Injectafer® (ferric carboxymaltose injection) is available by prescription only. Ask your doctor or healthcare provider if Injectafer is right for you.

What is Injectafer?
Injectafer is a prescription iron replacement medicine administered only by or under the supervision of your healthcare provider. Injectafer is injected into your vein to treat iron deficiency anemia in adults. Injectafer should be used only if you have not responded well to treatment with oral iron, or if you are intolerant to oral iron treatment. It is also used to treat iron deficiency anemia in adults with chronic kidney disease who are not receiving dialysis.

It is not known if Injectafer is safe and effective for use in children.

SELECTED SAFETY INFORMATION
Who should not receive Injectafer?
You should not receive Injectafer if you are allergic to ferric carboxymaltose or any of the other ingredients in Injectafer. The active ingredient in Injectafer is ferric carboxymaltose, the inactive ingredients are: water for injection, sodium hydroxide and/or hydrochloric acid.
If you have IDA due to being postpartum or having heavy menstrual bleeding, and oral iron supplements haven’t worked well for you, ask your doctor about Injectafer.¹,²,⁴

**WOMEN MAY BE AT RISK OF IDA DUE TO CONDITIONS THAT INCREASE IRON DEMAND OR THAT CAUSE IRON DEPLETION THROUGH BLOOD LOSS**

- **Childbirth¹**
- **Long or abnormal menstrual periods²**

**IF YOU’RE BEING TREATED FOR IDA WITH ORAL IRON SUPPLEMENTS, TALK TO YOUR DOCTOR ABOUT RECHECKING YOUR IRON LEVELS TO MONITOR YOUR PROGRESS.⁵**

Certain lab markers in your blood are used to determine whether your iron levels are within the range your doctor feels is normal for you. These values can be used in diagnosing IDA and monitoring your progress on treatment¹,⁶

If your lab values are below the normal range, it’s important to talk with your doctor about the best option for restoring your iron levels

**COMMON LAB MARKERS FOR MONITORING IDA AND NORMAL VALUES IN ADULT WOMEN⁷,⁹**

- **Hemoglobin (Hb)**
  - 12.0 - 15.5 g/dL
- **Ferritin**
  - 20 - 200 μg/L
- **Transferrin saturation (TSAT)**
  - 20% to 50%

The information provided by Daiichi Sankyo, Inc., is informational only and not meant to provide medical advice.

An additional test for total iron binding capacity (TIBC) values may be required to diagnose IDA.⁴ Normal values for TIBC range from 240 to 450 μg/dL in healthy patients.¹⁰ Please note that TIBC values were not measured in Injectafer clinical trials.

*Normal values can vary for many reasons, including conditions you may have or where your lab work was done. That’s why it’s important to discuss your lab results with your doctor to find out what they mean for you.

**ORAL IRON SUPPLEMENTS MAY WORK WELL FOR SOME WOMEN, BUT MAY NOT FOR OTHERS.⁵**

- **Poor iron absorption**—the digestive tract is able to absorb only a portion of the iron in oral iron supplements³
- **Hard-to-tolerate side effects** may make daily dosing schedules difficult to stick with for some people³

It’s important to remember that all medicines, including oral and IV iron, have side effects³,⁴

**IF YOU HAVE SIDE EFFECTS FROM ORAL IRON, OR IF IT ISN’T WORKING WELL FOR YOU, TALK TO YOUR DOCTOR ABOUT THE BENEFITS AND RISKS OF ALL IDA TREATMENT OPTIONS TO DECIDE WHICH TREATMENT MIGHT BE BEST FOR YOU.⁵**

Injectafer has not been studied or approved for treating symptoms of IDA.

