Understanding Iron Deficiency Anemia

Feraheme® (ferumoxytol) Injection For Intravenous (IV) use is indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease (CKD). Feraheme can only be administered by a doctor or nurse as an intravenous injection. Feraheme is not for people known to be allergic to feraheme or any of its ingredients.

You should be aware that treatment with Feraheme may cause life-threatening or fatal reactions. These reactions were reported in clinical trials and in patients who received Feraheme after the clinical trials. Serious reactions may include severe allergic reactions, cardiaq arrest (sudden loss of heartbeat), a serious drop in blood pressure (hypotension), fainting, and unresponsiveness. When tested in clinical trials, three out of 1,726 people who received Feraheme had a serious drop in blood pressure. Sixty-three additional people had other adverse reactions that may have been related to an allergic reaction. These included itching, rash, hives, and wheezing.

After receiving Feraheme, you should be watched by a doctor or nurse for at least 30 minutes to make sure you do not have an allergic reaction or a drop in blood pressure.

Receiving Feraheme may affect magnetic resonance imaging (MRI) for up to three months. Ultrasound, x-ray, and other imaging are not affected.

After receiving feraheme, you may have dizziness, nausea, drowsiness, low blood pressure, convulsions, and swelling of the arms and legs. If you develop any of these conditions, tell your doctor or nurse. You should also inform the FDA by calling 1-800-FDA-1988 or going online to the web site www.fda.gov/mrwadwatch.

Some patients who received feraheme after the clinical trials experienced serious side effects; however, it is not certain how often these side effects may occur or if they are definitely related to the use of Feraheme. Serious side effects include life-threatening allergic reactions, cardiac arrest (sudden loss of heartbeat), loss of breathing, serious drop in blood pressure, unresponsiveness, fainting or loss of consciousness, increased heart rate or other abnormal rhythms of the heart, swelling of blood flow to the heart, heart failure, lack of a pulse (heartbeat), or blue coloration of the skin. These side effects happened in patients up to 30 minutes after receiving feraheme.

Please see full Prescribing Information in pocket.
Please see Important Safety Information About Feraheme on back cover.

### Blood tests and what they measure

<table>
<thead>
<tr>
<th>Test</th>
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<tbody>
<tr>
<td>RBC</td>
<td>The level of a protein in red blood cells that carries oxygen throughout the body</td>
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<td>Hemoglobin (Hgb)</td>
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<td>Serum ferritin</td>
<td>The level of a protein in the cells that store iron</td>
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### What causes anemia?

There are many different causes of anemia, including:

- Not enough iron
- Issues with substances soaking into your tissue
- Blood loss
- Not enough erythropoiesis (EPO)

### Building healthy RBCs

A doctor may prescribe an erythropoiesis stimulating agent (ESA) to help replace EPO in anemic patients. ESA and iron supplements may be necessary to create healthy RBCs.

### What is IDA?

Anemia due to iron deficiency, or IDA, occurs when a person has too little iron in their body. IDA is the most common form of anemia.

### Common signs and symptoms of IDA

- Pale skin
- Fatigue
- Shortness of breath
- Blood spots on the white part of the eyes
- Brittle fingernails
- Frequent headaches

### How does my doctor know if I have IDA?

Several different blood tests help your doctor to determine whether you may have too little iron in your blood.

### Stages of anemia or IDA

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<tr>
<th>Stage</th>
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<tr>
<td>1</td>
<td>Kidney damage for at least 3 months with normal GFR</td>
<td>&gt;90 to 60</td>
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<td>2</td>
<td>Kidney damage for at least 3 months with mild decrease in GFR</td>
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<td>3</td>
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<td>&lt;15</td>
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*Your GFR reflects your doctor's estimation of how well your kidneys are working. A CKD program may help improve your GFR number.*

### What is CKD?

CKD occurs when the kidneys are unable to function properly. CKD usually develops over time and has 4 stages. To determine your kidney function, your doctor will calculate your glomerular filtration rate (GFR) using the results of a blood test. After measuring GFR, your doctor will know how your kidneys are working.

### How does IV therapy with Feraheme help?

#### How it’s given

- Feraheme® is an iron therapy that is given to adult patients with CKD through an IV injection.

