injectafer®
ferric carboxymaltose injection

Fax referral form

Dear Healthcare Provider:

Now that you have selected Injectafer for your patient, please fill out this form and fax it to the infusing practice or center. Be sure to attach a copy of your patient's insurance information and current lab values. If required, also include clinical documentation or attestation of failed treatments and/or emergency/rescue medication(s).

In addition, remember to give your patients or their caregivers the Patient Education Brochure, which is designed to provide an overview of iron deficiency anemia and/or iron deficiency in heart failure, the infusion process, and how the treatment you have selected may help.

If you need any assistance obtaining Injectafer, or have questions about reimbursement, please don't hesitate to contact us at this number: 1-866-4-DSI-NOW (1-866-437-4669). DSIAccessCentral.com. Available Monday–Friday,* 8:00 AM–6:00 PM ET.

Sincerely,

Daiichi-Sankyo

*Excludes holidays.

Please see Important Safety Information on the following page and click here for Full Prescribing Information.

Daiichi-Sankyo

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INDICATIONS

Injectafer® (ferric carboxymaltose injection) is indicated for the treatment of iron deficiency anemia (IDA) in adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron, and in adult patients who have non-dialysis dependent chronic kidney disease. Injectafer is also indicated for iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Injectafer is contraindicated in patients with hypersensitivity to Injectafer or any of its inactive components.

WARNINGS AND PRECAUTIONS

Symptomatic Hypophosphatemia

Symptomatic hypophosphatemia with serious outcomes including osteomalacia and fractures requiring clinical intervention has been reported in patients treated with Injectafer in the post-marketing setting. These cases have occurred mostly after repeated exposure to Injectafer in patients with no reported history of renal impairment. However, symptomatic hypophosphatemia has been reported after one dose. Possible risk factors for hypophosphatemia include a history of gastrointestinal disorders associated with malabsorption of fat-soluble vitamins or phosphate, inflammatory bowel disease, concurrent or prior use of medications that affect proximal renal tubular function, hyperparathyroidism, vitamin D deficiency, and malnutrition. In most cases, hypophosphatemia resolved within three months.

Correct pre-existing hypophosphatemia prior to initiating therapy with Injectafer. Monitor serum phosphate levels in patients at risk for chronic low serum phosphate. Check serum phosphate levels prior to a repeat course of treatment in patients at risk for low serum phosphate and in any patient who receives a second course of therapy within three months. Treat hypophosphatemia as medically indicated.

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Injectafer. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after Injectafer administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Injectafer when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. In clinical trials, serious anaphylactic/anaphylactoid reactions were reported in 0.1% (2/1775) of subjects receiving Injectafer. Other serious or severe adverse reactions potentially associated with hypersensitivity which included, but were not limited to, pruritus, rash, urticaria, wheezing, or hypotension were reported in 1.5% (26/1775) of these subjects.

Hypertension

In clinical studies, hypertension was reported in 4% (67/1775) of subjects in clinical trials 1 and 2. Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed in 6% (106/1775) of subjects in these two clinical trials. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each Injectafer administration.

Laboratory Test Alterations

In the 24 hours following administration of Injectafer, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in Injectafer.

ADVERSE REACTIONS

Adults

In two randomized clinical studies [Studies 1 and 2], a total of 1775 patients were exposed to Injectafer, 15 mg/kg of body weight, up to a maximum single dose of 750 mg of iron on two occasions, separated by at least 7 days, up to a cumulative dose of 1500 mg of iron. Adverse reactions reported by >2% of Injectafer-treated patients were nausea (7.2%); hypertension (4%); flushing (4%); injection site reactions (3%); erythema (3%); hypophosphatemia (2.1%); and dizziness (2.1%).

Pediatric

The safety of Injectafer in pediatric patients was evaluated in Study 3. Study 3 was a randomized, active-controlled study in which 40 patients (1 to 12 years of age: 10 patients, 12 to 17 years of age: 30 patients) received Injectafer 15 mg/kg to a maximum single dose of 750 mg (whichever was smaller) on Days 0 and 7 for a maximum total dose of 1500 mg; 38 patients evaluable for safety in the control arm received an age-dependent formulation of oral ferrous sulfate for 28 days. The median age of patients who received Injectafer was 14.5 years (range, 1-17); 83% were female; 88% White and 13% Black. The most common adverse reactions (≥4%) were hypophosphatemia (13%), injection site reactions (8%), rash (8%), headache (5%), and vomiting (5%).

