

GET TO KNOW INJECTAFER, AN IV IRON TREATMENT FOR PEDIATRIC PATIENTS WITH IRON DEFICIENCY ANEMIA (IDA)

**INJECTAFER IS THE
MOST-STUDIED IV
IRON IN THE WORLD***

IV=intravenous.

*Source: Trialtrove®,
Mar 2021.



Actor portrayal.

Injectafer® (ferric carboxymaltose injection) is available by prescription only. Ask your 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 and children 1 year of age and older. 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. Injectafer is used to improve the ability to exercise (exercise capacity) in adult patients with iron deficiency and mild to moderate heart failure. It is not known if Injectafer is safe and effective in children with iron deficiency anemia who are under 1 year of age or in children with iron deficiency and mild to moderate heart failure to improve exercise capacity.

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 or hydrochloric acid.

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WHAT IS IRON DEFICIENCY ANEMIA (IDA)?

- **Iron deficiency anemia (IDA)** is a condition that impacts creation and function of red blood cells
- **Red blood cells contain hemoglobin**, which is a protein that helps carry oxygen from the lungs to cells in the body
- Anemia is when you don't have enough healthy red blood cells to carry oxygen to cells throughout the body

PEDIATRIC PATIENTS AT RISK FOR IDA INCLUDE THOSE WITH:



Low birth weight



Limited absorption of dietary iron



Insufficient dietary intake



Heavy menstrual bleeding*



Gastrointestinal (GI) conditions
such as inflammatory bowel disease (IBD)



Renal (kidney) disease



Cancer

WHAT ARE SOME COMMON SIGNS AND SYMPTOMS OF IDA?*



Fatigue



Weakness



Dizziness



Shortness of breath



Pica
(craving nonfood items such as ice or dirt)

Other signs and symptoms:

- headache
- chest pain
- pale skin
- arrhythmia (irregular heartbeat)
- brittle nails
- cold hands and feet
- poor appetite

*Some people with IDA may not experience symptoms. Injectafer has not been studied or approved for treating symptoms of IDA.

SELECTED SAFETY INFORMATION ABOUT INJECTAFER

What should I tell my 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 into your vein
- Have a history of trouble absorbing certain vitamins or phosphate in your body
- Have inflammatory bowel disease
- Have hyperparathyroidism
- Have low vitamin D levels
- Have high blood pressure
- Have previously received Injectafer

*Ask your daughter about her menstrual flow. If it's heavy, consider talking to her doctor.

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TALKING TO YOUR CHILD ABOUT IDA

Children may benefit from active participation in their medical care. Communicate openly with them about the condition and the steps you are taking together to manage it. Here are some suggestions:

- Let your child know that IDA in children is common and treatable
- Provide a detailed explanation of your child's treatment plan
- Reassure your child that treatment may help them

HOW IDA IS DIAGNOSED AND MONITORED

IDA is evaluated by testing three different lab markers in your child's blood: **hemoglobin (Hb)**, **ferritin**, and **transferrin saturation (TSAT)**.

NORMAL PEDIATRIC LAB VALUES*†

LAB MARKERS	NORMAL VALUES IN HEALTHY PATIENTS	
Hb [‡]	10.5 g/dL-16 g/dL (male)	10.5 g/dL-16 g/dL (female)
Ferritin [§]	36 µg/L-311 µg/L (male)	36 µg/L-92 µg/L (female)
TSAT	15%-44% (male)	11%-44% (female)

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

†An additional test for total iron binding capacity (TIBC) values may be required to diagnose IDA.

‡Hb: 7 months-2 years: 10.5 g/dL-14 g/dL; 3-6 years: 11.5 g/dL-14.5 g/dL; 7-12 years: 11.5 g/dL-15.5 g/dL; 13-18 years: 13 g/dL-16 g/dL (male), 12 g/dL-16 g/dL (female).

§Ferritin: 1-5 years: 36 µg/L-84 µg/L; >6 years: 36 µg/L-311 µg/L (male), 36 µg/L-92 µg/L (female).

||TSAT (transferrin saturation): 0-11 years: 15%-39%; 12-17 years: 16%-44% (male), 11%-44% (female).

SELECTED SAFETY INFORMATION ABOUT INJECTAfer

What should I tell my healthcare provider before receiving Injectafer? (cont'd)

- Are pregnant or plan to become pregnant. Injectafer may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with Injectafer.
- Are breastfeeding or plan to breastfeed. Injectafer passes into your breast milk. It is not known if Injectafer will harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with Injectafer

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Actor portrayal.

HOW IS IDA TREATED?