**SELECTED SAFETY INFORMATION (CONT’D)**

**What should I tell my doctor or healthcare provider before receiving Injectafer?**

Before you receive Injectafer, tell your healthcare provider about all of your medical conditions, including if you

- Have had an allergic reaction to iron given intravenously (into your vein), including Injectafer, or to other non-oral iron treatments
- If you have, or have previously experienced, iron overload, or if your body has difficulty using iron appropriately
- Have high blood pressure
- Are pregnant or plan to become pregnant. It is not known if Injectafer will harm your unborn baby. Your healthcare provider will decide if it is safe for you to take Injectafer
- Are breastfeeding or plan to breast feed. Injectafer passes into your breast milk. It is unknown whether Injectafer would pose a risk to your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with Injectafer

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

Click here to see the Full Prescribing Information and see Important Safety Information on pages 10-11.
IF ORAL IRON ISN’T WORKING FOR YOUR IDA, IV IRON MAY BE AN OPTION

With IV treatment (known as infusions), iron is delivered into the bloodstream through a vein.

Since IV iron isn’t processed by the digestive system, 100% is delivered into the bloodstream.

Injectafer has been studied in women who were postpartum or had heavy uterine bleeding.

• Unlike with pills, 100% of the iron in Injectafer goes directly into the bloodstream.

• In clinical studies, Injectafer showed greater increases in hemoglobin, a protein that helps carry oxygen throughout the body, than either oral iron or another IV iron did.

• Injectafer is typically administered at an infusion center, and treatments may take only 15 minutes followed by a period of about 30 minutes, during which you will be monitored for signs of an allergic reaction.

• Each dose provides up to 750 mg of iron, so you can get 1500 mg of iron in just 2 doses.

• Potential side effects with Injectafer include, but are not limited to, allergic reactions, nausea, temporary hypertension, and flushing (see list of side effects on pages 10-11).

ONLY INJECTAFER CAN PROVIDE 1500 mg OF IRON IN TWO DOSES OF 750 mg, SEPARATED BY AT LEAST 7 DAYS

Speak with your doctor or healthcare professional to find out if Injectafer may be appropriate for you.

SELECTED SAFETY INFORMATION (CONT’D)

What are the possible side effects of Injectafer?

Injectafer can cause serious side effects, including:

• Serious allergic reactions that may be life-threatening, including shock, low blood pressure, loss of consciousness, and death. Your doctor or healthcare provider will monitor you for signs and symptoms of an allergic reaction during and after each dose of Injectafer for at least 30 minutes. Other serious allergic reactions include itching, rash, hives, wheezing, or low blood pressure. You should report any signs and symptoms of an allergic reaction to Injectafer, in particular rashes, shortness of breath and wheezing to your doctor or healthcare provider.

Click here to see the Full Prescribing Information and see Important Safety Information on pages 10-11.
GETTING INJECTAFAER IV IRON TREATMENTS

INJECTAFAER IS USUALLY GIVEN AT AN INFUSION CENTER\textsuperscript{11}

• Infusion centers are medical facilities equipped and staffed for \textit{administering infusions} and maximizing your comfort\textsuperscript{11}

• Injectafer is given by IV infusion \textit{directly into the bloodstream} through a vein\textsuperscript{4}

• Each Injectafer infusion may take \textbf{about 15 minutes}, followed by about 30 minutes of being monitored for possible signs of an allergic reaction\textsuperscript{4}

INJECTAFAER IS USUALLY GIVEN AT AN INFUSION CENTER\textsuperscript{11}

BE SURE TO SCHEDULE YOUR 2nd INJECTAFAER TREATMENT SO YOU’LL GET THE FULL 1500 mg COURSE OF TREATMENT\textsuperscript{4}

Your iron stores are replenished over time, so it’s important to follow up with your doctor and check your levels.\textsuperscript{14}

SELECTED SAFETY INFORMATION (CONT’D)

What are the possible side effects of Injectafer? (CONT’D)

• \textbf{High blood pressure}, sometimes with facial flushing, dizziness, or nausea, has been seen during treatment with Injectafer. This increase in blood pressure typically resolves within 30 minutes. Your doctor or healthcare provider will monitor you for signs and symptoms of an increase in blood pressure following each use of Injectafer.

Other serious side effects that have been reported include rash, difficulty breathing, itching, rapid heartbeat, fever, chest discomfort, chills, swelling of the face, lips, or tongue, back pain, muscle aches, and fainting.

