



نتقدم بثقة
Moving Forward
with Confidence



To:

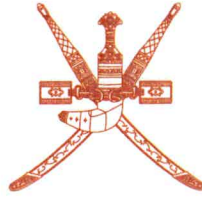
**Director of Pharmaceutical Care, Royal Hospital
Director of Pharmaceutical Care, Khoula Hospital
Pharmacist Incharge, Al Nahda Hospital
Director General of Health Services in all Governorates
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Health Institutions)
Director of Pharmaceutical Care, DGMS
Pharmacist Incharge, Al Massarah Hospital
The Head of Medical Services in University Medical City
The Head of Medical Services in Medical City for Military and Security Services
Director of Pharmacy of Qaboos Comprehensive Cancer Care & Research Center
Pharmacist Incharge, The Sultan's Special Force
Pharmacist Incharge, Internal Security Services
Pharmacist Incharge, Petroleum Development of Oman
Pharmacist Incharge, LNG Oman
All Private Pharmacies & Drug Stores**

After Compliments,

Kindly find attached our Circular No **94** dated **30/09/2026** Regarding Update to Health Care Professionals About **Ferric Carboxymaltose – New Boxed Warning for Symptomatic Hypophosphatemia**.

Copy to:

- Director of Pharmacovigilance Department, DSC
- Director of Medicine Registration Department, DSC
- Director of Regulatory Compliance Department, DSC
- Director of Central Quality Control Lab., DSC
- Director of Medical Device Department, DSC
- Section Head of Medicine Safety Evaluation
- Section Head of Quality Problems and Medication Errors.
- Section Head of Pharmacovigilance
- Section Head of Clinical Trials



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Circular No. 94 /2026

20 -04-1448 H

30 -09-2026

Subject: Ferric Carboxymaltose – New Boxed Warning for Symptomatic Hypophosphatemia

The Drug Safety Center (DSC) would like to share new safety information published by the U.S. Food and Drug Administration (FDA) regarding **ferric carboxymaltose injection**. The FDA has added a Boxed Warning to the prescribing information regarding the risk of **symptomatic hypophosphatemia**.

Ferric carboxymaltose is an iron replacement medication that can cause severe and prolonged hypophosphatemia. **Serious clinical outcomes** associated with hypophosphatemia have been reported, including **hospitalization, osteomalacia, and fractures requiring medical intervention**. These cases have occurred after both single and repeated administrations, including in patients with normal baseline serum phosphate levels and without apparent risk factors.

Advice for Healthcare Professionals:

- Inform patients about the risk of symptomatic hypophosphatemia associated with ferric carboxymaltose.
- Correct **pre-existing** hypophosphatemia before initiating treatment.
- Check serum phosphate levels before a repeat course of treatment in patients **at risk for hypophosphatemia and in any patient who receives a repeat course of therapy within three months of the prior course**.
- Monitor serum phosphate levels in patients **at risk for chronic hypophosphatemia**.
- Treat hypophosphatemia as medically indicated.
- Consider permanent **discontinuation** of ferric carboxymaltose in patients who develop severe symptomatic hypophosphatemia or persistent hypophosphatemia.



DSC
مركز سلامة الدواء
Drug Safety Center



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
✉ @DSCPHO Email: dscpho@moh.gov.om



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Advice for Healthcare Professionals to Provide to Patients:

- Ferric carboxymaltose can cause **low phosphate levels** in the blood, which may be severe or prolonged.
- Patients should contact their healthcare professional if they develop **new or worsening fatigue, muscle weakness or pain, bone or joint pain, or confusion.**
- Patients should be aware that some symptoms of hypophosphatemia may be **similar to symptoms of iron deficiency anemia.**

Reference: <https://www.fda.gov/drugs/drug-safety-communications/fda-adds-boxed-warning-labeling-ferric-carboxymaltose-injection-injectafer-describe-risk-low>

Call to report:

Ferric carboxymaltose is registered in Oman. All healthcare professionals, patients, and caregivers are requested to submit any adverse drug reactions through Ministry of Health e-portal to the Pharmacovigilance Department under the Drug Safety Center.

Ph. Ibrahim Nasser Al Rashdi
Director General



DSC
مركز سلامة الدواء
Drug Safety Center



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