table 1: Study A: Hemoglobin, Hematocrit, and Iron Studies

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Mean Change from Baseline to Two Weeks after Cessation of Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferrlecit 1000 mg IV (N=44)</td>
<td></td>
</tr>
<tr>
<td>Ferrlecit 500 mg IV (N=39)</td>
<td></td>
</tr>
<tr>
<td>Historical Control Oral Iron (N=25)</td>
<td></td>
</tr>
<tr>
<td>Hemoglobin (g/dL)</td>
<td>1.1</td>
</tr>
<tr>
<td>Hematocrit (%)</td>
<td>3.6</td>
</tr>
<tr>
<td>Transferrin Saturation (%)</td>
<td>8.5</td>
</tr>
<tr>
<td>Serum Ferritin (ng/mL)</td>
<td>199</td>
</tr>
</tbody>
</table>

Study B

Study B was a single-center, non-randomized, open-label, historically controlled, study of the safety and efficacy of variable, cumulative doses of intravenous Ferrlecit in iron-deficiency hemodialysis patients. Ferrlecit administration was identical to Study A. The primary efficacy variable was the change in hemoglobin from baseline to the last available observation through Day 51. Inclusion and exclusion criteria were identical to those of Study A as was the historical control population. Sixty-three patients were evaluated in this study: 38 in the Ferrlecit-treated group (37% female, 63% male; 95% white, 5% Asian; mean age 56 years, range 22–84 years) and 25 in the historical control group (88% female, 3% male; 5% white, 92% black, 20% Hispanic, 4% Asian, 4% unknown; mean age 53 years, age range 25–84 years).

Ferrlecit-treated patients were considered to have completed the study per protocol if they received at least eight Ferrlecit doses of either 62.5 mg or 125 mg of elemental iron. A less-stringent protocol (57%) completeness of protocol requirement (95% Ferrlecit-treated patients received less than eight doses, and 12% (32%) patients had incomplete information on the sequence of dosing. Not all patients received Ferrlecit at consecutive dialysis sessions and many received oral iron during the study.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term carcinogenicity studies of sodium ferric gluconate in animals were not performed.

Sodium ferric gluconate was not genotoxic in the Ames test or the rat micronucleus test. Sodium ferric gluconate produced a clastogenic effect in an in vitro chromosomal aberration assay in Chinese hamster ovary cells.

Studies to assess the effects of sodium ferric gluconate on fertility were not conducted.

14 CLINICAL STUDIES

Two clinical studies (Studies A and B) were conducted in adults and one clinical study was conducted in pediatric patients (Study C) to assess the efficacy and safety of Ferrlecit.

Study A

Study A was a three-center, randomized, open-label study of the safety and efficacy of two doses of Ferrlecit administered intravenously to iron-deficient hemodialysis patients. The study included both a dose-response concurrent control and an historical control. Enrolled patients received a test dose of Ferrlecit (25 mg of elemental iron) and were then randomly assigned to receive Ferrlecit at cumulative doses of either 500 mg (low dose) or 1000 mg (high dose) of elemental iron of each regimen. Ferrlecit was given to both dose groups in eight divided doses during sequential dialysis sessions (a period of 16 to 17 days). At each dialysis session, patients in the low-dose group received Ferrlecit 62.5 mg of elemental iron over 30 minutes, and those in the high-dose group received Ferrlecit 125 mg of elemental iron over 60 minutes. The primary endpoint was the change in hemoglobin from baseline to the last available observation through Day 40.

Eligibility for this study included chronic hemodialysis patients with a hemoglobin below 10 g/dL (or hematocrit at or below 32%) and either serum ferritin below 100 mg/mL or transferrin saturation below 18%. The evaluated population consisted of 39 patients in the low-dose Ferrlecit (sodium ferric gluconate complex in sucrose injection) group (50% female, 50% male; 74% white, 18% black, 5% Hispanic, 3% Asian; mean age 54 years, range 22–83 years), 44 patients in the high-dose Ferrlecit group (50% female, 46% male, 2% unknown; 75% white, 11% black, 5% Hispanic, 7% other, 2% unknown; mean age 56 years, range 20–87 years), and 25 historical control patients (68% female, 32% male; 40% white, 32% black, 20% Hispanic, 4% Asian, 4% unknown; mean age 52 years, range 25–84 years).

The mean baseline hemoglobin and hematocrit were similar between treatment and historical control patients: 9.8 g/dL and 29% and 9.6 g/dL and 29% in low- and high-dose Ferrlecit-treated patients, respectively, and 9.4 g/dL and 29% in historical control patients. Baseline serum ferritin and hematocrit were similar between treatment and historical control patients: 106 mg/mL in the low-dose group, 88 mg/mL in the high-dose group, and 606 mg/mL in the historical control.

Patients in the high-dose Ferrlecit group achieved significantly higher increases in hemoglobin and hematocrit than patients in the low-dose Ferrlecit group. See Table 1.
Baseline hemoglobin and hematocrit values were similar between the treatment and control groups, and were 9.1 g/dL and 27.3%, respectively, for Ferrlecit-treated patients. Serum iron studies were also similar between treatment and control groups, with the exception of serum ferritin, which was 606 ng/mL for historical control patients, compared to 77 ng/mL for Ferrlecit-treated patients.

