

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-180

LABELING

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Feraheme safely and effectively. See full prescribing information for Feraheme.

Feraheme™ (ferumoxytol) Injection
For Intravenous (IV) use
Initial U.S. Approval: XXXX

INDICATIONS AND USAGE

Feraheme is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease (CKD). (1)

DOSAGE AND ADMINISTRATION

- The recommended dose of Feraheme is an initial 510 mg intravenous injection followed by a second 510 mg intravenous injection 3 to 8 days later.
- Administer Feraheme as an undiluted intravenous injection delivered at a rate of up to 1 mL/sec (30 mg/sec).
- The recommended Feraheme dose may be readministered to patients with persistent or recurrent iron deficiency anemia.

DOSAGE FORMS AND STRENGTHS

Feraheme (30 mg/mL) is available for intravenous injection in single use vials. Each vial contains 510 mg of elemental iron in 17 mL.

CONTRAINDICATIONS

Evidence of iron overload. (4)
Known hypersensitivity to Feraheme or any of its components. (4)
Anemia not caused by iron deficiency. (4)

WARNINGS AND PRECAUTIONS

- Hypersensitivity Reactions: Observe for signs and symptoms of hypersensitivity for at least 30 minutes following the administration of Feraheme. (5.1)
- Hypotension: Feraheme may cause hypotension. Monitor for signs and symptoms of hypotension following the administration of Feraheme. (5.2)
- Iron Overload: Regularly monitor hematologic responses during Feraheme therapy. Do not administer Feraheme to patients with iron overload. (5.3)
- Magnetic Resonance Imaging: Feraheme can alter magnetic resonance imaging (MRI) studies. (5.4)

ADVERSE REACTIONS

The most common adverse reactions ($\geq 2\%$) following the administration of Feraheme are diarrhea, nausea, dizziness, hypotension, constipation, and peripheral edema. (6.1)

To report SUSPECTED ADVERSE REACTIONS with Feraheme, contact AMAG Pharmaceuticals, Inc. at 1-877-411-2510, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

Revised: Month/Year

FULL PRESCRIBING INFORMATION: CONTENTS*

1	INDICATIONS AND USAGE
2	DOSAGE AND ADMINISTRATION
3	DOSAGE FORMS AND STRENGTHS
4	CONTRAINDICATIONS
5	WARNINGS AND PRECAUTIONS
5.1	Hypersensitivity Reactions
5.2	Hypotension
5.3	Iron overload
5.4	Magnetic Resonance (MR) Imaging
6	ADVERSE REACTIONS
6.1	Adverse Reactions in Clinical Studies
7	DRUG INTERACTIONS
8	USE IN SPECIFIC POPULATIONS
8.1	Pregnancy
8.3	Nursing Mothers
8.4	Pediatric Use
8.5	Geriatric Use

10	OVERDOSAGE
10.1	Nonclinical Data
11	DESCRIPTION
12	CLINICAL PHARMACOLOGY
12.1	Mechanism of Action
12.2	Pharmacodynamics
12.3	Pharmacokinetics
13	NONCLINICAL TOXICOLOGY
13.1	Carcinogenesis, Mutagenesis, Impairment of Fertility
13.2	Animal Toxicology and Pharmacology
13.3	Reproductive and Developmental Toxicology
14	CLINICAL STUDIES
16	HOW SUPPLIED/STORAGE AND HANDLING
16.1	How Supplied
16.2	Stability and Storage
17	PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Feraheme™ (ferumoxytol) Injection is indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease (CKD).

2 DOSAGE AND ADMINISTRATION

The recommended dose of Feraheme is an initial 510 mg intravenous injection followed by a second 510 mg intravenous injection 3 to 8 days later. Administer Feraheme as an undiluted intravenous injection delivered at a rate of up to 1 mL/sec (30 mg/sec). The dosage is expressed in terms of mg of elemental iron, with each mL of Feraheme containing 30 mg of elemental iron. Evaluate the hematologic response (hemoglobin, ferritin, iron and transferrin saturation) at least one month following the second Feraheme injection. The recommended Feraheme dose may be readministered to patients with persistent or recurrent iron deficiency anemia.

