Venofer is an iron replacement product indicated for the treatment of iron deficiency anemia in patients with chronic kidney disease (CKD) (1).

The following serious adverse reactions are described elsewhere in the labeling:

- **Hypersensitivity Reactions**: Anaphylactic and/or anaphylactoid reactions, including angioedema, have been reported in patients receiving Venofer treatment. Patients receiving Venofer may experience intra- and/or extravascular anaphylactic reactions (2).

- **Hypothetical Reactions**: Venofer treatment may be repeated if necessary.

- **Dose Administration**: Admister Venofer at a dose of 0.5 mg/kg, not to exceed 100 mg per dose, every two weeks for 12 weeks given undiluted or diluted in 0.9% NaCl over a period of at least 15 minutes, per consecutive hemodialysis session (see Dosing and Administration and Use in Specific Populations).

- **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 iron overload.

- **ADVERSE REACTIONS**

- **Adult patients**: The most common adverse reactions (≥2%) are diarrhea, nausea, vomiting, headache, dizziness, hypotension, pruritus, pain in extremities, arthralgia, back pain, muscle cramp, injection site reactions, chest pain, and periorbital edema (0.1).

- **Pediatric patients**: The most common adverse reactions (2%) are headache, respiratory tract viral infection, periorbital edema, vomiting, pyrexia, dizziness, cough, nausae, arteriosclerotic renal thrombosis, hypotension, and peripheral edema (0.1).

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.

See 17 for Patient Counseling Information.

Revised: 1/2019

[Table](#)

### Table 1. Adverse Reactions Reported in a ≥3% of Study Populations and for which the Rate for Venofer Exceeds the Rate for Comparator

<table>
<thead>
<tr>
<th>Body System/Adverse Reaction</th>
<th>Venofer (N=1 151)</th>
<th>Comparator (N=2 304)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypotension</td>
<td>0.4%</td>
<td>0%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2.5%</td>
<td>0%</td>
</tr>
<tr>
<td>Nausea</td>
<td>3.0%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Rash</td>
<td>3.0%</td>
<td>2.7%</td>
</tr>
<tr>
<td>Injection site reaction</td>
<td>2.7%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Pruritus</td>
<td>3.0%</td>
<td>2.7%</td>
</tr>
<tr>
<td>Musculoskeletal and Connective Tissue Disorders</td>
<td>2.7%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Hypersensitivity reactions</td>
<td>1.3%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>2.7%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>2.7%</td>
<td>2.7%</td>
</tr>
</tbody>
</table>

### 10. OVERDOSAGE

**11. DESCRIPTION**

**12. CLINICAL PHARMACOLOGY**

**13. NONCLINICAL TOXICOLOGY**

**14. STUDIES**

**15. CONTRAINDICATIONS**

**16. HOW SUPPLIED/STORAGE AND HANDLING**

**17. PATIENT COUNSELING INFORMATION**

* Patients or their caregivers are advised that the full prescribing information is not listed.

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**ADVERSE REACTIONS**

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- **Pediatric patients**: The most common adverse reactions (2%) are headache, respiratory tract viral infection, periorbital edema, vomiting, pyrexia, dizziness, cough, nausea, arteriosclerotic renal thrombosis, hypotension, and peripheral edema (0.1).

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.

See 17 for Patient Counseling Information.

Revised: 1/2019
Iron sucrose was not mutagenic in the following tests: mouse lymphoma cell (L5178Y) mutation assay, mouse bone marrow micronucleus assay, and studies in bacterial and mammalian cultured cells. In the mouse micronucleus assay, no increase in micronucleated polychromatic erythrocytes was observed. In the mouse bone marrow micronucleus assay, no increase in micronucleated polychromatic erythrocytes was observed. In the bacterial and mammalian cultured cell systems, no increase in mutations was observed.

14.2 Study A: Hemodialysis-Dependent Chronic Kidney Disease (HDD-CKD)
Study A was a multicenter, open-label, randomized controlled trial of 279 patients with HDD-CKD (77 patients with Venofer treatment and 24 in the historical control group) with no iron deficiency assessed by IDES (see Clinical Considerations). Eligibility criteria for Venofer included undergoing chronic hemodialysis, receiving an erythropoiesis-stimulating agent, and having transferrin saturation ≤30% and serum ferritin levels ≤100 ng/mL. In the HDD-CKD population, 24% of patients with HDD-CKD entered the study with saturated transferrin of ≤10% and serum ferritin ≤100 ng/mL and 39% entered the study with saturated transferrin of ≤20% and serum ferritin ≤100 ng/mL. The overall age of patients in the Venofer group was 62 years (range 19–82 years) and 61 years (range 19–82 years) in the historical control group (mean age 62 years range 19–82 years). Of 279 patients enrolled in this study, 267 (95%) had diabetes mellitus at study entry.

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In the study population, 96% of patients had diabetes mellitus. Of the 131 patients in the Venofer group, 42 (32%) were male and 89 (68%) were female. In the historical control group, 48 (31%) were male and 93 (69%) were female. The mean age of patients in the Venofer group was 62 years (range 19–82 years) and 58 years (range 19–82 years) in the historical control group. Of 279 patients enrolled in this study, 267 (95%) had diabetes mellitus at study entry.

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