#### What to expect

- Intravenous iron therapy can help stimulate healthy RBC production in your body.
- Adding iron to the body with Feraheme has been shown to significantly increase the percentage of RBCs that carry oxygen throughout the body.
- Once you receive your full course of Feraheme, it can take several weeks for your iron levels to rise.

#### Questions to ask your doctor

If you have CKD and are experiencing symptoms of IDA, or if you have been diagnosed with CKD, you should talk to your doctor about different iron treatments that are available, including IV iron. Consider the following questions:

1. When were my GFR and iron levels last tested?
2. What are my GFR and iron levels?
3. What can I do to help manage my anemia?
4. Is Feraheme right for me?
5. What are the possible side effects of Feraheme?

Feraheme is available only by prescription. Feraheme can cause side effects, some of which can be life-threatening or fatal. Call your doctor for medical advice about side effects. You are encouraged to report negative effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.
Please see Important Safety Information About Feraheme on back cover.
Please see full Prescribing Information in pocket.

Introduction
If you or someone you know has iron deficiency anemia (IDA), this brochure may be for you. You’ll find information about what IDA means to you and how your doctor may treat it.

What is anemia?
Anemia is a condition in which people do not have enough healthy red blood cells (RBCs). Without sufficient RBCs, the body doesn’t have enough hemoglobin (Hgb). Hgb is the substance in RBCs that allows them to carry oxygen to the tissues of the body. When you aren’t getting enough oxygen due to anemia or some other medical reason, you may start to feel tired, pale, or have trouble breathing.

How common is anemia?
Nearly 3.5 million Americans have some form of anemia. This number might be even greater since many cases of anemia are without knowing it.

What causes anemia?
There are many different causes of anemia, including:

• Blood disorders
• Low levels of certain vitamins
• Not enough iron
• Not enough erythropoietin (EPO)

Building healthy RBCs
A doctor may prescribe an erythropoiesis stimulating agent (ESA) to help replace EPO in anemic patients. EPO is a hormone that is important to RBC production. ESA may be used to increase production of RBCs in order to significantly increase your Hgb (Hematocrit).

What is IDA?
Anemia due to iron deficiency, or IDA, occurs when a person has too little iron in their blood.

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Several different blood tests help your doctor to determine whether you may have too little iron in your blood.

Blood tests and what they measure

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<tr>
<td>Hgb</td>
<td>The level of Hgb in the blood, which indicates the level of iron in the body.</td>
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<tr>
<td>Hct</td>
<td>The percentage of Hgb in the blood, which is a measure of the volume of packed RBCs.</td>
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<td>Serum ferritin</td>
<td>The level of a protein in the cells that stores iron.</td>
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How does IV iron therapy with Feraheme help?
Feraheme® (ferumoxytol) Injection For Intravenous (IV) use is an intravenous iron therapy that is given to adult patients with chronic kidney disease (CKD). Feraheme provides a full dose of iron intravenously (IV) in 2 visits to your doctor. Once you receive a full course of Feraheme, it can take several weeks for your iron levels to rise.

Questions to ask your doctor
If you have CKD and are experiencing symptoms of IDA, or if you have been diagnosed with anemia, your doctor should talk to you about different iron treatments that are available, including IV iron.

Consider the following questions:
1. When were my Hgb and iron levels last tested?
2. What are my Hgb and iron levels?
3. What can I do to help manage my anemia?
4. Is Feraheme right for me?
5. What are the possible side effects of Feraheme?

Feraheme is available only by prescription. Feraheme can cause side effects, some of which can be life-threatening or fatal. Call your doctor for medical advice about side effects. You are encouraged to report negative effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

How it’s given
• Feraheme is an iron therapy that is given to adult patients with CKD through an IV injection.

A normal dose, one full gram of iron, is given in 2 doses:
• After the first dose, the second dose is given within 3 to 8 days.
• Each dose takes less than a minute to give. You will be watched for at least 30 minutes.

What to expect
• Intravenous iron therapy can help stimulate healthy RBC production in your body.
• Adding iron to the body with Feraheme has been shown to significantly increase the RBCs in patients that receives oxygen throughout the body.
• Once you receive a full course of Feraheme, it can take several weeks for your iron levels to rise.

It is important to discuss treatment options and side effects with your healthcare provider. Your doctor will keep you in the office for at least 30 minutes after your injection. Your doctor may experience any allergic reactions or other side effects during or following your treatment.

