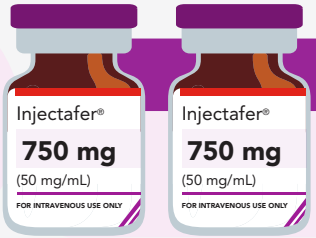
Injectafer: maximum IV iron delivery to treat iron deficiency anemia (IDA)[1-6]

Up to 1500 mg of iron in 1 course of treatment for total iron repletion[1,7*]

100% delivered into the bloodstream

At least 7 days apart[1]



Artist's rendering

1500 mg
in one course of treatment[1†‡]

IV infusion over at least 15 minutes

Slow IV push over 7.5 minutes

Injectafer treatment may be repeated if iron deficiency anemia reoccurs. Monitor serum phosphate levels in patients at risk for low serum phosphate who require a repeat course of treatment.[1]

Most studied IV iron treatment
with more than 40 clinical trials and >8800 participants treated worldwide[8§]

#1 IV iron treatment by volume
among oncologists and gastroenterologists[8‖¶]

Over 1.7 million patients
in the United States have been treated with Injectafer[8#]

*1 course of treatment is 2 administrations of 750 mg separated by at least 7 days.[1] †For adult patients weighing less than 50 kg (110 lb), give each dose as 15 mg/kg body weight for a total cumulative dose not to exceed 1500 mg of iron per course of treatment.[1] ‡When administered via IV infusion, dilute up to 750 mg of iron in no more than 250 mL of sterile 0.9% sodium chloride injection, USP, such that the concentration of the infusion is not <2 mg of iron per mL, and administer over at least 15 minutes. When administered as a slow IV push, give at the rate of approximately 100 mg (2 mL) per minute.[8] §Source: Trialtrove® | Mar 2021. ‖Source: Symphony Health Solutions PHAST® Non-Retail December 2019-November 2020 (MAT Nov 2020). ¶Source: IQVIA® IV Iron Landscape (Dx and CDM Data, Jul-Oct 2020). #Source: Injectafer forecast model, Dec 20 demand. Jan 21 forecast.

INDICATIONS

Injectafer® (ferric carboxymaltose injection) is indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, or who have non-dialysis dependent chronic kidney disease.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Symptomatic hypophosphatemia requiring clinical intervention has been reported in patients at risk of low serum phosphate in the postmarketing setting. These cases have occurred mostly after repeated exposure to Injectafer in patients with no reported history of renal impairment. Possible risk factors for hypophosphatemia include a history of gastrointestinal disorders associated with malabsorption of fat-soluble vitamins or phosphate, 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.

Monitor serum phosphate levels in patients at risk for low serum phosphate who require a repeat course of treatment.

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.

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.

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

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%); dizziness (2.1%); and vomiting (2%).

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 (rarely reported event); *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.

Please click here for Full Prescribing Information.

References: 1. Injectafer [package insert]. Shirley, NY: American Regent, Inc.; April 2021. **2.** Venofer® (iron sucrose) injection, USP [package insert]. Shirley, NY: American Regent, Inc.; 2020. **3.** Ferrlecit® (sodium ferric gluconate complex in sucrose injection) [package insert]. Bridgewater, NJ: sanofi-aventis US LLC; 2020. **4.** INFeD® (Iron Dextran Injection USP) [package insert]. Parsippany, NJ: Allergan, Inc; 2021. **5.** Feraheme® (ferumoxytol injection) [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc; 2020. **6.** Monoferric® (ferric derisomaltose) [package insert]. Holbaek, Denmark: Pharmacosmos A/S; 2020. **7.** Koch TA, Myers J, Goodnough LT. Intravenous iron therapy in patients with iron deficiency anemia: dosing considerations. *Anemia*. 2015. doi:10.1155/2015/763576. **8.** Data on file. Daiichi Sankyo Inc., Basking Ridge, NJ.

Daiichi-Sankyo

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injectafer® ferric carboxymaltose injection