Patients with Iron Deficiency and Heart Failure

The safety of Injectafer was evaluated in adult patients with iron deficiency and heart failure in randomized controlled trials FAIR-HF (NCT00520780), CONFIRM-HF (NCT01453608) and AFFIRM-AHF (NCT02937454) in which 1016 patients received Injectafer versus 857 received placebo. The overall safety profile of Injectafer was consistent across the studied indications.

Post-Marketing Experience

The following adverse reactions have been identified during post approval use of Injectafer. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions have been reported from the post-marketing spontaneous reports with Injectafer: *cardiac disorders*: tachycardia; *general disorders and administration site conditions*: chest discomfort, chills, pyrexia; *metabolism and nutrition disorders*: hypophosphatemia; *musculoskeletal and connective tissue disorders*: arthralgia, back pain, hypophosphatemic osteomalacia; *nervous system disorders*: syncope; *respiratory, thoracic and mediastinal disorders*: dyspnea; *skin and subcutaneous tissue disorders*: angioedema, erythema, pruritus, urticaria; *pregnancy*: fetal bradycardia.

CLINICAL CONSIDERATIONS IN PREGNANCY

Untreated IDA in pregnancy is associated with adverse maternal outcomes such as postpartum anemia. Adverse pregnancy outcomes associated with IDA include increased risk for preterm delivery and low birth weight.

Severe adverse reactions including circulatory failure (severe hypotension, shock including in the context of anaphylactic reaction) may occur in pregnant women with parenteral iron products (such as Injectafer) which may cause fetal bradycardia, especially during the second and third trimester.

You are encouraged to report Adverse Drug Events to American Regent, Inc. at 1-800-734-9236 or to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

Click here to see the Full Prescribing Information.

injectafer® ferric carboxymaltose injection

PP-US-IN-4129 03/24

Daiichi-Sankyo

Daiichi-Sankyo

Fax referral form

injectafer® ferric carboxymaltose injection

Referring physician

Name: _____

Phone: _____

Fax: _____

Date: _____

Stamp area for convenience

Dear Doctor/medical office:

I am referring my patient to you for administration of Injectafer® (ferric carboxymaltose injection) as follows[1]:

Patient weight _____

Indications

- ☐ Patient has iron deficiency anemia and has intolerance to oral iron or unsatisfactory response to oral iron.*
- ☐ Patient has iron deficiency anemia and has non-dialysis dependent chronic kidney disease (NDD-CKD).*
- ☐ Adult patient has iron deficiency and heart failure and New York Heart Association class II/III.†

First dose ☐ 750 mg[1] ☐ Alternate dose: _____ mg

Second dose ☐ 750 mg[1] ☐ Alternate dose: _____ mg

Please note: If administering 1 course of treatment of 1500 mg, each dose of up to 750 mg must be separated by at least 7 days.[1]*†

*For patients weighing less than 50 kg (110 lb), the recommended dosage is Injectafer 15 mg/kg body weight intravenously in 2 doses separated by at least 7 days per course.[1]

†Please see the Full Product Information for Injectafer for the recommended weight-based dosing for iron deficiency in patients with heart failure and New York Heart Association class II/III.[1]

Patient information

Please note: Include a copy of the patient's insurance information and current lab values with this fax. If required, also include clinical documentation or attestation of failed treatments and/or emergency/rescue medication(s).

Name | Phone

Address | Date of birth | SS#

Primary insurance | Phone

Secondary insurance | Phone

Diagnosis coding

Injectafer has a product-specific J code: **J1439**
National Drug Code (NDC):
100 mg: 00517-0602-01
750 mg: 00517-0650-01

ICD-10-CM code

Secondary ICD-10-CM code for underlying condition

Please note: Injectafer prescriptions require a primary ICD-10-CM code for ID and IDA as well as a secondary code for the underlying condition causing ID or IDA.

Physician's signature X **Date**

To be completed by the infusion center

Please get in touch with this patient to make an appointment for each Injectafer infusion.

Infusion confirmation: Please fax back confirmation of each infusion.

Patient name | Date of infusion

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SELECTED SAFETY INFORMATION

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Reference: 1. Injectafer. Package insert. American Regent, Inc; 2023.