TWO OPTIONS TO TREAT IDA ARE:



Oral iron
supplements



IV iron

ORAL IRON MAY NOT BE SUITABLE FOR SOME CHILDREN WITH IDA

- Oral iron supplements can cause hard-to-tolerate **side effects**
- **Poor absorption:** the digestive tract is only able to absorb a small portion of the iron in an oral iron supplement, so your child's body may not get the full dose of iron needed from pills. Even in healthy patients, **less than 10% of oral iron is absorbed**

IF ORAL IRON IS INADEQUATE OR NOT WELL TOLERATED, IV IRON MAY HELP YOUR CHILD

WITH IV IRON, 100% OF IRON IS
DELIVERED DIRECTLY INTO THE
BLOODSTREAM THROUGH A VEIN

The information provided by Daiichi Sankyo, Inc. is not intended to replace the medical advice of your child's healthcare provider.

SELECTED SAFETY INFORMATION ABOUT INJECTAFER

What should I tell my healthcare provider before receiving Injectafer? (cont'd)

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

How will I receive Injectafer?

Injectafer is given into your vein (intravenously) by your healthcare provider in 2 doses at least 7 days apart.

INJECTAFER PROVIDES MORE IRON IN LESS TIME VS ORAL IRON

HOW CAN INJECTAFER HELP?

- Injectafer is a form of iron that is given directly into the vein. It's for pediatric patients 1 year of age and older* with IDA who can't tolerate oral iron or who don't respond well to it
- Injectafer provides **the most iron per course of treatment†**



For patients weighing less than 50 kg, the recommended dosage is Injectafer 15 mg/kg body weight intravenously in 2 doses separated by at least 7 days per course.

For patients weighing 50 kg or more, the recommended dosage is Injectafer 750 mg intravenously in 2 doses separated by at least 7 days for a total cumulative dose of 1500 mg of iron per course.

TALK WITH YOUR CHILD'S DOCTOR TO LEARN
MORE ABOUT INJECTAFER

*Safety and effectiveness of Injectafer have not been established in pediatric patients with IDA who are less than 1 year of age.

†One course of treatment with up to 750 mg separated by at least 7 days.

[Click here](#) to see the Full
Prescribing Information
and see Important
Safety Information
on pages 15-17.



GETTING YOUR CHILD'S INJECTAFER INFUSIONS

Your child's doctor has prescribed Injectafer because it may be an effective way to replace the iron they need.

WHERE INJECTAFER IS GIVEN

- **Injectafer is usually given at an infusion center** and administered by a healthcare professional
 - An infusion center can sometimes be at a hematology (blood specialty) or oncology (cancer specialty) clinic, because hematologists and oncologists have experience treating IDA
- Infusion centers are medical facilities equipped and staffed for **administering infusions**



Find an infusion center that provides Injectafer by using the Injectafer Infusion Center Locator at injectafer.com/iron-infusion-center

BEFORE YOUR CHILD'S FIRST INJECTAFER INFUSION

- ✓ **Call ahead** to confirm that the infusion center can provide Injectafer IV iron
- ✓ **Your child can dress comfortably and eat as they normally would.** There are no special dietary requirements
- ✓ **Bring your child's insurance card** and any other information your child's doctor has asked you to bring

SELECTED SAFETY INFORMATION ABOUT INJECTAFER

How will I receive Injectafer? (cont'd)

For certain patients with heart failure, 2 doses may need to be given 6 weeks apart. If your healthcare provider decides it is right for you, Injectafer may be given intravenously by your healthcare provider as a single-dose treatment. Injectafer treatment may be repeated if your healthcare provider decides it is needed.

DURING YOUR CHILD'S INFUSION



Each Injectafer infusion may take about **15 minutes**.

- Children take cues from their parents, so try to be relaxed and calm. They may be comforted by a favorite toy, entertainment as a distraction, or a reward to look forward to



If your child is over 50 kg (110 lbs), the dosage is 1500 mg, administered in 2 separate doses of 750 mg each separated by at least 7 days. Your child's dosage may vary based on their weight.

AFTER EACH INFUSION

- ✓ Afterward, your healthcare provider will **monitor your child for about 30 minutes** for signs of allergic reaction
- ✓ In some patients, injection site reactions, rash, headache, vomiting, flushing, and low levels of phosphorous in the blood may occur.
Call your child's doctor right away if symptoms persist or worsen
- ✓ **Iron stores are replenished over time.** So, it's important for you to follow up with your child's doctor to retest levels and see how Injectafer is working

BE SURE YOUR CHILD COMPLETES THEIR FULL COURSE OF TREATMENT WITH INJECTAFER

REMEMBER, INJECTAFER IS GIVEN IN 2 DOSES (750 MG EACH) AT LEAST 7 DAYS APART

Click here to see the Full Prescribing Information and see Important Safety Information on pages 15-17.



WHAT SIDE EFFECTS COULD OCCUR IN THE DAYS FOLLOWING AN INFUSION?

- Some patients experience low levels of phosphorus in their blood, pain or bruising at the injection site during or immediately after an infusion, rash, headache, and vomiting
- These are not all of the possible side effects of Injectafer. Call your child's doctor for medical advice about side effects

SEEK MEDICAL ATTENTION IF MORE SERIOUS SIDE EFFECTS ARISE

Serious side effects may include, but are not limited to:

Allergic reactions including itching, hives, wheezing, low blood pressure, and high blood pressure, sometimes with face flushing, dizziness, or nausea.

SELECTED SAFETY INFORMATION ABOUT INJECTAFER

What are the possible side effects of Injectafer?

Injectafer may cause serious side effects, including:

- **Allergic reactions.** Serious life-threatening allergic reactions that can lead to death have happened in people who receive Injectafer and may include the following signs or symptoms: low blood pressure, feeling dizzy or lightheaded, loss of consciousness, trouble breathing, swelling, fast heartbeat, cold or clammy skin, feet or hands turn blue, itching, rash, hives, and/or wheezing. Your healthcare provider will watch you during and for at least 30 minutes after you receive Injectafer. Tell your healthcare provider right away if you develop any signs or symptoms of allergic reactions during or after treatment with Injectafer



Actor portrayal.

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injectconnect™

SUPPORT PROGRAM

If your child has an Injectafer prescription, you may be able to get help with their out-of-pocket costs.

TWO WAYS TO HELP YOU PAY FOR INJECTAFER TREATMENTS†

†Restrictions apply.

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IF INJECTAFER IS COVERED BY YOUR CHILD'S COMMERCIAL INSURANCE, BUT THEY HAVE A CO-PAY



INJECTAFER SAVINGS PROGRAM

The Injectafer Savings Program may help eligible patients with their Injectafer prescription out-of-pocket responsibility.

PATIENTS RECEIVE **EACH DOSE** FOR AS LITTLE AS **\$50***

For eligible patients:

- Assistance of up to \$500 per dose
- Enrollment is valid for 2 courses of treatment per 12-month period

HOW TO ENROLL

Ask your doctor to enroll your child prior to receiving Injectafer treatment.

If your doctor cannot enroll your child, you can do so in one of two ways:

- The best way to enroll is by visiting injectafercopay.com

OR

- Call Daiichi Sankyo Access Central (1-866-437-4669)



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IF YOUR CHILD DOES NOT HAVE INSURANCE TO COVER TREATMENT OR IS COMMERCIALY UNDERINSURED



PATIENT ASSISTANCE PROGRAM

The Patient Assistance Program was created to help patients who lack health insurance or are commercially underinsured and cannot afford therapy.



Daiichi Sankyo Access Central
1-866-4-DSI-NOW (1-866-437-4669)

is available Monday–Friday†,
8:00 AM–6:00 PM ET.

†Excludes holidays.

*The Injectafer Savings Program is only available for patients 1 year or older who are commercially insured. Insurance out-of-pocket must be over \$50 per dose. Additional restrictions may apply. Please see full Terms and Conditions on page 14.

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Injectafer Savings Program Terms and Conditions

1. This offer is valid for commercially insured patients. Uninsured and cash-paying patients are NOT eligible for this Program.
2. 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.
3. For full program terms and conditions, please [click here](#) or scan this QR Code:



Eligibility requirements for the Patient Assistance Program:

To be eligible for the program, you must

- Meet established income limits
- Lack health insurance completely or be commercially underinsured
- Be a resident of the USA or its territories, including Puerto Rico

Your provider (eg, physician, infusion center) applies to the program on your behalf.

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IMPORTANT SAFETY INFORMATION (CONT'D)

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

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- **Symptoms of low blood phosphate levels.** Injectafer may cause low levels of phosphate in your blood that may be serious and can lead to softening of your bones and broken bones (fractures), especially in people who have received multiple Injectafer treatments. Your healthcare provider may check your blood phosphate levels before a repeat treatment with Injectafer if you are at risk for low blood phosphate levels. If a repeat treatment is needed within 3 months of your last treatment, your healthcare provider should check your blood phosphate levels.

Tell your healthcare provider if you develop any of the following signs or symptoms of low blood phosphate levels during treatment with Injectafer: feeling very tired, muscle weakness or pain, bone or joint pain, broken bones

- **High blood pressure.** High blood pressure, sometimes with redness and warmth of the face (facial flushing), dizziness, or nausea, has happened during treatment with Injectafer. Your healthcare provider will check your blood pressure and check for any signs and symptoms of high blood pressure after you receive Injectafer.

The most common side effects of Injectafer include:

- In adults: nausea, high blood pressure, flushing, injection site reactions, skin redness, low levels of phosphate in your blood, and dizziness.
- In children: low levels of phosphate in your blood, injection site reactions, rash, headache, and vomiting.

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

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

General information about the safe and effective use of Injectafer

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about Injectafer that is written for health professionals.

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 www.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 www.injectafer.com/pdf/pi.pdf or call 1-800-645-1706.

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SEE WHAT INJECTAFER CAN DO FOR YOUR CHILD WITH IDA



Scan the QR code or
[click here](#) to learn
more about Injectafer



Actor portrayal.

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

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