The most common side effects of Injectafer include:

• \textbf{Nausea}, high blood pressure, flushing, low levels of phosphorus in your blood, dizziness, vomiting, headache, an increase in certain liver enzymes, and pain or bruising at the injection site. Potentially long-lasting brown staining of skin near the injection site may occur if Injectafer leaks out of the vein.

Excessive amounts of Injectafer may lead to a condition called iron overload, which is a buildup of iron and may be harmful.

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

Tell your doctor if you have any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects.

Click here to see the Full Prescribing Information and see Important Safety Information on pages 10-11.
Great news! The InjectConnect Patient Support Program offers different ways that may help you access your IDA treatment*

*Restrictions apply.

If Injectafer is covered by your commercial insurance, but you have a co-pay

INJECTAFER SAVINGS PROGRAM

Injectafer is the only IV iron with a copay assistance program†

If you’re eligible,‡ you may:

• Receive assistance of up to $500 per dose
• Receive a maximum benefit of $1000 per course of treatment (2 doses)
• Re-enroll once during a 12-month period if you need another course of treatment

FIRST DOSE for as little as
$50
Up to 750 mg of iron for qualified patients§

SECOND DOSE for as little as
$0
Up to 750 mg of iron for qualified patients§

HAY HOW TO ENROLL
To find out if you’re eligible, or to enroll, apply online at injectafercopay.com. You will be asked to provide information about yourself, your doctor, and your current healthcare plan. You can also call the IV Iron Hotline to learn more.

†As of November 2019.

‡The Injectafer Savings Program is only available for adults 18 years or older who are commercially insured or cash-paying patients. The program provides up to a maximum savings limit of $500 per dose and a maximum benefit of up to $1000 per course of treatment (2 doses). Enrollment is valid for 2 courses of therapy (4 doses). Insurance out-of-pocket expense must be over $50. Additional restrictions may apply. Please see full Terms and Conditions on page 12.

If you do not have insurance to cover your Injectafer treatments

PATIENT ASSISTANCE PROGRAM

The Patient Assistance Program was created to help patients who lack health insurance and cannot afford therapy. Call the IV Iron Hotline to find out if you are eligible (see page 12 for eligibility requirements).

Call the IV Iron Hotline to learn if one of these programs may help you

1-877-4-IV-IRON (1-877-448-4766)
Monday through Friday, 9 AM to 8 PM ET.

Get the latest information about IDA and Injectafer

To learn more about IDA and Injectafer, visit injectafer.com/womenshealth.
For news about Injectafer, sign up for the Infuse News email updates by visiting injectafer.com/signup.

Click here to see the Full Prescribing Information and see Important Safety Information on pages 10-11.
About Injectafer

Injectafer® (ferric carboxymaltose injection) is available by prescription only. Ask your doctor or healthcare provider if Injectafer is right for you.

What is Injectafer?

Injectafer is a prescription iron replacement medicine administered only by or under the supervision of your healthcare provider. Injectafer is injected into your vein to treat iron deficiency anemia in adults. Injectafer should be used only if you have not responded well to treatment with oral iron, or if you are intolerant to oral iron treatment. It is also used to treat iron deficiency anemia in adults with chronic kidney disease who are not receiving dialysis.

It is not known if Injectafer is safe and effective for use in children.

IMPORTANT SAFETY INFORMATION

Who should not receive Injectafer?

You should not receive Injectafer if you are allergic to ferric carboxymaltose or any of the other ingredients in Injectafer. The active ingredient in Injectafer is ferric carboxymaltose, the inactive ingredients are: water for injection, sodium hydroxide and/or hydrochloric acid.

What should I tell my doctor or healthcare provider before receiving Injectafer?

Before you receive Injectafer, tell your healthcare provider about all of your medical conditions, including if you:

• Have had an allergic reaction to iron given intravenously (into your vein), including Injectafer, or to other non-oral iron treatments
• If you have, or have previously experienced, iron overload, or if your body has difficulty using iron appropriately
• Have high blood pressure
• Are pregnant or plan to become pregnant. It is not known if Injectafer will harm your unborn baby. Your healthcare provider will decide if it is safe for you to take Injectafer
• Are breastfeeding or plan to breast feed. Injectafer passes into your breast milk. It is unknown whether Injectafer would pose a risk to your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with Injectafer.

