COMMUNICATION

COM-2026-034

September 1, 2026

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate the latest up-to-date drug safety information.

FDA Adds Boxed Warning to Labeling for Ferric Carboxymaltose Injection (Injectafer) to Describe Risk of Low Phosphate Levels

U.S. Food & Drug Administration Publication Date:

09/01/2026

Drug Indication:

[1] Iron deficiency anemia in adults and pediatric patients 1 year of age and older who have intolerance to oral iron or an inadequate response to oral iron therapy, as well as in adults with non-dialysis-dependent chronic kidney disease.
[2] Iron deficiency in adults with NYHA Class II/III heart failure to improve exercise capacity.

Safety Topic:

FDA found that symptomatic hypophosphatemia continues to be reported with ferric carboxymaltose injection, despite labeling changes in February 2020 and May 2023 adding and strengthening the warning about this risk.

It is for this reason that we are notifying you that on September 1, 2026, the U.S. Food and Drug Administration (FDA) published a safety communication for the following product(s): Injectafer (ferric carboxymaltose injection).

Reason for Communication

The FDA has approved a boxed warning for ferric carboxymaltose injection (Injectafer) highlighting the risk of symptomatic hypophosphatemia, which can result in muscle weakness, fatigue, confusion, seizures, cardiac arrhythmias, and, with prolonged severe cases, osteomalacia and fractures. The updated labeling recommends monitoring serum phosphate levels in patients at risk for hypophosphatemia and in those receiving a repeat treatment course within three months.

This action follows several prior labeling updates, including warnings added in 2020 and expanded in 2023 to include phosphate monitoring recommendations, additional risk factors, and long-term skeletal complications. Despite these measures, a 2026 FDA review of postmarketing reports, published literature, and real-world safety data found that symptomatic hypophosphatemia continues to occur and that phosphate monitoring remains underutilized, prompting the addition of the agency's strongest safety warning.

Pharmacy Required Action

Advise patients that they should immediately report any new or worsening symptoms of low phosphate levels (e.g., muscle weakness or pain, fatigue, bone and joint pain, confusion) to their health care provider. Some of these symptoms may mimic those of iron deficiency anemia.

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication. Health care providers should inform patients of the risk of hypophosphatemia with ferric carboxymaltose injection use.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252-ext.219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

REFERENCES:

1. U.S. Food and Drug Administration. (2026). *FDA Adds Boxed Warning to Labeling for Ferric Carboxymaltose Injection (Injectafer) to Describe Risk of Low Phosphate Levels (Hypophosphatemia).* https://www.fda.gov/drugs/drug-safety-communications/fda-adds-boxed-warning-labeling-ferric-carboxymaltose-injection-injectafer-describe-risk-low