

Injectable iron-containing medicines: A review to assess risk of low blood phosphate levels and related bone problems

09/09/2026 | Circular Number P11/2026

Information on injectable iron-containing medicines

- Injectable iron-containing medicines are used to treat iron deficiency and iron deficiency anaemia (low red blood cell counts). They are used when there is a need to increase iron levels quickly or when iron supplements taken by mouth cannot be used or do not work well enough, especially in people receiving dialysis for kidney failure, before and after operations, people with heart failure, women with severe iron deficiency during or after pregnancy or in cases of disorders that affect the absorption of nutrients from the gut.
- Depending on the medicine, they may be given as an injection into a vein, as a drip (infusion) into a vein, as an injection into a muscle, or through the dialysis machine during a dialysis session.
- These medicines contain iron bound to for example sugar molecules, forming iron complexes. The review covers medicines containing the active substances ferric carboxymaltose, ferric derisomaltose, iron dextran, ferric gluconate, ferric hydroxide polymaltose complex and iron sucrose.
- Iron-containing medicines taken by mouth are not included in the review because they provide considerably lower amounts of iron over time than injectable medicines and are therefore less likely to cause hypophosphataemia.

In Malta the following products are authorised nationally and through Article 20 exemption:

Active Ingredients	Product Name	Pharmaceutical Form	Classification	Authorisation Number	MAH/license holder
IRON 50 milligram(s)/millilitre	Ferric carboxymaltose 50 mg iron/ml solution for injection/infusion	SOLUTION FOR INJECTION/I NFUSION	POM	MA1122/02801	Rowex Ltd
IRON 50 milligram(s)/millilitre	Ferric carboxymaltose 50 mg iron/ml solution for injection/infusion	SOLUTION FOR INJECTION/I NFUSION	POM	MA1122/02802	Rowex Ltd

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IRON (III) - HYDROXIDE 20 milligram(s)/millilitre	Ferric Oxide Saccharate Generis 100 mg/5 ml Solution for Injection	SOLUTION FOR INJECTION	POM	AA565/56202	Central Procurement & Supplies Unit
IRON SUCROSE 20 milligram(s)/millilitre	FERROVIN 20 mg iron/ml	CONCENTR ATE FOR SOLUTION FOR INFUSION	POM	AA214/01303	Rafarm S.A.

Information from the EMA about the safety concern

- EMA's safety committee, PRAC, has started a review of injectable iron-containing medicines following concerns about the risk of hypophosphataemia (low blood phosphate levels) and related bone problems, including osteomalacia (softening of the bones). Phosphate is important for keeping bones healthy. When phosphate levels become too low, osteomalacia can occur causing symptoms such as bone pain. In some cases, it can result in fractures.
- Hypophosphataemia and hypophosphataemic osteomalacia (softening of the bones caused by low blood phosphate levels) are known side effects of injectable iron medicines containing the active substance ferric carboxymaltose.
- Hypophosphataemia is listed as a common side effect in the product information, meaning it affects up to 1 in 10 people taking the medicine. However, the frequency of hypophosphataemic osteomalacia is unknown because the available data do not allow an estimate of how often it occurs. The product information also includes measures to reduce the risk of hypophosphataemic osteomalacia including recommendations to monitor blood phosphate levels in people receiving high doses or long-term treatment and those with known risk factors.
- The review was triggered following reports that raised concerns about the effectiveness of the current measures to reduce this risk for medicines containing ferric carboxymaltose. These included serious cases of hypophosphataemia, some of which resulted in osteomalacia, including in people who had received only one or two doses of ferric carboxymaltose and who did not have recognised risk factors. Furthermore, in some cases there were delays in diagnosing hypophosphataemia. This could be because symptoms of hypophosphataemia such as tiredness, muscle pain and bone pain may overlap with those of iron deficiency. In addition, the bone problems reported in these cases, such as osteomalacia, may not always be visible on X-rays.

For more information visit <https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-31-august-3-september-2026> on the European Medicines Agency's website and the SmPC for iron-containing medicines.

In Malta

For Patients

- If you are receiving, or have recently received, an injectable iron medicine and develop symptoms such as persistent tiredness, muscle pain, bone pain, weakness or fractures, contact your healthcare professional.
- Attend any follow-up appointments and blood tests recommended by your healthcare professional.
- Inform your doctor if you have previously experienced low phosphate levels or bone problems.
- Do not stop your treatment without speaking to your doctor.

For Healthcare Professionals

- Remain vigilant for signs and symptoms suggestive of hypophosphataemia in patients receiving injectable iron products.
- Consider hypophosphataemia in patients presenting with:
 - Persistent fatigue
 - Myalgia
 - Muscle weakness
 - Bone pain
 - Difficulty walking
 - Fragility fractures or recurrent fractures
- Be aware that these symptoms may overlap with those of iron deficiency and may contribute to delayed diagnosis.
- Follow currently approved product information regarding monitoring of serum phosphate where recommended.
- Evaluate patients with suspected persistent or severe hypophosphataemia for possible bone complications, including osteomalacia.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on iron-containing medicines. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences

Park, San Ġwann SĠN 3000 or online to <http://www.medicinesauthority.gov.mt/adrportal> or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate

Malta Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Malta Medicines Authority website for product safety updates as these are issued on an ongoing basis.

[Archived Safety Circulars](#)

[Archived Direct Healthcare Professional Communications](#)

[Archived Risk Minimisation Measures](#)

Feedback Form

The Malta Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Malta Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this form (address side up), stapling the ends and then posting (no stamp required)

Feedback:

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