

## **FDA Approval - Ferumoxytol (Feraheme) Injection**

The safety and efficacy of ferumoxytol in the episodic treatment of iron deficiency anemia were assessed in three randomized, open-label, controlled clinical trials enrolling approximately 800 patients with CKD. In all three controlled trials, patients were randomized to either ferumoxytol or oral iron. Two trials evaluated patients with non-dialysis dependent CKD and a third assessed patients undergoing hemodialysis. These trials assessed hemoglobin alterations and clinical outcomes over 35 days. Ferumoxytol was administered as two 510 mg IV injections, with most patients receiving their second injection 3 to 8 days after their initial injection.

In all three clinical trials, ferumoxytol administration increased the mean blood hemoglobin concentrations by approximately 1.0 g/dL over the 35 day period, a mean increase that was greater than what was observed in patients receiving oral iron. Patients receiving ferumoxytol also had increases in blood transferrin saturation and ferritin values.

In the follow-up supportive trial, 69 patients with persistent iron deficiency anemia received two additional injections of ferumoxytol. On day 35 following the additional injections, 70% showed an increase in hemoglobin, transferrin saturation and ferritin.

Overall, of the 1,726 subjects exposed to ferumoxytol, 1,562 of the patients had CKD. The most important safety concerns were hypotension and/or hypersensitivity reactions, including anaphylaxis and/or anaphylactoid reactions. In the clinical trials, serious hypersensitivity reactions were reported in 0.2% (3/1,726) of subjects receiving ferumoxytol. Hypotension was observed in 1.9% (33/1,726), including three patients with serious hypotensive reactions.

Ferumoxytol administration may transiently affect the diagnostic ability of magnetic resonance imaging and the drug label provides further information regarding this effect.

The recommended dose of ferumoxytol is an initial 510 mg IV injection followed by a second 510 mg IV injection 3 to 8 days later. The drug is administered as an undiluted IV injection delivered at a rate not exceeding 1.0 mL/sec. For patients receiving hemodialysis, ferumoxytol is administered after the blood pressure has stabilized and the patient has completed at least one hour of hemodialysis. Patients should be monitored for signs and symptoms of hypotension following each ferumoxytol injection. The drug is supplied in single use vials which contain 510 mg of elemental iron in 17 mL of solution.

Full prescribing information is available at

[http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/022180lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022180lbl.pdf)