For patients receiving hemodialysis, administer Feraheme once the blood pressure is stable and the patient has completed at least one hour of hemodialysis. Monitor for signs and symptoms of hypotension following each Feraheme injection.

Inspect parenteral drug products visually for the absence of particulate matter and discoloration prior to administration.

3 DOSAGE FORMS AND STRENGTHS

Feraheme (30 mg/mL) is available for intravenous injection in single use vials. Each vial contains 510 mg of elemental iron in 17 mL.

4 CONTRAINDICATIONS

Feraheme is contraindicated in patients with:

- Evidence of iron overload
- Known hypersensitivity to Feraheme or any of its components
- Anemia not caused by iron deficiency

5 WARNINGS AND PRECAUTIONS

5.1 HYPERSENSITIVITY REACTIONS

Feraheme may cause serious hypersensitivity reactions, including anaphylaxis and/or anaphylactoid reactions. 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 30 minutes following Feraheme injection and only administer the drug when personnel and therapies are readily available for the treatment of hypersensitivity reactions [*see Adverse Reactions (6.1)*].

5.2 HYPOTENSION

Hypotension may follow Feraheme administration. In clinical studies, hypotension was reported in 1.9% (33/1,726) of subjects, including three patients with serious hypotensive reactions. Monitor patients for signs and symptoms of hypotension following Feraheme administration [*see Dosage and Administration (2)* and *Warnings and Precautions (5.1)*].

5.3 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 [*see Dosage and Administration (2)*]. Do not administer Feraheme to patients with iron overload [*see Contraindications (4)*].

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.

5.4 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 [*see Clinical Pharmacology (12.3)*].

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.

6 ADVERSE REACTIONS

Feraheme injection may cause serious hypersensitivity reactions and hypotension [*see Warnings and Precautions (5.1)(5.2)*].

In clinical studies, 1,726 subjects were exposed to Feraheme; 1,562 of these had CKD and 164 did not have CKD. Of these subjects 46% were male and the median age was 63 years (range of 18 to 96 years).

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug may not reflect the rates observed in practice.

6.1 ADVERSE REACTIONS IN CLINICAL STUDIES

Across the three randomized clinical trials [Trial 1, 2, and 3, *see Clinical Studies (14)*], a total of 605 patients were exposed to two injections of 510 mg of Feraheme and a total of 280 patients were exposed to 200 mg/day of oral iron for 21 days. Most patients received their second Feraheme injection 3 to 8 days after the first injection.

Adverse reactions related to Feraheme and reported by $\geq 1\%$ of Feraheme-treated patients in the randomized clinical trials are listed in Table 1. Diarrhea (4.0%), constipation (2.1%) and hypertension (1.0%) have also been reported in Feraheme-treated patients.

Table 1: Adverse Reactions to Feraheme Reported in $\geq 1\%$ of Patients with CKD

Adverse Reactions	Feraheme 2 x 510 mg (n = 605)	Oral Iron (n = 280)
Nausea	3.1%	7.5%
Dizziness	2.6%	1.8%
Hypotension	2.5%	0.4%
Peripheral Edema	2.0%	3.2%
Headache	1.8%	2.1%
Edema	1.5%	1.4%
Vomiting	1.5%	5.0%
Abdominal Pain	1.3%	1.4%
Chest Pain	1.3%	0.7%
Cough	1.3%	1.4%
Pruritus	1.2%	0.4%
Pyrexia	1.0%	0.7%
Back Pain	1.0%	0%
Muscle Spasms	1.0%	1.4%
Dyspnea	1.0%	1.1%
Rash	1.0%	0.4%

In clinical trials, adverse reactions leading to treatment discontinuation and occurring in ≥ 2 Feraheme-treated patients included hypotension, infusion site swelling, increased serum ferritin level, chest pain, diarrhea, dizziness, ecchymosis, pruritus, chronic renal failure, and urticaria.

