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

What is INJECTAFER?

INJECTAFER is a prescription iron replacement medicine used for the treatment of:

- iron deficiency anemia (IDA) in:
  - adults and children 1 year of age and older who cannot tolerate iron taken by mouth (oral) or who have not responded well to oral iron.
  - adults who have chronic kidney disease who are not on dialysis (non-dialysis dependent chronic kidney disease).
- iron deficiency in adults with mild to moderate heart failure to improve the ability to exercise (improve exercise capacity).

It is not known if INJECTAFER is safe and effective in children with IDA who are under 1 year of age.

It is not known if INJECTAFER is safe and effective in children with iron deficiency and mild to moderate heart failure to improve exercise capacity.

Do 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 Patient Information 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 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 medicines 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.
- INJECTAFER is usually given in 2 doses at least 7 days apart for IDA, or 6 weeks apart for iron deficiency with mild to moderate heart failure to improve exercise capacity.
- 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
  - 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 in adults include:

- nausea
- high blood pressure
- flushing
- injection site reactions
- skin redness
- low levels of phosphate in your blood
- dizziness

The most common side effects of INJECTAFER in children include:

- low levels of phosphate in your blood
- injection site reactions
- rash
- headache
- vomiting

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 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.

What are the ingredients in INJECTAFER?

Active ingredient: ferric carboxymaltose.

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

Distributed by:

AMERICAN REGENT, INC.
SHIRLEY, NY 11967

INJECTAFER is manufactured under license from Vifor (International) Inc, Switzerland.

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

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 05/2023