**INDICATIONS AND USAGE**

Venofer (iron sucrose) injection, for intravenous use is indicated for the treatment of iron deficiency anemia (IDA) in patients with chronic kidney disease (CKD). (1)

**How Supplied/Storage and Handling**

Venofer (iron sucrose) injection, USP is available in single-dose vials containing 500 mg of elemental iron (as iron sucrose) in 5 mL of a diluent solution, in each mL containing 1 mg/mL of sucrose; do not perform serum iron measurements for at least 48 hours after intravenous dosing [see Warnings and Precautions (5.2)]. (2)

**Dosage Forms and Strengths**

- **Oral Iron Venofer**
  - 0.4 mg/mL
  - 0.7 mg/mL

- **Parenteral Iron Venofer**
  - 100 mg/mL
  - 200 mg/mL

**ADVERSE REACTIONS**

- **Hypersensitivity Reactions**
  - Anaphylaxis
  - Hypertension
  - Hypotension
  - Other cardiovascular effects (e.g., tachycardia, chest pain, myocardial ischemia, heart failure, angina, pulmonary edema)

- **Respiratory Effects**
  - Shortness of breath
  - Dyspnea
  - Other respiratory effects

- **Gastrointestinal Effects**
  - Abdominal pain
  - Diarrhea

- **Hepatobiliary Effects**
  - Hepatitis

- **Skin and Appendage Effects**
  - Rash

- **Other Effects**
  - Tissue disorders
  - Fluid overload

**OVERDOSAGE**

**CONTRAINDICATIONS**

- **Hypersensitivity:** Venofer is contraindicated in patients with known hypersensitivity to iron or any component of the formulation.

**WARNINGS AND PRECAUTIONS**

- **Iron Overload:** Regularly monitor hematologic responses during therapy. Do not administer to patients with iron overload.

**FULL PRESCRIBING INFORMATION**

- **INDICATIONS AND USAGE**
  - **Hemodialysis Dependent-Chronic Kidney Disease (HDD-CKD)**
  - **Peritoneal Dialysis Dependent-Chronic Kidney Disease (PDD-CKD)**

- **HOW SUPPLIED/STORAGE AND HANDLING**

- **ADOPTED REFERENCES**

**Table 1:** Adverse Reactions Reported in Clinical Trials

<table>
<thead>
<tr>
<th>Body System/Adverse Reaction</th>
<th>Venofer</th>
<th>Comparator</th>
<th>History</th>
<th>Venofer</th>
<th>Comparator</th>
<th>History</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiovascular</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>2.3</td>
<td>1.1</td>
<td>0.5</td>
<td>2.4</td>
<td>1.1</td>
<td>0.5</td>
</tr>
<tr>
<td>Hypotension</td>
<td>2.9</td>
<td>2.0</td>
<td>0.5</td>
<td>3.4</td>
<td>2.2</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Respiratory</strong></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Dyspnea</td>
<td>1.7</td>
<td>1.2</td>
<td>0.5</td>
<td>2.5</td>
<td>1.9</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Gastrointestinal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>1.8</td>
<td>1.2</td>
<td>0.5</td>
<td>2.3</td>
<td>1.9</td>
<td>0.5</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>0.6</td>
<td>0.5</td>
<td>0.5</td>
<td>0.8</td>
<td>0.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

**REFERENCES**

- **Full prescribing information for VENOFER.**

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

- **Indications and Usage:** Venofer is indicated for the treatment of iron deficiency anemia (IDA) in patients with chronic kidney disease (CKD).

**CONTRAINdications:**

- **Hypersensitivity:** Venofer is contraindicated in patients with known hypersensitivity to iron or any component of the formulation.

**WARNINGS AND PRECAUTIONS:**

- **Iron Overload:** Regularly monitor hematologic responses during therapy. Do not administer to patients with iron overload.

**ADVERSE REACTIONS:**

- **Hypersensitivity Reactions:** Anaphylaxis, 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, perianal, vomiting, pyrexia, dizziness, cough, nausea, arteriovenous fistula thrombosis, hypotension, and hypertension. (6.1)

**To report SUSPECTED ADVERSE REACTIONS, contact American Regent, Inc. at 1-800-734-9236 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

**Revised:** 10/2020
Venofer (iron sucrose) injection, USP, an iron replacement product, is a brown, sterile, aqueous, complex of polynuclear iron (III)-hydroxide in sucrose for intravenous injection [see NDC-0517-2340-10 100 mg/5 mL Single-Dose Vial Packages of 10].

1. DESCRIPTION

Venofer (iron sucrose) injection, USP, is an iron replacement product, in a brown, sterile, aqueous, complex of polynuclear iron (III)-hydroxide in sucrose for intravenous injection [see NDC-0517-2340-10 100 mg/5 mL Single-Dose Vial Packages of 10].

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Venofer is an excellent source of iron in patients with iron deficiency anemia during pregnancy should be treated. Untreated IDA in pregnancy is associated with adverse maternal and fetal outcomes, including an increased risk of post-partum hemorrhage, intrauterine growth restriction, and preterm birth.

12.2 Pharmacokinetics

In healthy adults administered intravenous doses of Venofer, its iron component exhibited first order kinetics with an elimination half-life of 6 h, total clearance of 1.2 L/h, and steady state apparent volume of distribution of 7.9 L. The iron component appeared to distribute mainly in blood and to some extent in extracellular space.

13. HUMANephelometry and Hematometry

In healthy adults administered intravenous doses of Venofer, iron sucrose was not detected in the bacterial reverse mutation assay (Ames test) or the mouse lymphoma assay. Iron sucrose was not cytotoxic in human lung fibroblast cell lines in the human lymphoma assay and did not affect cell proliferation or the epidermal growth factor receptor expression.

14. CLINICAL STUDIES

14.1 Clinical Studies Overview

14.1.1 Studies Overview

Clinical trials involving 407 adult patients and 1 one clinical trial involving 317 patients were conducted to assess the safety and efficacy of Venofer. Of these, 349 patients were enrolled in 14 randomized, double-blind, placebo-controlled trials, including 13 pivotal trials that met specified study criteria [see Warnings and Precautions (5.3)].

14.1.2 Study A: Hemodialysis Dependent-Chronic Kidney Disease (HDD–CKD)

Study A was a multicenter, open-label, historically-controlled study in 101 patients with HDD–CKD (77 patients with Venofer treatment and 24 in the historical control population). The historical control population consisted of patients with HDD–CKD exposed to placebo, treatment with iron sucrose, or a combination of both that consisted of at least 20% of the delivered dose or these values remained above 4 ng/dL of the delivered dose [see Adverse Reactions (6.1)].

14.1.3 Study B: Hemodialysis Dependent-Chronic Kidney Disease (HDD–CKD)

Study B was a multicenter, open-label, historically-controlled study in 138 patients with HDD–CKD who had been discontinued from treatment by their attending physician [see Warnings and Precautions (5.3)].

14.2 Study C: Hemodialysis Dependent-Chronic Kidney Disease (HDD–CKD)

Study C was a multicenter, open-label study in patients with HDD–CKD who had been discontinued from treatment by their attending physician [see Warnings and Precautions (5.3)].

15.8 Stability and Storage

15.8.2 Stability in Storage

Venofer is supplied as 100 mg (2 mL) and 200 mg (4 mL) single-dose vials. Each 100 mg single-dose vial contains 100 mg elemental iron, as iron sucrose (200 mg iron equivalent) and 55 mg sodium chloride (110 mg sodium equivalent).

15.8.3 Stability and Storage

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