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

What are the possible side effects of Injectafer?

Injectafer can cause serious side effects, including:

• Serious allergic reactions that may be life-threatening, including shock, low blood pressure, loss of consciousness, and death. Your doctor or healthcare provider will monitor you for signs and symptoms of an allergic reaction during and after each dose of Injectafer for at least 30 minutes. Other serious allergic reactions include itching, rash, hives, wheezing, or low blood pressure. You should report any signs and symptoms of an allergic reaction to Injectafer, in particular rashes, shortness of breath and wheezing to your doctor or healthcare provider.

• High blood pressure, sometimes with facial flushing, dizziness, or nausea, has been seen during treatment with Injectafer. This increase in blood pressure typically resolves within 30 minutes. Your doctor or healthcare provider will monitor you for signs and symptoms of an increase in blood pressure following each use of Injectafer.

Other serious side effects that have been reported include rash, difficulty breathing, itching, rapid heartbeat, fever, chest discomfort, chills, swelling of the face, lips, or tongue, back pain, muscle aches, and fainting.

The most common side effects of Injectafer include:

• Nausea, high blood pressure, flushing, low levels of phosphorus in your blood, dizziness, vomiting, headache, an increase in certain liver enzymes, and pain or bruising at the injection site. Potentially long-lasting brown staining of skin near the injection site may occur if Injectafer leaks out of the vein.

Excessive amounts of Injectafer may lead to a condition called iron overload, which is a buildup of iron and may be harmful. These are not all of the possible side effects of Injectafer.

Tell your doctor if you have any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects.

General information about Injectafer

Injectafer may impact laboratory tests that measure iron in your blood for 24 hours after receiving Injectafer. Let your healthcare provider and laboratory staff know if you have received Injectafer within 24 hours of having blood tests.

To report side effects, contact American Regent at 1-800-734-9236 or E-mail: pv@americanregent.com or Fax: 1-610-650-0170.

You may also report side effects to the FDA at 1-800-332-1088 or fda.gov/medwatch.

The risk information provided here is not comprehensive. To learn more about Injectafer, talk with your healthcare provider or pharmacist. The FDA-approved product labeling can be found at injectafer.com/pdf/pi.pdf or call 1-800-645-1706.

Click here to see the Full Prescribing Information.
Terms and Conditions for the Injectafer Savings Program:

1. This offer is valid for commercially-insured as well as cash paying patients.

2. Depending on insurance coverage, eligible insured patients may pay no more than $50 for Injectafer for the first dose and $0 for Injectafer for the second dose, up to a maximum savings limit of $500 per dose, a $1,000 program limit per course of therapy. Check with your pharmacist or healthcare provider for your copay discount. Patient out-of-pocket expense may vary.

3. This offer is not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs, or private indemnity or HMO insurance plans that reimburse you for the entire cost of your prescription drugs. Patients may not use this card if they are Medicare-eligible and enrolled in an employer-sponsored health plan or medical or prescription drug benefit program for retirees.

4. This offer is not valid for patients enrolled in Medicaid, Medicare, or other federal or state healthcare programs, or private indemnity or HMO insurance plans that reimburse you for the entire cost of your prescription drugs. Patients may not use this card if they are Medicare-eligible and enrolled in an employer-sponsored health plan or medical or prescription drug benefit program for retirees.

5. The offer is valid for 2 courses, or 4 doses, of an Injectafer prescription. An explanation of benefits statement must be faxed in prior to transacting on the account numbers for assistance. One enrollment is allowed per 12-month period.

6. Offer good only in the USA, including Puerto Rico, at participating pharmacies or healthcare providers.

7. Void if prohibited by law, taxed, or restricted.

8. This account number is not transferable. The selling, purchasing, trading, or counterfeiting of this account number is prohibited by law.

9. This account number is not insurance.

10. By redeeming this account number, you acknowledge that you are an eligible patient and that you understand and agree to comply with the terms and conditions of this offer.

