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®
ferumoxytol
injection

Introduction

If you or someone you know has iron deficiency anemia (IDA), this brochure may be for you. You'll find information about what it means to have IDA 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, 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 have anemia without knowing it.

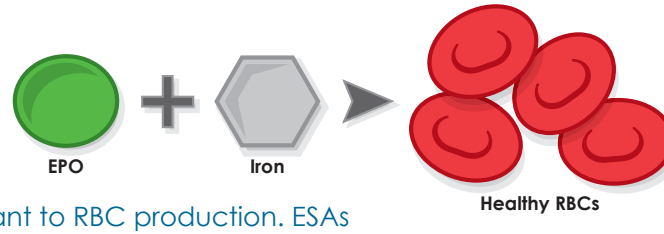
What causes anemia?

There are many different causes of anemia, including:

- **Not enough iron**
- **Low levels of certain vitamins**
- **Blood disorders**
- **Issues with substances soaking up iron in your stomach**
- **Blood loss**
- **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. ESAs 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**
- **Feeling tired**
- **Dizziness**
- **Shortness of breath**
- **Blue color to white part of the eyes**
- **Brittle fingernails**
- **Frequent headaches**

Please see Important Safety Information About *Feraheme* on back cover.

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

Blood tests	What they measure
Hgb	**The level of a protein in red blood cells that carries oxygen throughout the body**
Hematocrit	**The percentage of blood that is made up of RBCs**
Serum ferritin	**The level of a protein in the cells that stores iron**
Transferrin saturation (TSAT)	**The amount of iron bound to transferrin, which carries iron from storage to sites where red blood cells are made**

Treating IDA

There are a number of 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 IV irons are available
- A healthcare professional injects an iron product into the bloodstream
- IV irons may cause side effects and allergic reactions, some of which can be life-threatening or fatal; please be sure to discuss these risks with your doctor

What is *Feraheme*?

Feraheme® (ferumoxytol) Injection For Intravenous (IV) use 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 in 2 visits to your doctor.

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.

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

Please see full Prescribing Information in pocket.

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 a blood test. After measuring GFR, your doctor will know how your kidneys are working.

Stages of kidney disease

Stage	Description	GFR[a]
1	Kidney damage for at least 3 months with normal GFR	90 or above
2	Kidney damage for at least 3 months with mild decrease in GFR	60 to 89
3	Moderate decrease in GFR for at least 3 months	30 to 59
4	Severe reduction in GFR for at least 3 months	15 to 29
5	Kidney failure	Less than 15

[a]Your GFR number tells your doctor how much kidney function you have. As CKD progresses, your GFR number decreases.

Who is at risk for CKD?

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

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.

Feraheme®
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injection

How does IV iron 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
- 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 Hgb, the protein in RBCs that carries 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 in case you 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 this condition, 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?

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 full Prescribing Information in pocket.

Important Safety Information About *Feraheme*

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, constipation, 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-1088 or going online to the web site www.fda.gov/medwatch.

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 included 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, 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 (NKDEP) **www.nkdep.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**

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