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# IMPORTANT DRUG WARNING

Dear Healthcare Professional:

## Feraheme® (ferumoxytol) Injection: Serious Adverse Reactions from Post-marketing Spontaneous Reports

AMAG Pharmaceuticals, Inc. would like to inform you of important changes to the Prescribing Information (PI) for Feraheme® (ferumoxytol) Injection For Intravenous (IV) use based on post-marketing spontaneous safety data. These changes provide healthcare providers with more specific safety and risk information. *Feraheme* is indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease.[1]

The following serious adverse reactions have been reported from post-marketing spontaneous reports with *Feraheme*:

- *life-threatening anaphylactic/anaphylactoid reactions*
- *clinically significant hypotension*
- *unresponsiveness*
- *tachycardia/rhythm abnormalities*
- *ischemic myocardial events*
- *pulse absent*
- *cardiac/cardiorespiratory arrest*
- *syncope*
- *loss of consciousness*
- *angioedema*
- *congestive heart failure*
- *cyanosis*

These adverse reactions have occurred following the first dose or subsequent doses of *Feraheme*. Therefore, it is important for you to observe patients for signs and symptoms of hypersensitivity for at least 60 minutes following each *Feraheme* injection. Only administer *Feraheme* when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Listed below is the updated ***Warnings and Precautions*** section of the PI.[1]

**Warnings and Precautions Section of the Feraheme PI**

HYPERSENSITIVITY REACTIONS

***Feraheme* may cause life-threatening hypersensitivity reactions including anaphylaxis and/or anaphylactoid reactions. Anaphylactic type reactions presenting with cardiac/cardiorespiratory arrest, clinically significant hypotension, syncope, and unresponsiveness have been reported in the post-marketing experience.** In clinical studies, serious hypersensitivity reactions were reported in 0.2% (3/1,726) of subjects receiving *Feraheme*. Other adverse reactions potentially associated with hypersensitivity (e.g., pruritus, rash, urticaria or wheezing) were reported in 3.7% (63/1,726) of these subjects. Observe patients for signs and symptoms of hypersensitivity for at least 60 minutes following each *Feraheme* injection. Only administer the drug when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.

HYPOTENSION

**Severe adverse reactions of clinically significant hypotension have been reported.** In clinical studies, hypotension was reported in 1.9% (33/1,726) of subjects, including three patients with serious hypotensive reactions. Hypotension has also been reported in the post-marketing experience. Monitor patients for signs and symptoms of hypotension following each *Feraheme* administration.

IRON OVERLOAD

Excessive therapy with parenteral iron can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. Regularly monitor the hematologic response during parenteral iron therapy. Do not administer *Feraheme* to patients with iron overload.

In the 24 hours following administration of *Feraheme*, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in the *Feraheme* complex.

MAGNETIC RESONANCE (MR) IMAGING

Administration of *Feraheme* may transiently affect the diagnostic ability of MR imaging. Anticipated MR imaging studies should be conducted prior to the administration of *Feraheme*. Alteration of MR imaging studies may persist for up to 3 months following the last *Feraheme* dose. If MR imaging is required within 3 months after *Feraheme* administration, use T1- or proton density-weighted MR pulse sequences to minimize the *Feraheme* effects; MR imaging using T2-weighted pulse sequences should not be performed earlier than 4 weeks after the administration of *Feraheme*. Maximum alteration of vascular MR imaging is anticipated to be evident for 1 – 2 days following *Feraheme* administration. *Feraheme* will not interfere with X-ray, computed tomography (CT), positron emission tomography (PET), single photon emission computed tomography (SPECT), ultrasound or nuclear medicine imaging.

AMAG Pharmaceuticals, Inc. is committed to ensuring that *Feraheme* is used safely and effectively and to providing you with the most current Prescribing Information.

The current revised full Prescribing Information (PI), which includes additional information for *Warnings and Precautions* and *Adverse Reactions*, is available on the product web site at **www.feraheme.com**.

Should you have any questions about the information in this email, or wish to report adverse events related to *Feraheme*, please call **1-877-411-2510**. Alternatively, adverse events may be reported directly to FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**.

Sincerely,

Lee F. Allen, MD, PhD
Chief Medical Officer and Executive Vice President
AMAG Pharmaceuticals, Inc.

**Reference: 1.** Feraheme® Prescribing Information.