11. Qualified patients receiving Injectafer will be allowed a 60-day retroactive enrollment period to receive benefits under the program rules.

Eligibility Requirements for the Patient Assistance Program

To be eligible for the program, you must

- Completely lack health insurance and be ineligible for public insurance or financing
- Be a US citizen, legal entrant in the United States, or permanent resident. Proof of citizenship or legal residency may also be required
- Meet income and other criteria

Providers (hospitals, physicians, or infusion centers) must apply to the program on behalf of their patients. They will need to fill out and fax the Patient Assistance Request form and Enrollment Application.

Terms and Conditions for the Injectafer SMS Program:

1. By subscribing to Injectafer Mobile Communications Program alerts, the user consents to receive automated text messages from Injectafer, other parties within Injectafer, and its partners. Message & data rates may apply.

2. There is no fee from Daiichi Sankyo, Inc. to receive messages. Charges are billed and payable to your mobile service provider or deducted from your prepaid account. Consent is not a requirement for purchase.

3. Data obtained from you in connection with this SMS service may include your cell phone number, your carrier’s name and the date, time and content of your messages. We may use this information to contact you and to provide the services you request from us. Alerts sent via SMS may not be delivered if the mobile phone is not in range of a transmission site, or if sufficient network capacity is not available at a particular time. Even within a coverage area, factors beyond the control of the wireless carrier may interfere with message delivery, including the customer’s equipment, terrain, proximity to buildings, foliage, and weather. The wireless carrier does not guarantee that alerts will be delivered and will not be held liable for delayed or undelivered messages.

4. For information on data collection and use, please read our full corporate Privacy Policy.

5. We will not be liable for any delays in the receipt of any SMS messages as delivery is subject to effective transmission from your network operator. T-Mobile® is not liable for delayed or undelivered messages. Additionally, Daiichi Sankyo is not liable for any message or data rates in connection with the SMS service.


7. As a member of the Injectafer Mobile Communications Program, you will receive automated messages to the mobile number provided. You can unsubscribe from this service at any time by texting STOP to 86370. If you have any questions, text HELP to 86370 or contact us at 1-800-734-9236. To stop receiving messages text STOP to 86370.

References


IF YOU HAVE IRON DEFICIENCY ANEMIA

AND HAVEN’T MADE PROGRESS TREATING IT WITH ORAL IRON, ASK YOUR DOCTOR IF YOU MIGHT BENEFIT FROM INJECTAFER

If you’re taking oral iron supplements, talk to your doctor about rechecking your iron levels.

If your doctor has prescribed IV iron for you, ask about Injectafer, the only IV iron that can provide 1500 mg of iron in 2 doses of 750 mg separated by at least 7 days.

Injectafer® (ferric carboxymaltose injection) is available by prescription only. Ask your doctor or healthcare provider if Injectafer is right for you.

What is Injectafer?

Injectafer is a prescription iron replacement medicine administered only by or under the supervision of your healthcare provider. Injectafer is injected into your vein to treat iron deficiency anemia in adults. Injectafer should be used only if you have not responded well to treatment with oral iron, or if you are intolerant to oral iron treatment. It is also used to treat iron deficiency anemia in adults with chronic kidney disease who are not receiving dialysis.

It is not known if Injectafer is safe and effective for use in children.

Click here to see the Full Prescribing Information and see Important Safety Information on pages 10-11.

To report side effects, contact American Regent at 1-800-734-9236 or E-mail: pv@americanregent.com or Fax: 1-610-650-0170.

You may also report side effects to the FDA at 1-800-332-1088 or fda.gov/medwatch.

To contact us with questions or concerns about a Daiichi Sankyo product, please call us: 1-877-4DS-PROD (1-877-437-7763).

American Regent, Inc. is a member of the Daiichi Sankyo Group. Injectafer® and the Injectafer® logo are trademarks of Vifor (International) Inc., Switzerland. Injectafer® is manufactured under license from Vifor (International) Inc., Switzerland. Trademarks not owned by American Regent, Inc. or Vifor (International) are the property of their respective owners.

©2019 Daiichi Sankyo, Inc.  PP-US-IN-1210  12/19