Questions to ask your doctor
If you have CKD and are experiencing symptoms of IDA, or if you have been diagnosed with anemia, your doctor should talk to you about different iron treatments that are available, including IV iron.

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What are the possible side effects of Feraheme?
Feraheme may cause an anaphylactic or other allergic reaction. The most common reactions that may be life-threatening or fatal; please be sure to discuss these risks with your doctor.

Checking iron levels (such as serum ferritin and TSAT) regularly is important, as people with all stages of CKD are at risk for developing IDA.

Who is at risk for IDA?
• People with diabetes
• People with high blood pressure (hypertension)
• People undergoing chemotherapy
• Older people

What is CKD?
CKD occurs when the kidneys are unable to function properly. CKD usually develops over time and has 5 stages. To determine your kidney function, your doctor will calculate your glomerular filtration rate (GFR) using the results of a blood test. After measuring GFR, your doctor will know how your kidneys are working.

Stages of kidney disease

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<th>Stage</th>
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<th>GFR</th>
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<tr>
<td>1</td>
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</tr>
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<td>5</td>
<td>Kidney failure</td>
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*Your GFR number tells your doctor how much kidney function you have. A CKD program gives your GFR number.

Questions to ask your doctor
If you have CKD and are experiencing symptoms of IDA, or if you have been diagnosed with anemia, your doctor should talk to you about different iron treatments that are available, including IV iron.

Consider the following questions:
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What is IDA?
Anemia due to iron deficiency, or IDA, occurs when a person has too little iron in their blood.

Symptoms of IDA

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<tr>
<th>Symptom</th>
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<tr>
<td>Pale skin</td>
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</tr>
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Introduction
If you or someone you know has iron deficiency anemia (IDA), this brochure may be for you. You can find information about what IDA means to have and how your doctor can treat it.

What is anemia?
Anemia is a condition in which people do not have enough healthy red blood cells (RBCs). Without sufficient RBCs, the body doesn’t have enough hemoglobin (Hgb). Hgb is the substance in RBCs that allows them to carry oxygen to the tissues of the body. When you aren’t getting enough oxygen due to anemia or some other medical reason, you may start to feel tired, pale, or have trouble breathing.

How common is anemia?
Nearly 3.5 million Americans have some form of anemia. This number might be even greater since many people have anemia without knowing it.

What causes anemia?
There are many different causes of anemia, including:

- Blood loss
- Certain vitamins (such as iron, folate, and vitamin B-12)
- Kidney disease (such as chronic kidney disease or CKD)
- Problems with substances soaking into your skin or your bloodstream
- Low levels of a protein in the body (serum ferritin)
- Not enough iron in your diet

Building healthy RBCs:
A doctor may prescribe an epoetin alfa (an erythropoiesis-stimulating agent [ESA]) to help replace EPO in the bone marrow. EPO is a hormone that is important to RBC production. ESA and iron supplements may be necessary to create healthy RBCs.

What is IDA?
Anemia due to iron deficiency, or IDA, occurs when a person has too little iron in the body. IDA is the most common form of anemia.

Common signs and symptoms of IDA:
- Pale skin
- Fatigue
- Dizziness
- Shortness of breath
- A bluish white cast to the inner parts of the eyelids
- Brittle fingernails
- Frequent headaches

Common signs and symptoms of IDA
Managing anemia
What is Feraheme®?
Feraheme® (ferumoxytol) injection for intravenous (IV) injection is an intravenous iron approved for the treatment of adult iron deficiency anemia patients with chronic kidney disease (CKD). Feraheme provides a full dose of iron approved for clinical use in 2 doses of Feraheme within 3 to 8 days.

In clinical studies, Feraheme was shown to raise Hgb levels more effectively than oral iron. In certain people, such as those who have been diagnosed with CKD, anemia is especially common because inadequate kidney function can cause their red blood cell count to drop and anemia to develop.

Feraheme can only be administered by a doctor or nurse as an IV injection. Feraheme is not for people known to be allergic to ferumoxytol or any of its ingredients. Please see additional Important Safety Information.

