



Feraheme[®] *ferumoxytol* *injection*

For IDA in adults

2 doses* 3-8 days apart

FERAHEME[®] is a prescription medicine used to treat iron deficiency anemia in adults who have:

- Intolerance to oral iron or who have not responded well to treatment with oral iron or
- Chronic kidney disease (CKD)

IMPORTANT RISK INFORMATION

FERAHEME may cause serious side effects including: Serious allergic reactions that can lead to death. Serious allergic reactions have happened in people after receiving the first dose of FERAHEME or after receiving additional doses in people who did not previously have an allergic reaction. If you have a history of allergies to many different medicines, you may have an increased risk of serious allergic reactions to FERAHEME.

Please read the **Patient Information** and see the full **Prescribing Information** including **Boxed Warning** in pocket.

*Some patients may require additional courses of therapy.

What is iron deficiency anemia (IDA)?

IDA is a common type of anemia caused by too little iron in the body. Iron is a mineral that is part of hemoglobin. When you don't have enough iron, your body cannot make the hemoglobin it needs, and this causes anemia.

Causes and common symptoms of IDA

Common causes of IDA include chronic kidney disease (CKD), gastrointestinal disorders that cause loss of blood or interfere with absorbing iron, loss of blood, not enough iron in the body, abnormal uterine bleeding or inflammation in the body, and/or poor diet.

The most common symptom of anemia is fatigue (feeling very tired).

What tests will my healthcare provider use to see if I have IDA?

A complete blood count (CBC) test measures your hematocrit and hemoglobin (Hgb) levels. Low levels of either can signal iron deficiency anemia.

Your healthcare provider may also test your ferritin and transferrin saturation levels.

IDA may be associated with other diseases and conditions. Talk with your healthcare provider about all possible causes of IDA.

Key terms to know

Hemoglobin: The protein in red blood cells (RBCs) that carries oxygen throughout the body.

Hematocrit: The volume of RBCs in the blood.

Ferritin: The protein that stores iron in your body.

Transferrin: The protein that transports iron throughout the body.

What should I know about receiving FERAHEME?

Before receiving FERAHEME, tell your healthcare provider about all of your medical conditions, including if you:

- Have allergies to many different medicines
- Have iron overload
- Have low blood pressure (hypotension)
- Are pregnant or plan to become pregnant. It is not known if FERAHEME will harm your unborn baby
- Are breastfeeding or plan to breastfeed. It is not known if FERAHEME passes into your breast milk. You and your healthcare provider should decide if you will receive FERAHEME or breastfeed

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

For eligible patients with financial need, support may be available. Talk to your doctor to find out more.

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What is FERAHEME (ferumoxytol injection)?

FERAHEME is a prescription medicine used to treat iron deficiency anemia in adults who have:

- Intolerance to oral iron or who have not responded well to treatment with oral iron or
- Chronic kidney disease (CKD)

It is not known if FERAHEME is safe and effective in children less than 18 years of age.

Who should not receive FERAHEME?

Do not receive FERAHEME if you:

- Are allergic to FERAHEME or any of the ingredients in FERAHEME. The ingredients in FERAHEME are ferumoxytol and mannitol
- Have had an allergic reaction to any iron medicine given into your vein by intravenous (IV) infusion

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A treatment that fits your schedule

FERAHEME allows for a flexible treatment schedule

FERAHEME is given in 2 doses as an IV infusion by a healthcare provider or nurse.

- The IV infusion will take at least 15 minutes
- The second dose is given 3 to 8 days after the first

Your healthcare provider will watch you during the infusion and for at least 30 minutes after you receive FERAHEME.

Tell your healthcare provider or get medical help right away if you get any of these signs or symptoms:

- Rash
- Itching
- Dizziness or lightheadedness
- Swelling of the tongue or throat
- Wheezing or trouble breathing

See "What are the possible side effects of FERAHEME?" on the back panel for more information about side effects.

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What are the possible side effects of FERAHEME (ferumoxytol injection)?



FERAHEME can cause serious side effects, including:

- **Serious allergic reactions that can lead to death.** Serious allergic reactions have happened in people after receiving the first dose of FERAHEME or after receiving additional doses in people who did not previously have an allergic reaction. If you have a history of allergies to many different medicines, you may have an increased risk of serious allergic reactions to FERAHEME
- **Low blood pressure (hypotension)** is a common side effect of FERAHEME and can sometimes be serious. Your healthcare provider will check you for signs and symptoms of hypotension after each FERAHEME infusion
- **Iron overload.** Your healthcare provider will do blood tests to check your iron levels during treatment with FERAHEME

The most common side effects of FERAHEME include: diarrhea, headache, nausea, dizziness, constipation, and swelling of your legs, feet, arms, or hands.

These are not all of the possible side effects of FERAHEME.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

