

SFDA

Safety Communication

[05/10/2026]

Ferric Carboxymaltose: Risk of Symptomatic Hypophosphatemia

The Saudi Food and Drug Authority (SFDA) would like to inform healthcare professionals about the risk of symptomatic hypophosphatemia associated with the use of intravenous ferric carboxymaltose.

Ferric carboxymaltose is an intravenous iron therapy indicated for the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used, or when there is a clinical need for rapid iron administration. Cases of symptomatic hypophosphatemia have been reported following single and repeated doses of ferric carboxymaltose. Some cases were serious and required hospitalization, prolonged phosphate supplementation, and medical monitoring. Based on SFDA pharmacovigilance data, 7 local cases of hypophosphatemia associated with ferric carboxymaltose were reported in Saudi Arabia between 2021 and 2026. Globally, 1,420 cases of hypophosphatemia associated with ferric carboxymaltose have been reported, of which 1,107 were classified as serious.

The risk of hypophosphatemia is described in the approved Summary of Product Characteristics (SPC) for ferric carboxymaltose-containing products. The product information

recommends monitoring serum phosphate levels in patients receiving multiple doses or long-term treatment, as well as in patients with existing risk factors for hypophosphatemia.

Hypophosphatemia is also listed as a common adverse drug reaction in the approved product information. Healthcare professionals should be aware that repeated or prolonged exposure to ferric carboxymaltose may increase the risk of clinically significant hypophosphatemia, particularly in patients with pre-existing risk factors.

Recommendations for Healthcare Professionals

The SFDA recommends that healthcare professionals to:

- Correct pre-existing hypophosphatemia before initiating ferric carboxymaltose treatment.
- Assess patients for risk factors for hypophosphatemia before treatment.
- Monitor serum phosphate levels in patients receiving multiple doses or long-term treatment and in patients with existing risk factors for hypophosphatemia.
- Consider monitoring serum phosphate levels before repeat courses of treatment, particularly in patients at increased risk.
- Monitor serum phosphate in patients at risk of hypophosphatemia, particularly those receiving multiple doses or long-term treatment. In case of persistent hypophosphatemia, reconsider treatment with ferric carboxymaltose in patients with persistent hypophosphatemia.
- Advise patients to seek medical attention if they experience new or worsening symptoms suggestive of hypophosphatemia, including fatigue, muscle weakness or pain, bone or joint pain, or confusion

For a list of Ferric Carboxymaltose containing products registered in Saudi Arabia, please refer to the [SFDA Drug List](#)

Reporting of Adverse Drug Reactions

Healthcare professionals are encouraged to report suspected adverse drug reactions associated with ferric carboxymaltose, particularly **hypophosphatemia and its related complications**, through the national adverse drug reaction reporting system.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

SFDA Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: <https://ade.sfda.gov.sa>

For more information on the approved Additional Risk Minimization Measures (aRMMs), please refer to the SFDA aRMMs webpage using the QR code below:

