

To: Department of Radiology, University of Wisconsin, Madison, WI
From: Scott Reeder, MD, PhD (Chief of Magnetic Resonance Imaging)
Re: **Guidelines for Safe Administration of Ferumoxytol as an MRI Contrast Agent**
Date: 5/1/15

Purpose: The purpose of this document is to establish departmental guidelines for administration of ferumoxytol as a contrast agent for patients undergoing MRI.

Background: Ferumoxytol (“feraheme”) is an intravenously-administered iron-based agent with an FDA-approved marketing indication for treatment of anemia. Recently, it has been shown that ferumoxytol is also an effective and safe agent for off-label use as an alternative MRI contrast agent, with significant R1, R2, and R2* relaxivity. For this reason, ferumoxytol may be of benefit to patients with contraindications to gadolinium-based contrast agents (GBCA), such as renal failure and known GBCA allergies. Based on published literature, injection guidelines from Duke University, and a 3/31/15 communication from the FDA (<http://www.fda.gov/Drugs/DrugSafety/ucm440138.htm>), the following guidelines have been adopted:

1. The use of ferumoxytol is limited to those patients with known contraindications to GBCA, such as renal failure or a history of allergic reactions to GBCA.
2. Ferumoxytol is contraindicated in patients with a history of allergic reactions to ferumoxytol or other IV iron products.
3. The typical dose of ferumoxytol is 3 mg of ferumoxytol/kg of patient body mass. Doses of 1-5 mg/kg may be substituted by a radiologist. The total dose of ferumoxytol shall not exceed one bottle (510 mg).
4. The concentration of ferumoxytol is 30 mg/mL, therefore the typical dose is 0.1 mL/kg. For example, the volume needed to administer 3 mg/kg to a 70 kg patient is $(3 \text{ mg/kg}) / (30 \text{ mg/mL}) \times 70 \text{ kg} = 7 \text{ mL}$. Future modifications of the on-line UW gadolinium calculator will be made to assist with volume calculations of ferumoxytol (<https://www.radiology.wisc.edu/fileShelf/contrastCorner/gadcalc.php>).
5. Ferumoxytol should always be diluted in normal saline to 5 times the volume. For example, a 7 mL dose of ferumoxytol should be diluted with 28 mL of normal saline to a total volume of 35 mL. Ferumoxytol should always be diluted regardless of the rate of injection, even for slow infusion.
6. In light of the 3/31/15 FDA communication, whenever possible, ferumoxytol should be injected via slow infusion over ~15 minutes. As ferumoxytol is an intravascular agent, a slow infusion may be appropriate for applications such as MR venography where a steady-state distribution of contrast is needed. To improve workflow, slow infusions should be performed outside of the magnet room.
7. For applications that require dynamic imaging, such as time-resolved MR angiography, bolus injection of diluted ferumoxytol should be performed using a standard power injector. Diluted ferumoxytol should be injected at a rate of 1-2 mL/s, followed by a 20-50 mL saline flush, injected at the same rate.
8. The need to use ferumoxytol, and the FDA black-box warning, should be discussed with the referring physician prior to administering this agent, and documentation of this discussion should be included in the radiology report.
9. All standard precautions and monitoring used for GBCA with regards to adverse reactions and IV infiltration also apply to ferumoxytol. This includes immediate availability of a physician who is trained in the management of contrast reactions, and is located in close proximity to the MRI scanner.
10. In addition to standard monitoring procedures, blood pressure should be measured before, and 5 and 30 minutes after the administration of ferumoxytol. The monitoring physician should be called to assess the patient if, after administration of ferumoxytol, the patient becomes a) symptomatic, b) develops hypotension (systolic blood pressure < 90 mmHg) or hypertension (systolic blood pressure > 160 mmHg), or c) has an increase or decrease in systolic blood pressure of more than 30 mmHg.

Adherence to the above guidelines is important to ensure the safest possible use of this important, alternative contrast agent. Please direct questions to Scott Reeder, MD, PhD (pager 6713, sreeder@uwhealth.org) or Howard Rowley, MD (pager 2518, hrowley@uwhealth.org).