How does my doctor know if I have IDA?
Several different blood tests help your doctor to determine whether you may have too little iron in your blood.

blood tests and what they measure

| Hgb | The level of a protein in red blood cells that carries oxygen throughout the body |
| HemaCt | The percentage of blood that is made up of RBCs |
| Serum ferritin | The level of protein in the cells that store iron |
| Transferrin saturation (TSAT) | The amount of iron in transferrin, which carries iron from storage to sites where red blood cell production takes place |

Treating IDA
There are many ways to treat IDA, including taking iron pills or receiving intravenous (IV) injections. Due to certain medications, treatments, and/or conditions, your body may not absorb enough iron. Your doctor may determine that adding iron to your diet or taking pills doesn’t work well enough. As a result, your doctor may suggest IV iron. Regarding intravenous iron:

- Various IVs are available
- A healthcare professional injects an iron product into the bloodstream
- IV iron may cause side effects and allergic reactions, some of which can be life-threatening or fatal. Call your doctor for medical advice about side effects. You are encouraged to report negative effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

What is CKD?
CKD occurs when the kidneys are unable to function properly. CKD usually develops over time and has 5 stages. To determine your kidney function, your doctor will calculate your glomerular filtration rate (GFR) using the results of a blood test. After measuring GFR, your doctor will know how your kidneys are working.

Stages of kidney disease

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*Your GFR number tells your doctor how much kidney function you have. AKI programs your GFR number to less than 15.

Who is at risk for CKD?
- People with diabetes
- People with high blood pressure (hypertension)
- People undergoing chemotherapy
- Older people

In clinical studies, Feraheme was shown to raise patients’ Hgb levels more effectively than oral iron. In certain people, such as those who have been diagnosed with CKD, anemia is especially common because inadequate kidney function can cause their red blood cell count to drop and anemia to develop.

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Checking iron levels (such as serum ferritin and TSAT) regularly is important, as people with all stages of CKD are at risk for developing IDA.

How does IV iron therapy with Feraheme help?
Feraheme is an iron therapy that is given to adult patients with CKD through an IV injection. A normal dose, one full gram of iron, is given in 2 doses.

- After the first dose, the second dose is given within 3 to 8 days.
- Each dose takes less than a minute to give. You will be watched for up to 30 minutes.

What to expect
- Intravenous iron therapy can help stimulate healthy RBC production in your body.
- Adding iron to the body with Feraheme has been shown to significantly increase your body’s ability to absorb iron from your diet or to add iron to your body.
- You can have side effects with your healthcare provider. Your doctor will keep you in the office for at least 30 minutes after your injection. Your doctor can experience any allergic reactions or other side effects during or following your treatment.

Questions to ask your doctor
If you have CKD and are experiencing symptoms of IDA, or if you have been diagnosed with CKD, you should talk to your doctor about different iron treatments that are available, including IV iron.

Consider the following questions:
1. When were my Hgb and iron levels last tested?
2. What are my Hgb and iron levels now?
3. What can I do to help manage my anemia?
4. Is Feraheme right for me?
5. What are the possible side effects of Feraheme?

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Please see full prescribing information in pocket.

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Anemia is a condition in which people do not have enough healthy red blood cells (RBCs). Without sufficient RBCs, the body cannot transport oxygen to the tissues of the body. When you aren’t getting enough oxygen due to anemia or some other medical reason, you may start to feel tired, look pale, or have trouble breathing.

How common is anemia?

Nearly 3.5 million Americans have some form of anemia. This number might be even greater since many people are anemic without knowing it.

What causes anemia?

There are many different causes of anemia, including:

- Not enough iron
- Low levels of certain vitamins
- Blood disorders
- Blood loss
- Not enough erythropoietin (EPO)
- Kidney disease
- Blood disorders
- Certain disorders of the gastrointestinal tract
- Some medications
- Radiation treatment
- An inherited disorder
- Several medical conditions

Building healthy RBCs

A doctor may prescribe an erythropoiesis-stimulating agent (ESA) to help replace RBCs. EPO is a hormone that is important to RBC production. ESAs can help your body make more RBCs, which improve oxygen-carrying ability.

What is IDA?

Anemia due to iron deficiency, or IDA, occurs when a person has too little iron in the body. IDA is the most common form of anemia.

Common signs and symptoms of IDA

- Pale skin
- Fatigue
- Shortness of breath
- Bradycardia (slower heart rate)
- Frequent headaches
- Brittle fingernails
- Gastrointestinal upset
- Night sweats

How does my doctor know if I have IDA?

Several different blood tests help your doctor to determine whether you may have too little iron in your blood.

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Treating IDA

There are a number of ways to treat IDA, including:

- Adding iron to your diet or taking pills
- Receiving 3 weekly IV injections
- Using an iron product intravenously

What is Feraheme®?

Feraheme® (ferumoxytol) Injection is an intravenous iron complex approved for the treatment of adult iron deficiency anemia with chronic kidney disease (CKD). It helps increase your Hgb levels and provides a full dose of iron in 2 IV injections.

Feraheme® is available only by prescription. Feraheme® is contraindicated in patients with a known or suspected allergy to iron or any of its ingredients. Please see Important Safety Information About Feraheme® on back cover.

Feraheme® is a powder in vials for injection. Each vial contains 100mg of Feraheme®. Each dose contains 10mg of ferumoxytol. Each vial also contains ascorbic acid and sodium hydroxide to adjust the pH to between 5 and 8

What is CKD?

CKD occurs when the kidneys are unable to function properly. CKD usually develops slowly over time and has 5 stages. To determine your kidney function, your doctor will calculate your glomerular filtration rate (GFR) using the results of blood tests. After measuring GFR, your doctor will know how your kidneys are working.

Stages of kidney disease

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kidney damage for at least 3 months with normal GFR</td>
</tr>
<tr>
<td>2</td>
<td>Kidney damage for at least 3 months with mildly decreased GFR</td>
</tr>
<tr>
<td>3</td>
<td>Moderate decrease in GFR for at least 6 months</td>
</tr>
<tr>
<td>4</td>
<td>Severe reduction in GFR for at least 3 months</td>
</tr>
<tr>
<td>5</td>
<td>Kidney failure</td>
</tr>
</tbody>
</table>

Who is at risk for CKD?

- People with diabetes
- People with high blood pressure (hypertension)
- People undergoing chemotherapy
- Diabetics

Questions to ask your doctor

If you have CKD and are experiencing symptoms of IDA, or if you have been diagnosed with the condition, you should talk to your doctor about different iron treatments that are available, including IV iron.

Consider the following questions:

1. What were my Hgb and iron levels last tested?
2. What are my Hgb and iron levels now?
3. Can I do to help manage my anemia?
4. Is Feraheme® right for me?
5. What are the possible side effects of Feraheme®?

Feraheme® is available only by prescription. Feraheme® can cause side effects, some of which can be life-threatening or fatal. Call your doctor for medical advice about side effects. You are encouraged to report negative effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.
Understanding Iron Deficiency Anemia

Feraheme® (ferumoxytol) Injection

Feraheme® is an iron replacement product that has been approved to treat iron deficiency anemia (IDA) in adult patients with chronic kidney disease (CKD). Feraheme® can only be administered by a doctor or nurse as an intravenous injection. Feraheme® is not for people known to be allergic to Feraheme® or any of its ingredients.

You should be aware that treatment with Feraheme® may cause life-threatening or fatal reactions. These reactions were reported in clinical trials and in patients who received Feraheme® after the clinical trials. Serious reactions may include severe allergic reactions, cardiac arrest (sudden loss of heartbeat), a serious drop in blood pressure (hypotension), fainting, and unresponsiveness. When tested in clinical trials, three out of 1,726 people who received Feraheme® had a serious drop in blood pressure. Sixty-three additional people had other adverse reactions that may have been related to an allergic reaction. These included itching, rash, hives, and wheezing.

After receiving Feraheme®, you should be watched by a doctor or nurse for at least 30 minutes to make sure you do not have an allergic reaction or a drop in blood pressure.

Receiving Feraheme® may affect magnetic resonance imaging (MRI) for up to three months. Ultrasound, x-ray, and other imaging are not affected.

After receiving Feraheme®, you may have diarrhea, nausea, dizziness, low blood pressure, coughing, and swelling of the arms and legs. If you develop any of these symptoms, tell your doctor or nurse. You should also inform the FDA by calling 1-800-FDA-1088 or going online to the web site www.fda.gov/medwatch.

