Direct Healthcare Professional Communication

November 2026

Important safety information on hypophosphataemia, including hypophosphataemic osteomalacia Associated with Ferric Carboxymaltose Injection

Dear Healthcare Professional,

MAH in agreement with the General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at the Egyptian Drug Authority would like to inform you of the following:

Summary

- Ferric carboxymaltose is associated with a risk of hypophosphataemia, which is usually transient and asymptomatic but may, in some cases, become symptomatic and clinically significant. Cases of hypophosphataemic osteomalacia and fractures requiring clinical intervention, including surgery, have been reported after market introduction.
- Patients receiving multiple higher doses over prolonged periods and those with underlying risk factors, including vitamin D deficiency, calcium and phosphate malabsorption, secondary hyperparathyroidism, hereditary haemorrhagic telangiectasia, inflammatory bowel disease, and osteoporosis, may be at increased risk of clinically relevant hypophosphataemia and hypophosphataemic osteomalacia.
- Healthcare professionals should advise patients to seek medical attention if symptoms suggestive of hypophosphataemia or hypophosphataemic osteomalacia occur, including bone pain, or arthralgia.
- Patients at risk and those receiving multiple higher doses as part of long-term treatment should be appropriately monitored, including consideration of serum phosphate assessment, and treatment with Ferric carboxymaltose should be re-evaluated in patients with persistent hypophosphataemia.
- This DHPC aims to reinforce awareness of the known risk of hypophosphataemia associated with Ferric carboxymaltose following the recent US FDA boxed warning update, while the benefit-risk balance of Ferric carboxymaltose remains favorable when used in accordance with the approved Egyptian product information.

Background

- In Egypt, Ferric carboxymaltose injection is approved for iron deficiency in adult patients in whom oral iron therapy is not sufficiently effective, is ineffective or cannot be undertaken, such as cases where oral iron preparations cannot be tolerated or in the presence of inflammatory gastrointestinal diseases, e.g. ulcerative colitis, which may be exacerbated by oral iron therapy, or in the case of

treatment-refractory iron-deficiency states where it is suspected that the oral iron preparations are being taken unreliably.

- Ferric carboxymaltose should only be administered if the diagnosis of iron deficiency has been established and confirmed through appropriate laboratory investigations (e.g. plasma ferritin levels, transferrin saturation (TSAT), haemoglobin, haematocrit, red cell count, MCV and MCH).
- Hypophosphataemia, including post-marketing cases of symptomatic hypophosphataemia leading to hypophosphataemic osteomalacia and fractures requiring clinical intervention, including surgery, is described in the current Egyptian product information.
- This DHPC is intended to reinforce awareness of this recognized risk and the existing risk-minimization recommendations.

International regulatory context:

- In the United States of America (US), the FDA has required a Boxed Warning in the US prescribing information for Ferric carboxymaltose. This is a US-specific regulatory labelling action based on US requirements; it does not amend or define the approved Egyptian product information.
- In the European Union / European Economic Area, an European Medicines Agency (EMA) Article 31 referral concerning injectable iron-containing medicinal products and hypophosphataemia is ongoing. The procedure is ongoing and no final regulatory conclusions have yet been adopted.
- The Marketing Authorization Holder will continue to monitor this procedure and assess any implications for the Egyptian product information through the appropriate local regulatory pathway. Based on the Marketing Authorization Holder's current cumulative safety evaluation, the benefit-risk balance of Ferric carboxymaltose remains favorable for its approved Egyptian indication.

Recommendations for Healthcare Professionals

Healthcare professionals should inform patients about the risk of hypophosphatemia associated with Ferric carboxymaltose and implement the following measures:

- Be aware that hypophosphataemia may occur following administration of Ferric carboxymaltose.
- Advise patients to seek medical attention if symptoms (bone pain or arthralgia) suggestive of hypophosphataemia or hypophosphataemic osteomalacia occur.
- Monitor patients receiving multiple high doses over prolonged periods and those with recognized risk factors (e.g. vitamin D deficiency, calcium and phosphate malabsorption, secondary hyperparathyroidism, hereditary haemorrhagic telangiectasia, inflammatory bowel disease and osteoporosis), including serum phosphate assessment where clinically appropriate.
- Re-evaluate treatment in patients who develop persistent hypophosphataemia.

References

1. FDA: https://www.fda.gov/drugs/drug-safety-communications/fda-adds-boxed-warning-labeling-ferric-carboxymaltose-injection-injectafer-describe-risk-low
2. EMA: https://www.ema.europa.eu/en/documents/referral/parenteral-iron-containing-medicinal-products-article-31-referral-prac-starts-review-injectable-iron-containing-medicines_en.pdf

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt,

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://vigiflow-eforms.who-umc.org/eg/med

QR Code:

Hotline: 15301