

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.



# GET TO KNOW INDECTAFER

Injectafer is the only FDA-approved intravenous (IV) iron treatment for certain adults with iron deficiency and mild to moderate heart failure.\*

In a study, Injectafer helped patients walk farther in a test that measures exercise capacity.



\*For appropriate adult patients with heart failure and New York Heart Association (NYHA) class II/III.

#### **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.



## COULD YOU HAVE BOTH HEART FAILURE AND IRON DEFICIENCY?

## IRON DEFICIENCY OCCURS WHEN THE BODY IS DEFICIENT (OR LOW) IN IRON, AN ESSENTIAL NUTRIENT.

If you have heart failure, you may be at a high risk for iron deficiency because of:







IRON
ABSORPTION
ISSUES



BLEEDING IN THE STOMACH OR INTESTINES



CHRONIC BLOOD IN URINE



CHRONIC INFLAMMATION



ADVANCED STAGE OF HEART FAILURE

Iron deficiency can damage the muscles of the heart and may negatively impact how the heart functions. If you have heart failure, these consequences may aggravate your condition.

**For awareness:** Black Americans are diagnosed with heart failure at an almost 2X greater rate compared to White Americans. If you're at an increased risk, ask your healthcare professional whether additional follow-ups are needed.

## DON'T OVERLOOK THE OVERLAP®

Because some of the symptoms of iron deficiency can overlap with and look similar to the symptoms of heart failure, it can be difficult differentiating between the two.

## KNOW THE SIMILARITIES AND DIFFERENCES BETWEEN IRON DEFICIENCY AND HEART FAILURE

## IRON DEFICIENCY SYMPTOMS

- Cold hands and feet
- Irritability
- Brittle nails
- Strange food or non-food cravings

## IRON DEFICIENCY AND HEART FAILURE SYMPTOMS

- Fatigue and weakness
- Irregular heartbeat
- Difficulty concentrating
- Shortness of breath
- Chest pain
- Lack of appetite

## HEART FAILURE SYMPTOMS

- Swelling in the legs, ankles, abdomen, and feet
- Weight gain
- Nausea

# HOW IRON DEFICIENCY IN HEART FAILURE IMPACTS EXERCISE CAPACITY

As heart failure progresses, symptoms may worsen, reducing physical activity and exercise capacity. This is especially true if you have iron deficiency that remains undiagnosed and/or untreated. Prepare for your next appointment by continuing to evaluate your day-to-day routine and how much exercise you're able to do.

### **MONITOR YOUR DAY-TO-DAY ROUTINE**

Before your next appointment, keep a log to share with your healthcare professional.

## **SELECTED SAFETY INFORMATION**

What should I tell my healthcare provider before receiving Injectafer® (ferric carboxymaltose)?

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

<sup>\*</sup>Injectafer is not indicated to treat the symptoms of iron deficiency, heart failure, or iron deficiency in heart failure.

## WITH IRON DEFICIENCY, SCREEN TO BE SEEN

Your healthcare professional may order lab tests and/or blood draws to evaluate changes related to heart failure and to look for other causes of worsening symptoms, including iron deficiency. These tests include checking your **ferritin**, **transferrin saturation** (**TSAT**), **and hemoglobin** levels.

How can you tell from your lab values if you may have iron deficiency in heart failure?\*† Check to see if your:

- Ferritin levels are below 100 ng/mL
- Ferritin levels are between 100 ng/mL and 300 ng/mL, if your TSAT is <20%

CLICK HERE TO VISIT
INJECTAFER.COM/SCREENING

## TALK TO YOUR HEALTHCARE PROFESSIONAL

During your next visit, ask if they will be testing for ferritin, TSAT, and hemoglobin.

#### **SELECTED SAFETY INFORMATION**

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

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

Have hyperparathyroidism

- Have low vitamin D levels
- Have high blood pressure
- Have previously received Injectafer

## For appropriate adults with iron deficiency in heart failure,

## INDECTAFER IS THE ONLY FDA-APPROVED IV IRON

#### Is Injectafer an option for you?

- Injectafer is approved to treat adults with:
- Iron deficiency who have been diagnosed with heart failure, and
- New York Heart Association (NYHA) class II/III (ask your healthcare professional if this includes you)
- Injectafer may improve your ability to perform certain physical activities (exercise capacity)

## Your healthcare professional will determine the right dosage of Injectafer for you

- Each dose of Injectafer is based on your weight and hemoglobin levels
- You'll receive Injectafer based on their prescribed recommendation
- Additional doses past 6 weeks may be given if iron deficiency is still present

Please <u>click here</u> for Full Prescribing Information and see Important Safety Information on pages <u>22-23</u>.

## INJECTAFER IS THE MOST-STUDIED IV IRON AND IS WIDELY USED





<sup>\*</sup>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 healthcare professional to find out what those results mean.

<sup>&</sup>lt;sup>†</sup>Your healthcare professional may also look at your hemoglobin levels.

## INDECTAFER MAY HELP YOU GO FARTHER

In a study of adults with heart failure and iron deficiency who were treated with Injectafer, a 6-minute walk test was used to assess a person's ability to perform light exercise. This test measures the distance one can walk in a total of 6 minutes.

INJECTAFER INCREASED THE DISTANCE STUDY PARTICIPANTS COULD WALK BY 82 FEET.

People treated with Injectafer also saw significant improvement in their ferritin, TSAT, and hemoglobin values.

## **HOW FAR IS ~82 FEET?**



THREE QUARTERS OF AN AVERAGE GROCERY STORE AISLE



ABOUT THE LENGTH OF A TENNIS COURT



A QUARTER OF THE WIDTH OF A CITY BLOCK





When it comes to your health, don't miss a step!

## POSSIBLE SIDE EFFECTS

## WHAT IMPORTANT INFORMATION DO I NEED TO KNOW ABOUT INJECTAFER?

Some patients experience nausea, high blood pressure, flushing, pain or bruising at the injection site, redness, low levels of phosphorous in the blood, dizziness, and vomiting.

These are not all of the possible side effects of Injectafer. Call your healthcare professional for medical advice about side effects.

## SEEK MEDICAL ATTENTION IF THESE SERIOUS SIDE EFFECTS OCCUR:

**Allergic (hypersensitivity) reactions.** Serious, life-threatening allergic reactions have happened in people who receive Injectafer. Other serious reactions including itching, rash, hives, wheezing, and low blood pressure have also happened during treatment with Injectafer. Tell your healthcare professional if you have ever had any unusual or allergic reaction to any iron given by vein.

**Symptoms of low blood phosphate levels.** Tell your healthcare professional if you develop any of these 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 (hypertension).** High blood pressure, sometimes with facial flushing, dizziness, or nausea, has happened during treatment with Injectafer. After receiving a dose of Injectafer, your healthcare professional will monitor you for signs and symptoms of high blood pressure.

#### **SELECTED SAFETY INFORMATION**

What should I tell my healthcare provider before receiving Injectafer? (cont'd) Before you receive Injectafer, tell your healthcare provider about all of your medical conditions, including if you:

• 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.



## HOW TO GET YOUR INDECTAFER INFUSION

## WHERE TO GO:

- •Injectafer is usually given at an infusion center, and is administered by a healthcare professional
- Infusion centers are medical facilities equipped and staffed for administering infusions

**CLICK HERE TO VISIT** INJECTAFER.COM/LOCATOR





## AFTER YOUR INFUSION

## **ONCE YOU RECEIVE YOUR INFUSION, IT'S IMPORTANT TO:**



#### **TRACK YOUR PROGRESS**

by keeping a record of how you're feeling.



## **CALL YOUR HEALTHCARE PROFESSIONAL**

if you're experiencing side effects.



## **FOLLOW UP WITH YOUR HEALTHCARE PROFESSIONAL**

to see how well your treatment is working. You may need an additional maintenance dose of Injectafer.



#### **SELECTED SAFETY INFORMATION**

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

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

• 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

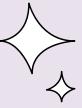
Tell your healthcare provider about all the medications you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.





## TRACK YOUR PROGRESS

## **HOW ARE YOU FEELING?**



Date: Symptom(s):	Date: Symptom(s):
Date: Symptom(s):	Date: Symptom(s):
Λ	



Date:	Date:
Symptom(s):	Symptom(s):
	_



#### **SELECTED SAFETY INFORMATION**

## How will I receive Injectafer?

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





## TWO WAYS TO HELP YOU PAY FOR INDECTAFER TREATMENTS

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





## IF INJECTAFER IS COVERED BY YOUR COMMERCIAL INSURANCE, BUT YOU 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 healthcare professional to enroll you prior to receiving Injectafer treatment. If your healthcare professional cannot enroll you, you can enroll yourself 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)



## IF YOU DO NOT HAVE INSURANCE TO COVER TREATMENT OR ARE COMMERCIALLY 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 SANKVO ACCESS CENTRAL**

1-866-4-DSI-NOW (1-866-437-4669) is available.

\*The Injectafer Savings Program is only available for patients aged 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 at <a href="DSIAccessCentral.com/patient/home">DSIAccessCentral.com/patient/home</a>. 
†Terms and conditions apply.





## TERMS YOU MAY HEAR WHEN DISCUSSING IRON DEFICIENCY



#### **FERRITIN**

Ferritin is a blood protein that holds onto iron until it is needed. A ferritin test is used to determine how much iron your body is storing.



#### **IRON DEFICIENCY**

Iron deficiency is when the body's iron stores are low and cannot meet the body's needs.



#### HEMOGLOBIN

Hemoglobin is an iron-rich protein found in red blood cells that carries oxygen throughout the body.



#### **IRON DEFICIENCY ANEMIA**

This means the body is deficient, or low, in iron, causing an inability to produce red blood cells.



## **SELECTED SAFETY INFORMATION**

What are the possible side effects of Injectafer?

Injectafer may cause serious side effects, including:

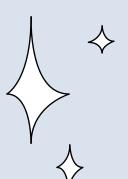
• Allergic reactions. Serious life-threatening allergic reactions that can lead to death have happened in people who receive Injectafer and may include the following signs or symptoms: low blood pressure, feeling dizzy or lightheaded, loss of

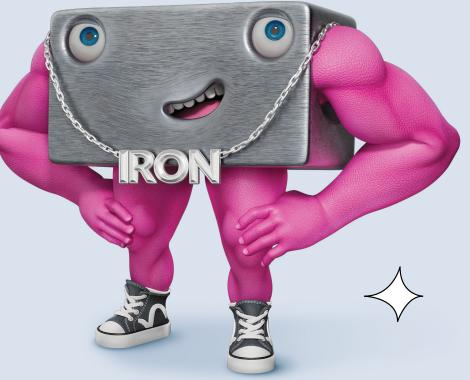
consciousness, trouble breathing, swelling, fast heartbeat, cold or clammy skin, feet or hands turn blue, itching, rash, hives, and/or wheezing. Your healthcare provider will watch you during and for at least 30 minutes after you receive Injectafer. Tell your healthcare provider right away if you develop any signs or symptoms of allergic reactions during or after treatment with Injectafer



## TRANSFERRIN SATURATION (TSAT)

Transferrin is a protein that transports iron in the body.
The TSAT test is used to measure how much of your transferrin is available to hold iron.









## TAKING CARE OF A LOVED ONE WITH HEART FAILURE IS AN IMPORTANT TASK THAT MAY REQUIRE A LOT OF ENERGY.

To help with the day-to-day tasks, see the following collection of tips.



## **SELECTED SAFETY INFORMATION**

What are the possible side effects of Injectafer? (cont'd) Injectafer may cause serious side effects, including:

• 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.





## TRACKER FOR LAB VALUES



#### **NORMAL LAB VALUES**

Adults	Ferritin	TSAT	Hemoglobin
Female:	20 ng/mL-200 ng/mL	20%-50%	12.0 g/dL-15.5 g/dL
Male:	40 ng/mL-300 ng/mL	20%-50%	13.5 g/dL-17.5 g/dL



## HELP YOUR LOVED ONE WITH SCHEDULING APPOINTMENTS

Consider using a shared calendar so that you can keep track of their visits.



## COMMUNICATE THE BENEFITS OF THEIR TREATMENTS

Living with heart failure can be frustrating, but the benefits of starting (and adhering to) their treatment regimen can help your loved one see improvements.



#### **COLLECT NOTES**

During appointments, many patients have difficulty remembering everything they want to say. You can assist by having notes handy.



#### **GET ORGANIZED**

Managing daily medications can be a challenge. Consider organizing medications using a day-of-the-week pill box. Keep medications in handy locations and schedule reminders of when to take them on their phone.



## GET TO KNOW YOUR LOVED ONE'S CARE TEAM IF POSSIBLE

Explore all the resources that are needed to support them.



#### **LISTEN TO THEIR CONCERNS**

A heart failure diagnosis can take a toll on your loved one's mental health. It's common for patients to express questions about their future, and you can help reassure them that the right support is in place.



#### TAKE CARE OF YOURSELF

To show up for them, you have to show up for yourself, too. Make sure, if you can, that you're taking time for yourself to help avoid burnout.



#### **TAKE IT DAY-BY-DAY**

It's easy to become overwhelmed on this journey as a caregiver. The right support and tools can be helpful.



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### **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 or hydrochloric acid.

## 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
- 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

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. 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.

## 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
- 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

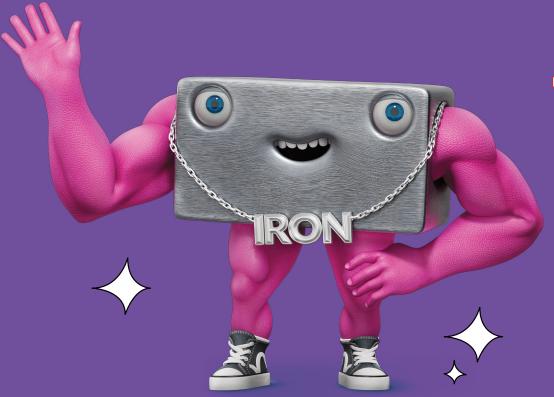
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about Injectafer that is written for health professionals.

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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>.

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 <a href="https://www.injectafer.com/pdf/pi.pdf">www.injectafer.com/pdf/pi.pdf</a> or call 1-800-645-1706.





FOR IRON DEFICIENCY IN HEART FAILURE,

## REMEMBER THE 3 "T"s

**TAKE NOTICE** of your signs and symptoms (some iron deficiency and heart failure symptoms may look alike).

**TALK** to your healthcare professional and discuss your symptoms.

**TEST** and maintain regular checkups. Ask your healthcare professional if they're measuring your ferritin, TSAT, and hemoglobin levels.

CLICK HERE TO VISIT INJECTAFER.COM/IDINHF

#### **SELECTED SAFETY INFORMATION**

Who should not receive Injectafer?

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Please <u>click here</u> for Full Prescribing Information and see Important Safety Information on pages <u>22-23</u>.



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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