### Hemodialysis Dependent-Chronic Kidney Disease (HDD-CKD) (2.1)
- 100 mg slow intravenous injection

### Non-Dialysis Dependent-Chronic Kidney Disease (NDD-CKD) (2.3)
- 200 mg slow intravenous injection

### Peritoneal Dialysis Dependent-Chronic Kidney Disease (PDD-CKD) (2.4)
- 300 mg or 400 mg intravenous injection

### Pediatric patients

<table>
<thead>
<tr>
<th>Population</th>
<th>Hemoglobin</th>
<th>Ferritin</th>
<th>Transferrin Saturation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HDD-CKD (2.2)</td>
<td>2.3 mg/dL</td>
<td>170 ng/mL</td>
<td>46%</td>
</tr>
<tr>
<td>PDD-CKD (2.6)</td>
<td>2.6 mg/dL</td>
<td>180 ng/mL</td>
<td>46%</td>
</tr>
</tbody>
</table>
Pharmacokinetics in Pediatric Patients

12.3 Pharmacokinetics (recombinant human erythropoietin) therapy treated with iron sucrose containing 100 mg of iron, three times weekly for three weeks, significant increases incorporated into hemoglobin as the cells mature into red blood cells.

6.2 Adverse Reactions from Post-Marketing Experience

Following intravenous administration of Venofer, iron sucrose is dissociated into iron and sucrose. The sucrose component is eliminated mainly by urinary fluids, hydrocortisone, and/or antihistamines. Slowing the infusion rate may alleviate symptoms.

12.1 Mechanism of Action

Each mL contains 20 mg elemental iron as iron sucrose in water for injection. Venofer is available in 10 mL single-dose vials (200 mg elemental iron per mL) and 50 mg/2.5 mL single-dose vial packages of 10.

14 CLINICAL STUDIES

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

Healthy volunteers and patients with ESRD were randomized to receive Venofer or placebo. In patients with ESRD, Venofer was administered in sequential dialysis sessions until a pre-determined (calculated) total dose of iron was administered. Patients were randomized to receive 100 mg or 150 mg total dose of iron. ESRD patients were randomized to receive Venofer 100 mg or 150 mg. The mean age was 56 years, with an age range of 29 to 80 years. Patient age and serum ferritin level were similar between treatment and historical control patients. The mean serum ferritin level was 1304 ng/mL (range 434.6 ng/mL to 2930 ng/mL) in the control group compared to 2930 ng/mL (range 434.6 ng/mL to 6550 ng/mL) in patients treated with Venofer.

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

The study was a randomized, open-label, split-dose controlled study of the safety and efficacy of intravenous iron sucrose in patients with ESRD. The study included 263 patients with ESRD who were randomized to receive 200 mg of iron sucrose or 200 mg of iron sucrose plus a single dose of erythropoietin. The patients had a mean serum ferritin level of 1304 ng/mL (range 434.6 ng/mL to 2930 ng/mL) and a mean age of 56 years, with a range of 29 to 80 years. The mean ferritin level was 2438 ng/mL (range 434.6 ng/mL to 6550 ng/mL) in the control group compared to 2930 ng/mL (range 434.6 ng/mL to 6550 ng/mL) in patients treated with Venofer.

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

Published studies on intravenous iron sucrose treatment after the first trimester of pregnancy have not shown adverse maternal or fetal outcomes (see [see Warnings and Precautions (5.3)]).

14.4 Study D: Hemodialysis Dependent-Chronic Kidney Disease (HDD–CKD)

Patients with PDD-CKD, stable erythropoietin for 8 weeks, who had a mean hemoglobin of ≥ 11 g/dL at any time during the study were randomized to receive Venofer 100 mg (n=13) or placebo (n=13). The mean age was 50 years, with an age range of 30 to 80 years. Patient age and serum ferritin level were similar between treatment and historical control patients. The mean serum ferritin level was 1304 ng/mL (range 434.6 ng/mL to 2930 ng/mL) in the control group compared to 2930 ng/mL (range 434.6 ng/mL to 6550 ng/mL) in patients treated with Venofer.