

Patient Information
INJECTAFER (in-jekt-a-fer)
(ferric carboxymaltose injection)

What is INJECTAFER?

INJECTAFER is a prescription iron replacement medicine used to treat iron deficiency anemia (IDA) in:

- Adults and pediatric patients 1 year of age and older who have either intolerance to oral iron or an unsatisfactory response to oral iron.
- Adult patients who have non-dialysis dependent chronic kidney disease

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

Who should not receive INJECTAFER?

Do not receive INJECTAFER if you are allergic to ferric carboxymaltose or any of the ingredients in INJECTAFER. See the end of this leaflet for a complete list of ingredients in INJECTAFER.

Before receiving 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 high blood pressure
- are pregnant or plan to become pregnant. It is not known if INJECTAFER will harm your unborn baby.
- are breastfeeding or plan to breastfeed. 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 medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive INJECTAFER?

- INJECTAFER is given intravenously (into your vein) by your healthcare provider in 2 doses at least 7 days apart.
- If your healthcare provider decides it is right for you, INJECTAFER may be given intravenously to adults by your healthcare provider as a single dose treatment.

What are the possible side effects of INJECTAFER?

INJECTAFER may cause serious side effects, including:

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

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|---------------------------|-----------------------|---|
| • nausea | • rash | • injection site reactions |
| • flushing | • vomiting | • low levels of phosphorous in your blood |
| • skin redness (erythema) | • high blood pressure | • headache |

These are not all the possible side effects of INJECTAFER.

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


General information about 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.

What are the ingredients in INJECTAFER?

Active ingredient: ferric carboxymaltose.

Inactive ingredients: water for injection. Sodium hydroxide and/or hydrochloric acid may have been added to adjust pH to 5.0-7.0.

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For more information go to www.injectafer.com or call 1-800-734-9236.