Following completion of the controlled phase of the trials, 69 patients received two additional 510 mg intravenous injections of Feraheme (for a total cumulative dose of 2.04 g). Adverse reactions following this repeat Feraheme dosing were similar in character and frequency to those observed following the first two intravenous injections.

In a placebo-controlled, cross-over trial, 713 patients with CKD received a single 510 mg dose of Feraheme. Adverse reactions reported by these patients were similar in character and frequency to those observed in other clinical trials.

7 DRUG INTERACTIONS

Drug-drug interaction studies with Feraheme were not conducted. Feraheme may reduce the absorption of concomitantly administered oral iron preparations.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

There are no studies of Feraheme in pregnant women. In animal studies, Feraheme caused decreased fetal weights and fetal malformations at maternally toxic doses of 13-15 times the human dose. Use Feraheme during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In rats, administration of Feraheme at maternally toxic doses during organogenesis, i.e., daily doses approximately 2 times the recommended 510 mg human dose (on a mg/m^2 basis) for 12 days, caused a decrease in fetal weights. The cumulative animal exposure was approximately 13 times the human therapeutic course of 1.02 g (on a mg/m^2 basis). In rabbits, administration of Feraheme at maternally toxic doses during organogenesis, i.e., daily doses approximately 2 times the recommended 510 mg human dose (on a mg/m^2 basis) for 14 days, was associated with decreased fetal weights and external and/or soft tissue fetal malformations. The cumulative animal exposure was approximately 15 times the human therapeutic course of 1.02 g on a mg/m^2 basis [see *Nonclinical Toxicology* (13.3)].

8.3 Nursing Mothers

It is not known whether Feraheme is present in human milk. Because many drugs are excreted in human milk and because of the potential for adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to avoid Feraheme, taking into account the importance of Feraheme to the mother and the known benefits of nursing.

8.4 Pediatric Use

The safety and effectiveness of Feraheme in pediatric patients have not been established.

8.5 Geriatric Use

In controlled clinical trials, 330 patients ≥ 65 years of age were treated with Feraheme. No overall differences in safety and efficacy were observed between older and younger patients in these trials, but greater sensitivity of older individuals cannot be ruled out. In general, dose administration to an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy [see *Dosage and Administration (2) and Clinical Studies (14)*].

10 OVERDOSAGE

No data are available regarding overdosage of Feraheme in humans. Excessive dosages of Feraheme may lead to accumulation of iron in storage sites potentially leading to hemosiderosis. Do not administer Feraheme to patients with iron overload [see *Contraindications (4)*].

10.1 Nonclinical Data

No macroscopic or microscopic signs of toxicity and no changes in the clinical pathology data related to toxicity were observed following single intravenous doses of Feraheme up to 450 mg iron/kg in rats (approximately 10 times the recommended 510 mg human dose on a mg/m^2 basis) and in dogs (approximately 33 times the recommended 510 mg human dose on a mg/m^2 basis).

11 DESCRIPTION

Feraheme is a non-stoichiometric magnetite (superparamagnetic iron oxide) coated with polyglucose sorbitol carboxymethylether. The overall colloidal particle size is 17-31 nm in diameter. The chemical formula of Feraheme is $\text{Fe}_{5874}\text{O}_{8752}\text{-C}_{11719}\text{H}_{18682}\text{O}_{9933}\text{Na}_{414}$ with an apparent molecular weight of 750 kDa.

Feraheme injection is an aqueous colloidal product that is formulated with mannitol. It is a black to reddish brown liquid, and is provided in single use vials containing 510 mg of elemental iron. Each mL of the sterile colloidal solution of Feraheme injection contains 30 mg of elemental iron and 44 mg of mannitol, and has low bleomycin-detectable iron. The formulation is isotonic with an osmolality of 270-330 mOsm/kg. The product contains no preservatives, and has a pH of 6 to 8.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Feraheme consists of a superparamagnetic iron oxide that is coated with a carbohydrate shell, which helps to isolate the bioactive iron from plasma components until the iron-carbohydrate complex enters the reticuloendothelial system macrophages of the liver, spleen and bone

marrow. The iron is released from the iron-carbohydrate complex within vesicles in the macrophages. Iron then either enters the intracellular storage iron pool (e.g., ferritin) or is transferred to plasma transferrin for transport to erythroid precursor cells for incorporation into hemoglobin.

