



NEW DRUG FAX SHEET

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SPECIAL ISSUE

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FERAHEME (FUROMOXYTOL) MAY BE ASSOCIATED WITH FATAL ALLERGIC REACTIONS

This special issue of *New Drug FAX Sheet* provides information from the FDA regarding the risk of a potentially fatal allergic reaction with Feraheme (ferumoxytol). The verbatim safety alert can be found below. If you need further information, please contact the Samford University Global Drug Information Service at (205) 726-2659.

AUDIENCE: Hematology, Nephrology, Pharmacy

ISSUE: FDA is strengthening an existing warning that serious, potentially fatal allergic reactions can occur with the anemia drug Feraheme (ferumoxytol). FDA changed the prescribing instructions and approved a Boxed Warning, FDA's strongest type of warning, regarding these serious risks. Also added is a new Contraindication, a strong recommendation against use of Feraheme in patients who have had an allergic reaction to any intravenous (IV) iron replacement product.

All IV iron products carry a risk of potentially life-threatening allergic reactions. At the time of Feraheme's approval in 2009, this risk was described in the Warnings and Precautions section of the drug label. Since then, serious reactions, including deaths, have occurred despite the proper use of therapies to treat these reactions and emergency resuscitation measures (see [Drug Safety Communication/Data Summary](#)). FDA evaluated this risk further and has identified ways to reduce the risk of serious allergic reactions with Feraheme.

FDA is continuing to monitor and evaluate the risk of serious allergic reactions with all IV iron products, and we will update the public as new information becomes available.

BACKGROUND: Feraheme is in a class of medicines called IV iron replacement products. It is used to treat iron-deficiency anemia—a condition in which there is a lower than normal number of oxygen-carrying red blood cells because of too little iron. Feraheme is specifically approved for use only in adults with iron deficiency anemia in patients with chronic kidney disease.

RECOMMENDATIONS: Based on FDA's evaluation, the prescribing instructions and other label information were updated, adding a Boxed Warning that describes these serious risks and recommending that health care professionals:

- Only administer IV iron products to patients who require IV iron therapy.
- Do not administer Feraheme to patients with a history of allergic reaction to Feraheme or other IV iron products.
- Only administer diluted Feraheme as an IV infusion over a minimum of 15 minutes. Feraheme should not be given as an undiluted IV injection.
- Closely monitor patients for signs and symptoms of serious allergic reactions, including monitoring blood pressure and pulse during Feraheme administration and for at least 30 minutes following each infusion.
- Carefully consider the potential risks and benefits of Feraheme administration in elderly patients with multiple or serious medical conditions, as these patients may experience more severe reactions.
- Carefully consider the potential risks and benefits of Feraheme administration in patients with a history of multiple drug allergies. Patients with multiple drug allergies may also be at higher risk.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the FDA Drug Safety Communication, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm440479.htm>

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