Some patients who received Feraheme® after the clinical trials experienced side effects; however, it is not certain how often these side effects may occur or if they are definitely related to the use of Feraheme®. Serious side effects included life-threatening allergic reactions, cardiac arrest (sudden loss of heartbeat), loss of breathing, a serious drop in blood pressure, unresponsiveness, fainting or loss of consciousness, increased heart rate or other abnormal rhythms of the heart, swelling, loss of blood flow to the heart, heart failure, lack of a pulse (heartbeat), or blue coloration of the skin. These side effects happened in patients up to 30 minutes after receiving Feraheme®.

Please see full Prescribing Information in pocket.

Where to get more information

More information is available online. These websites provide trusted information to assist you in understanding and properly managing your condition.

• National Kidney Foundation (NKF) www.kidney.org
• American Association of Kidney Patients (AAKP) www.aakp.org
• National Kidney Disease Education Program (NKEP) www.rkdep.nih.gov
• U.S. Food and Drug Administration www.fda.gov
• National Heart, Lung, and Blood Institute (NHLBI) www.nhlbi.nih.gov
• Centers for Disease Control and Prevention (CDC) www.cdc.gov
• American Academy of Family Physicians (AAFP) www.aafp.org

Understanding Iron Deficiency Anemia

Feraheme® (ferumoxytol) Injection

For intravenous (IV) use is indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease (CKD).

ALEXIS NOTES
1/2/14
MUST RELINK LOGOS AND BOTTLE IMAGE TO OUR NEWER VERSIONS IN THE KITCHEN. PLEASE DO NOT USE WHAT IS IN THIS FILE.
Feraheme® (ferumoxytol) Injection
For Intravenous (IV) use
Initial U.S. Approval: 2009

RECENT MAJOR CHANGES
• Dosage and Administration (2) 06/2013

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 dose followed by a second 510 mg dose 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), or as an intravenous infusion in 50-200 mL 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP for at least 15 minutes.
• The recommended Feraheme dose may be readministered to patients with persistent or recurrent iron deficiency anemia.

DOSAGE FORMS AND STRENGTHS
Injection: 510 mg iron / 17 mL in single use vials. (3)

CONTRAINDICATIONS
Known hypersensitivity to Feraheme or any of its components. (4)

WARNINGS AND PRECAUTIONS
• Hypersensitivity Reactions: Observe for signs and symptoms of hypersensitivity during and after Feraheme administration for at least 30 minutes and until clinically stable following completion of each administration. (5.1)
• Hypotension: Feraheme may cause hypotension. Monitor for signs and symptoms of hypotension following each 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 (≥ 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: 12/2013

FULL PRESCRIBING INFORMATION: CONTENTS*

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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
6.2 Adverse Reactions from Post-marketing Spontaneous Reports
7 DRUG INTERACTIONS
8 USE IN SPECIFIC POPULATIONS
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10 OVERDOSAGE
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17 PATIENT COUNSELING INFORMATION

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

 Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Feraheme. Observe patients for signs and symptoms of hypersensitivity during and after administration of Feraheme for at least 30 minutes and until clinically stable following completion of each administration. Only administer the drug when personnel and resources are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions (see Adverse Reactions (6.2)). Anaphylactic-type reactions presenting with cardiac/cardiopulmonary arrest, clinically significant hypotension, syncope, and unresponsiveness have been reported in the post-marketing experience (see Adverse Reactions (6.2) in the Post-marketing Surveillance Report (p. 22). In clinical studies, serious hypersensitivity reactions were reported in 2.0% (36/1,812) of subjects, including three patients with serious anaphylactic reactions. Hypotension has also been reported in the post-marketing experience (see Adverse Reactions (6.2) in the Post-marketing Surveillance Report (p. 22). In clinical studies, adverse reactions leading to treatment discontinuation and occurring in ≥2 Feraheme-treated patients included hypotension, infusion site swelling, increased serum creatinine, proteinuria, chest pain, diarrhea, arrhythmias, pruritus, rash, and chronic renal failure, urticaria.