12.2 Pharmacodynamics

Cardiac Electrophysiology

In a randomized, positive- and placebo-controlled, parallel-group study, healthy subjects received a supratherapeutic regimen of Feraheme (1.02 g given as two 510 mg doses within 24 hours), placebo or a single dose of 400 mg moxifloxacin (positive control). Results demonstrated no effect of Feraheme on QT interval durations. No clinically meaningful effect of Feraheme on heart rate was observed.

12.3 Pharmacokinetics

The pharmacokinetic (PK) behavior of Feraheme has been examined in healthy subjects and in patients with CKD stage 5D on hemodialysis. Feraheme exhibited dose-dependent, capacity-limited elimination from plasma with a half life of approximately 15 hours in humans. The clearance (CL) was decreased by increasing the dose of Feraheme. Volume of distribution (Vd) was consistent with plasma volume, and the mean maximum observed plasma concentration (C_{max}) and terminal half-life ($t_{1/2}$) values increased with dose. The estimated values of CL and Vd following two 510 mg doses of Feraheme administered intravenously within 24 hours were 69.1 mL/hr and 3.16 L, respectively. The C_{max} and time of maximum concentration (t_{max}) were 206 mcg/mL and 0.32 hr, respectively. Rate of infusion had no influence on Feraheme PK parameters. No gender differences in Feraheme PK parameters were observed. Feraheme is not removed by hemodialysis.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Feraheme was not tested for carcinogenic effects. In standard genotoxicity tests, Feraheme showed no evidence of mutagenic activity in an *in vitro* Ames test or clastogenic activity in either an *in vitro* chromosomal aberration assay or an *in vivo* micronucleus assay.

No adverse effects on fertility or general reproductive performance were noted in animal studies. Feraheme had no effect on male or female fertility or general reproductive performance in rats.

13.2 Animal Toxicology and Pharmacology

Animal studies demonstrate that the plasma half-life of Feraheme increased with increasing dose. The highest tissue concentrations of Feraheme were found in the liver, spleen, and central lymph node pool; administered radiolabeled Feraheme (^{59}Fe) was found in the red blood cell fraction by 24 hr. Studies with radiolabeled drug product demonstrated that renal elimination of the iron in Feraheme was insignificant, while the carbohydrate coating was significantly excreted in the urine and feces.

Repeat-dose toxicity studies with Feraheme up to 12 mg Fe/kg/day for 13 weeks in rats (cumulative exposure approximately 12 times the anticipated exposure of a human therapeutic course of 1.02 g of Feraheme on mg/m² basis) and dogs (cumulative exposure approximately 40 times the anticipated exposure of a human therapeutic course of 1.02 g of Feraheme on mg/m² basis) demonstrated dose-dependent decreases in body weight gain and food consumption, and increases in pigmentation intensity. No systemic toxicity or immunotoxicity was observed at the relevant clinical doses. Changes in red blood cell counts, hemoglobin and serum iron, increases in liver and spleen weight, and the accumulation of iron-positive pigmentation in various organs were observed as expected with the administration of iron-containing agents.

13.3 Reproductive and Developmental Toxicology

In rats, no maternal or fetal effects of Feraheme were observed at daily doses of 31.6 mg Fe/kg during organogenesis for 12 days, approximately 1 time the recommended human dose of 510 mg (on mg/m² basis). The cumulative animal exposure was approximately 5 times the human therapeutic course of 1.02 g (on a mg/m² basis). Administration of Feraheme during organogenesis at maternally toxic doses of 100 mg Fe/kg/day (daily exposure was approximately 2 times the recommended 510 mg human dose on a mg/m² basis) for 12 days (cumulative exposure was approximately 13 times the human therapeutic course of 1.02 g on a mg/m² basis) caused a decrease in fetal weights.