In this patient population, only the Ferrlecit-treated group achieved increase in hemoglobin and hematocrit from baseline. See Table 2.

### Table 2: Study B: Hemoglobin, Hematocrit, and Iron Studies

<table>
<thead>
<tr>
<th></th>
<th>Ferrlecit (N=38) Change</th>
<th>Oral Iron (N=25) Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin (g/dL)</td>
<td>1.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Hematocrit (%)</td>
<td>3.8</td>
<td>0.2</td>
</tr>
<tr>
<td>Transferrin Saturation (%)</td>
<td>6.7</td>
<td>1.7</td>
</tr>
<tr>
<td>Serum Ferritin (ng/dL)</td>
<td>73</td>
<td>-145</td>
</tr>
</tbody>
</table>

### Study C

Study C was a multicenter, randomized, open-label study of the safety and efficacy of two Ferrlecit dose regimens (1.5 mg/kg or 3.0 mg/kg of elemental iron) administered intravenously to 66 iron-deficient (transferrin saturation <20% and/or serum ferritin <100 ng/mL) pediatric hemodialysis patients, 6 to 15 years of age, inclusive who were receiving a stable erythropoietin dosing regimen.

Ferrlecit at a dose of 1.5 mg/kg or 3.0 mg/kg (up to a maximum dose of 125 mg of elemental iron) in 25 mL 0.9% sodium chloride was infused intravenously over 1 hour during each hemodialysis session for eight sequential dialysis sessions. Thirty-two patients received the 1.5 mg/kg dosing regimen (47% male, 53% female; 66% Caucasian, 25% Hispanic, and 3% Black, Asian, or Other; mean age 12.3 years). Thirty-four patients received the 3.0 mg/kg dosing regimen (56% male, 44% female; 77% Caucasian, 12% Hispanic, 9% Black, and 3% Other; mean age 12.0 years).

The primary endpoint was the change in hemoglobin concentration from baseline to 2 weeks after last Ferrlecit administration. There was no significant difference between the treatment groups. Improvements in hematocrit, transferrin saturation, serum ferritin, and reticulocyte hemoglobin concentrations compared to baseline values were observed 2 weeks after the last Ferrlecit infusion in both the 1.5 mg/kg and 3.0 mg/kg treatment groups (Table 3).

### Table 3: Study C: Hemoglobin, Hematocrit, and Iron Status

<table>
<thead>
<tr>
<th></th>
<th>1.5 mg/kg Ferrlecit (N=25)</th>
<th>3.0 mg/kg Ferrlecit (N=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin (g/dL)</td>
<td>0.8</td>
<td>0.9</td>
</tr>
<tr>
<td>Hematocrit (%)</td>
<td>2.6</td>
<td>3.0</td>
</tr>
<tr>
<td>Transferrin Saturation (%)</td>
<td>5.5</td>
<td>10.5</td>
</tr>
<tr>
<td>Serum Ferritin (ng/mL)</td>
<td>192</td>
<td>314</td>
</tr>
<tr>
<td>Reticulocyte Hemoglobin Content (pg)</td>
<td>1.3</td>
<td>1.2</td>
</tr>
</tbody>
</table>

The increased hemoglobin concentrations were maintained at 4 weeks after the last Ferrlecit infusion in both the 1.5 mg/kg and the 3.0 mg/kg Ferrlecit dose treatment groups.

### 16 HOW SUPPLIED/STORAGE AND HANDLING

**How Supplied**

Ferrlecit is a clear, dark brown liquid supplied in colorless glass vials. Each sterile, single-dose vial contains 62.5 mg of elemental iron in 5 mL for intravenous use. Discard unused portion.

**Carton containing 10 vials:** NDC 0024-2792-10

**Storage**

Store at 20°C–25°C (68°F–77°F); excursions permitted to 15°C–30°C (59°F–86°F). See USP Controlled Room Temperature. Do not freeze.

Keep out of the reach of children.

**17 PATIENT COUNSELING INFORMATION**

Prior to Ferrlecit administration:

- Question patients regarding any prior history of reactions to parenteral iron products.
- Advise patients of the risks associated with Ferrlecit.
- Advise patients to report adverse reactions associated with the use of Ferrlecit, including hypersensitivity, allergic reactions, chest pain, dizziness, lightheadedness, swelling, and breathing problems [see Warnings and Precautions (5.1, 5.2) and Adverse Reactions (6.1, 6.2)].

**Pregnancy**

Advise pregnant women about the risk of hypersensitivity reactions which may have serious consequences for the fetus. Advise patients who may become pregnant to inform their healthcare provider of a known or suspected pregnancy (contains benzyl alcohol) [see Use in Specific Populations (8.1)].

**Lactation**

Advise patients that treatment with Ferrlecit is not recommended for use while breastfeeding [see Use in Specific Populations (8.2)].