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

6.2 Adverse Reactions from Post-Marketing Surveillance Reports

The following adverse reactions have been identified during post-approval use of Feraheme. These adverse reactions come from a variety of sources and have been reported voluntarily from a population of unknown size, so that it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following serious adverse reactions have been reported from the post-marketing surveillance reports with Feraheme: life-threatening anaphylactic-type reactions, cardiac/cardiopulmonary arrest, clinically significant hypotension, syncope, unresponsiveness, loss of consciousness, tachycardia, cardiac arrhythmias, angioedema, angioneurotic edema, congestive heart failure, pulmonary edema, and anaphylaxis. These adverse reactions have occurred up to 30 minutes after the administration of Feraheme. Reactions have occurred following the first dose or subsequent doses of Feraheme.

7 DRUG INTERACTIONS

Drug-drug interaction studies with Feraheme were not conducted. Feraheme may alter the absorption of other drugs or the absorption of Feraheme itself.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

There are no studies of Feraheme in pregnant women. In animal studies, ferumoxytol administered at a total ferrous iron dose of 31.6 mg/kg/day or more caused fetal malformations and decreased fetal weights at maternally toxic doses of ferumoxytol. Fetal malformations, including a variety of skeletal anomalies, were observed in rats and rabbits at exposures approximately 15 times the maximum human exposure following a single 510 mg dose of Feraheme administered intravenously. In rabbits, administration of ferumoxytol during organogenesis at doses of 31.6 mg Fe/kg/day in rats and 16.5 mg Fe/kg/day in rabbits, did not result in maternal or fetal effects. These doses are approximately 2.1 times the estimated human daily dose based on maternal body surface area. In rats, administration of ferumoxytol during organogenesis at a maternally toxic dose of 160 mg Fe/kg/day, approximately 6 times the estimated human daily dose, caused a decrease in fetal weight based on body surface area, caused a decrease in fetal weights at doses based on fetal body surface area, and was associated with external and/or soft tissue fetal malformations and decreased fetal weights.

8.2 Lactation

Feraheme is excreted in human milk. Breast-feeding should be interrupted for at least 48 hours following administration of ferumoxytol during organogenesis. In rats and rabbits, administration of ferumoxytol during organogenesis at a maternally toxic dose of 31.6 mg Fe/kg/day, approximately 6 times the estimated human daily dose based on body surface area, caused a decrease in fetal weights at doses based on fetal body surface area, which was associated with external fetal malformations and decreased fetal weights.

8.3 Pediatric Use

The safety and effectiveness of Feraheme for pediatric use have not been established.

8.4 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. However, older patients may be generally more susceptible to geriatric syndromes. Therefore, in administration of Feraheme to older patients, especially those with diabetes, chronic obstructive pulmonary disease, chronic lung disease, congestive heart failure, depression, Parkinson’s disease, peripheral vascular disease, Parkinson’s disease, or Alzheimer’s disease, concomitant drug therapy (see Dosage and Administration (2) and Warnings and Precautions (5.1)).

8.5 Pregnancy

Drug-drug interaction studies with Feraheme were not conducted. Feraheme may alter the absorption of other drugs or the absorption of Feraheme itself.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Feraheme was not tested for carcinogenic effects. In standard genotoxicity tests, ferumoxytol showed no evidence of mutagenic activity in an in vitro Ames test or chromosomal aberration assay in an in vivo chromosome aberration test. Ferumoxytol was not mutagenic in vivo. No adverse effects on fertility or general reproductive performance were noted in animal studies. Ferumoxytol had no effect on male or female fertility or general reproductive function in rats.
1 INDICATIONS AND USAGE
Feraheme 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 dose followed by a second 510 mg dose 3 to 8 days later. Administer Feraheme intravenously, either as an undiluted slow intravenous injection or by infusion.

3 ADVERSE REACTIONS
Feraheme injection may cause serious hypersensitivity reactions and hypotension [see Warnings and Precautions (5.2)].

4 USE IN SPECIFIC POPULATIONS
13 NONCLINICAL TOXICOLOGY
12.3 Pharmacokinetics
Cardiac Electrophysiology
In a randomized, positive- and platelet-controlled, parallel-group study, healthy subjects received a supratherapeutic regimen of Feraheme (1.02 g given as two 510 mg doses within 24 hours, plasmas or a single dose of 400 mg ferumoxytol [positive control]). Results demonstrated no effect of Feraheme on QT interval durations. No clinically meaningful ECG changes were noted on heart rate data was observed.