In rabbits, no maternal or fetal effects of Feraheme were observed at daily doses of 16.5 mg Fe/kg during organogenesis for 14 days, approximately 1 time the recommended human dose of 510 mg (on mg/m² basis). The cumulative animal exposure was approximately 7 times the human therapeutic course of 1.02 g (on a mg/m² basis). Administration of Feraheme during organogenesis at maternally toxic doses of 45 mg Fe/kg/day (daily exposure approximately 2 times the recommended 510 mg human dose on a mg/m² basis) for 14 days (cumulative exposure approximately 15 times the human therapeutic course of 1.02 g on a mg/m² basis) caused decreased fetal weights and external and/or soft tissue fetal malformations.

14 CLINICAL STUDIES

The safety and efficacy of Feraheme for the episodic treatment of iron deficiency anemia in patients with CKD were assessed in three randomized, open-label, controlled clinical trials (Trial 1, 2 and 3). These trials also included an uncontrolled, follow-up phase in which patients with persistent iron deficiency anemia could receive two additional 510 mg intravenous injections of Feraheme. The major efficacy results from the controlled phase of each study are shown in Table 2.

In all three trials, patients with CKD and iron deficiency anemia were randomized to treatment with Feraheme or oral iron. Feraheme was administered as two 510 mg intravenous single doses and oral iron (ferrous fumarate) was administered as a total daily dose of 200 mg elemental iron daily for 21 days. The major trial outcomes assessed the change in hemoglobin from baseline to Day 35. Trial 1 and 2 enrolled patients with non-dialysis dependent CKD and Trial 3 enrolled patients who were undergoing hemodialysis.

In Trial 1, the mean age of patients was 66 years (range, 23 to 95); 60% were female; 65% were Caucasian, 32% were Black, and 2% were other races. In the Feraheme and oral iron groups, 42% and 44% of patients, respectively, were receiving erythropoiesis stimulating agents (ESAs) at baseline.

In Trial 2, the mean age of patients was 65 years (range, 31 to 96); 61% were female; 58% were Caucasian, 35% were Black, and 7% were other races. In the Feraheme and oral iron groups, 36% and 43% of patients, respectively, were receiving ESAs at baseline.

In Trial 3, the mean age of patients was 60 years (range, 24 to 87); 43% were female; 34% were Caucasian, 59% were Black, and 7% were other races. All patients were receiving ESAs.

Table 2 shows the Baseline and mean change to Day 35 in hemoglobin (Hgb, g/dL), transferrin saturation (TSAT, %) and ferritin (ng/mL) in each treatment group for Trial 1, 2, and 3.

Table 2: Changes from Baseline to Day 35 in Hemoglobin, Transferrin Saturation and Ferritin (Intent to Treat Population)

ENDPOINT	Trial 1 Non-Dialysis CKD		Trial 2 Non-Dialysis CKD		Trial 3 CKD on Dialysis	
	Feraheme n = 226	Oral Iron n = 77	Feraheme n = 228	Oral Iron n = 76	Feraheme n = 114	Oral Iron n = 116
Baseline Hgb (mean ± SD, g/dL)	9.9 ± 0.8	9.9 ± 0.7	10.0 ± 0.7	10.0 ± 0.8	10.6 ± 0.7	10.7 ± 0.6
Hgb change from Baseline at Day 35 (mean ± SD, g/dL)	1.2* ± 1.3	0.5 ± 1.0	0.8* ± 1.2	0.2 ± 1.0	1.0* ± 1.1	0.5 ± 1.1
Baseline TSAT (mean ± SD, %)	9.8 ± 5.4	10.4 ± 5.2	11.3 ± 6.1	10.1 ± 5.5	15.7 ± 7.2	15.9 ± 6.3
TSAT change from Baseline at Day 35 (mean ± SD, %)	9.2 ± 9.4	0.3 ± 4.7	9.8 ± 9.2	1.3 ± 6.4	6.4 ± 12.6	0.6 ± 8.3
Baseline ferritin (mean ± SD, ng/mL)	123.7 ± 125.4	146.2 ± 136.3	146.1 ± 173.6	143.5 ± 144.9	340.5 ± 159.1	357.6 ± 171.7
Ferritin change from Baseline at Day 35 (mean ± SD, ng/mL)	300.7 ± 214.9	0.3 ± 82.0	381.7 ± 278.6	6.9 ± 60.1	233.9 ± 207.0	-59.2 ± 106.2

* $p \leq 0.001$ for main efficacy endpoint

Following completion of the controlled phase of each of the Phase 3 trials, patients who were iron deficient and anemic could receive two additional 510 mg intravenous injections of

Feraheme for a total cumulative dose of 2.04 g. Overall, 69 patients received two additional 510 mg intravenous injections of Feraheme, and on Day 35 following these additional injections, the majority of these patients (70%) experienced an increase in hemoglobin and iron parameters (TSAT and ferritin). The mean change (\pm SD) in hemoglobin level from the retreatment baseline for patients with an increase in hemoglobin was 0.86 (\pm 0.68) g/dL and was 0.5 (\pm 0.8) g/dL for all patients.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Feraheme is available in single use vials in the following package sizes (Table 3).

Table 3: Feraheme Packaging Description

NDC Code	Dose / Total volume per vial	Vials / Carton
NDC 59338-775-01	510 mg/ 17 mL	1
NDC 59338-775-10	510 mg/ 17 mL	10

16.2 Stability and Storage

Store at controlled room temperature (20° to 25°C [68° to 77°F]). Excursions permitted to 15° – 30°C (59° – 86°F).

17 PATIENT COUNSELING INFORMATION

Prior to Feraheme administration:

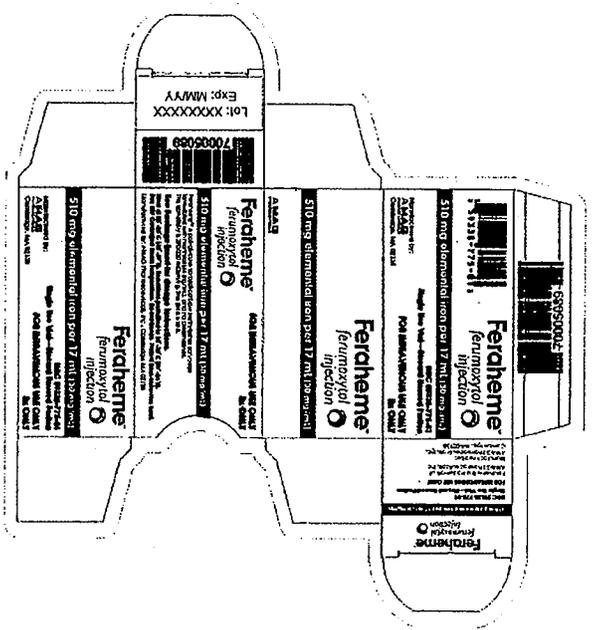
- Question patients regarding any prior history of reactions to parenteral iron products.
- Advise patients of the risks associated with Feraheme.
- Advise patient to report any signs and symptoms of hypersensitivity that may develop during and following Feraheme administration, such as rash, itching, dizziness, lightheadedness, swelling and breathing problems [*see Warnings and Precautions (5)*].

Manufactured and Distributed by:

AMAG Pharmaceuticals, Inc.
Lexington, MA 02421

FINAL DRAFT PROOF		DATE: 15-June-09
Ferheme™ 510 mg/17ml Carton (3 ml per carton)		Size: 1.4375 x 1.125 x 2.75 inches (36.5125 x 28.5375 x 69.15 mm)
Part No.: 70005089	MCC Code: 59338-775-01	
 AMAS AMERICAN MEDICAL ASSOCIATION		

(b)(4)



FINAL DRAFT PROOF		DATE: 15-June-09
Ferdinens™ 510 mg/17mm Vial (3 vial per carton)		Size: 3.5 x 1.25 inches (8.9 x 31.75 mm)
Part No.: 78005085	MDC Code: 59338-775-01	



Ferdinens™
Ferdinens™
510 mg/17mm Vial (3 vial per carton)

Lot: XXXXXXXX
Exp: MYY

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