

Take a step forward in treating iron deficiency*

*Innovative matrix technology to restore iron levels and treat fatigue with a robust safety profile¹⁻³

**ROUTINE
PHOSPHATE
MONITORING
NOT
REQUIRED**



Restore iron need from ONE visit¹

With MonoFer[®], your patients need ONE IV infusion when their required iron is up to 20 mg/kg body weight^{1,2,4,5}



Rapidly improves fatigue^{1,6}

In the PHOSPHERE-IBD[#] study, MonoFer[®] was associated with a greater improvement in patient-reported fatigue score at Day 35, compared with ferric carboxymaltose (p=0.005)⁶



Robust safety profile^{1,3}

Well tolerated across patient groups with an uncommon incidence of hypophosphataemia (0.1% to 1% of patients)^{1,3}

¹In the PHOSPHERE-IBD[#] study, MonoFer[®] was associated with greater improvement in patient-reported fatigue scores at Days 35 and 49, compared with ferric carboxymaltose (p=0.005 and 0.009 respectively).⁶

⁴A multicentre, randomised, head-to-head comparison of IV MonoFer[®] and ferric carboxymaltose in patients with both IBD and IDA. The primary endpoint for this study was the incidence of hypophosphataemia (serum phosphate < 2.0 mg/dL) at any time, Day 0-35 (SAS). Change in FACIT Fatigue Scale score (prespecified exploratory outcome; ITT) was a secondary endpoint in this study. A greater improvement in fatigue scores was observed among MonoFer[®]-treated patients compared to ferric carboxymaltose-treated patients at Day 35 (p=0.005) and Day 49 (p=0.009), despite the difference not being significant at Day 70.⁶

⁵Hypophosphatemia is an uncommon adverse drug reaction observed during clinical trials and post-marketing experience.

Abbreviations: IV, intravenous; IBD, inflammatory bowel disease; IDA, iron deficiency anaemia; FACIT, Functional Assessment of Chronic Illness Therapy; ITT, intention to treat; SAS, statistical analysis system.

MonoFer[®] 100 mg/ml solution for injection/infusion

Composition: 1 ml contains 100 mg iron as iron(III) isomaltoside 1000. Available in vials/ampoules of 1 ml and 5 ml. **Indications:** MonoFer[®] is indicated for the treatment of iron deficiency in the following conditions: (1) Oral iron preparations are ineffective or cannot be used. (2) There is a clinical need to deliver iron rapidly. The diagnosis must be based on laboratory tests. **Dosage and Administration:** Monitor patients for hypersensitivity reactions during and following each administration. Administer only when staff trained to evaluate and manage anaphylactic reactions is available. Calculate iron need using the Simplified Table or Ganzoni formula. Do not exceed 20 mg iron/kg body weight per week. Not recommended for children and adolescents <18 years. **IV bolus injection:** up to 500 mg up to three times a week, administered undiluted or diluted in max. 20 ml sterile 0.9% NaCl (to no less than 1 mg iron/ml). **Contraindications:** Hypersensitivity to the active substance or any excipients. Known serious hypersensitivity to other parenteral iron products. Non-iron deficiency anaemia. Iron overload or disturbances in iron utilisation. Decompensated liver disease. **Precautions:** Hypersensitivity reactions, including serious and potentially fatal anaphylactic/anaphylactoid reactions. Increased risk in patients with known allergies including drug allergies, including patients with a history of severe asthma, eczema or other atopic allergy, and patients with immune inflammatory conditions. Each patient should be observed for adverse effects for at least 30 minutes following each MonoFer injection. Avoid in patients with hepatic dysfunction where iron overload is a precipitating factor and patients with ongoing bacteraemia. Absorption of oral iron is reduced when administered concomitantly. **Fertility, Pregnancy, and Lactation:** Pregnancy: Limited data from use in pregnant women. Treatment should be confined to second and third trimester if the benefit outweighs the potential risk for both the mother and the foetus. Breast-feeding: At therapeutic doses, no effects on the breastfed newborns/infants are anticipated. Fertility: No data on human fertility. **Effects on ability to drive and use machines:** No studies on have been performed. **Undesirable Effects:** Acute severe hypersensitivity reactions may occur. In pregnancy, associated foetal bradycardia may occur. Distant skin discolouration has been reported. Common ADRs (≥1/100 to <1/10): Nausea; Rash; Injection site reactions. Uncommon ADRs (≥1/1000 to <1/100): Hypersensitivity; Headache, paraesthesia, dysgeusia, blurred vision, loss of consciousness, dizziness, fatigue; Tachycardia; Hypotension; hypertension; Chest pain, dyspnea, bronchospasm. Abdominal pain, vomiting, dyspepsia, constipation, diarrhoea; Pruritus, urticaria, flushing, sweating, dermatitis; Hypophosphataemia; Back pain, myalgia, arthralgia, muscle spasms; Pyrexia, chills/shivering, infection, local phlebitis reaction, skin exfoliation; Hepatic enzyme increase. For further information consult full prescribing information. [July 2022]

References. 1. MonoFer[®] Summary of Product Characteristics, Hong Kong, 13.07.2022. 2. Kalra PA, et al, Port J Nephrol Hypert 2012; 26: 13–24. 3. Kassianides X, et al, Expert Rev Hematol. 2021 Jan;14(1):7–29. 4. Kalra PA, Bhandari, Int J Nephrol Renovasc Dis 2016; 9: 53–64. 5. Jahn MR, et al, Eur J Pharm Biopharm 2011; 78: 480–91. 6. Zoller H, et al, Gut 2022; 0: 1–10 (doi:10.1136/gutjnl-2022-327897) – including supplementary material.

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