12.2 Pharmacodynamics
Pediatric use
Feraheme is not a replacement product, is a non-stoichiometric magnetite (superparamagnetic iron oxide) coated with polyglycolic acid/carboxymethylcellulose. The oral cobalt particle size is 17-31 nm in diameter. The chemical formula of Feraheme is C510H583FeO2180(NH4)2/3 • 32H2O. Feraheme contains an apolar molecular weight of 750 kDa. Feraheme 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 sterile colloidal solution of Feraheme injection contains 30 mg of elemental iron and 44 mg of mannitol, and has low bioaccessibility/extractability. The formation is isonic with an osmolarity of 270-330 mOsm/L. The product contains no preservatives, and has a pH of 6 to 8.

11 DESCRIPTION
Feraheme is a non-stoichiometric magnetite (superparamagnetic iron oxide) coated with polyglycolic acid/carboxymethylcellulose. The oral cobalt particle size is 17-31 nm in diameter. The chemical formula of Feraheme is C510H583FeO2180(NH4)2/3 • 32H2O. Feraheme contains an apolar molecular weight of 750 kDa. Feraheme 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 sterile colloidal solution of Feraheme injection contains 30 mg of elemental iron and 44 mg of mannitol, and has low bioaccessibility/extractability. The formation is isonic with an osmolarity of 270-330 mOsm/L. The product contains no preservatives, and has a pH of 6 to 8.

10 OVERDOSAGE
No data are available regarding overdose of Feraheme in humans. Excessive dosages of Feraheme may lead to accumulation of the iron in the liver and potentially enhance the risk of adverse effects.

8.1 Pregnancy
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.

7 DRUG INTERACTIONS
Drug-drug interaction studies with Feraheme were not conducted. Feraheme may reduce the absorption of concomitantly administered oral iron preparations.
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, 47% and 46% 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, 42% and 44% 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)**

<table>
<thead>
<tr>
<th>ENDPOINT</th>
<th>Trial 1 Non-Dialysis CKD</th>
<th>Trial 2 Non-Dialysis CKD</th>
<th>Trial 3 CKD on Dialysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Hgb (mean ± SD, g/dL)</td>
<td>9.9 ± 0.8 Feraheme</td>
<td>9.9 ± 0.7 Oral Iron</td>
<td>10.0 ± 0.7 Feraheme</td>
</tr>
<tr>
<td>Hgb change from Baseline at Day 35 (mean ± SD, g/dL)</td>
<td>1.2* ± 1.3 Feraheme</td>
<td>0.5 ± 1.0 Oral Iron</td>
<td>0.8* ± 1.2 Oral Iron</td>
</tr>
<tr>
<td>Baseline TSAT (mean ± SD, %)</td>
<td>9.8 ± 5.4 Feraheme</td>
<td>10.4 ± 5.2 Oral Iron</td>
<td>11.3 ± 6.1 Oral Iron</td>
</tr>
<tr>
<td>TSAT change from Baseline at Day 35 (mean ± SD, %)</td>
<td>9.2 ± 9.4 Feraheme</td>
<td>0.3 ± 4.7 Oral Iron</td>
<td>9.8 ± 9.2 Oral Iron</td>
</tr>
<tr>
<td>Baseline ferritin (mean ± SD, ng/mL)</td>
<td>123.7 ± 125.4 Feraheme</td>
<td>146.2 ± 136.3 Oral Iron</td>
<td>146.1 ± 173.6 Oral Iron</td>
</tr>
<tr>
<td>Ferritin change from Baseline at Day 35 (mean ± SD, ng/mL)</td>
<td>300.7 ± 214.9 Feraheme</td>
<td>0.3 ± 82.0 Oral Iron</td>
<td>381.7 ± 278.6 Oral Iron</td>
</tr>
</tbody>
</table>

* p<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 (±SD) in hemoglobin from the retreatment baseline for patients with an increase in hemoglobin was 0.86 (± 0.68) g/dL and was 0.5 (± 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**

<table>
<thead>
<tr>
<th>NDC Code</th>
<th>Dose / Total volume per vial</th>
<th>Vials / Carton</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDC 59338-775-01</td>
<td>510 mg / 17 mL</td>
<td>1</td>
</tr>
<tr>
<td>NDC 59338-775-10</td>
<td>510 mg / 17 mL</td>
<td>10</td>
</tr>
</tbody>
</table>

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

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)].

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