

Prescribing Information: Monover® (ferric derisomaltose)

Note: Before prescribing please read full Summary of Product Characteristics. **Pharmaceutical form:** Ferric derisomaltose is a dark brown, non-transparent solution for injection/infusion. **Presentations:** Iron in the form of ferric derisomaltose; 100 mg/ml available in vials of 100 mg/ml, 500 mg/5 ml and 1,000 mg/10 ml. **Indications:** Monover® is indicated in patients ≥18 years for treatment of iron deficiency when oral iron preparations are ineffective or cannot be used or when there is a need to deliver iron rapidly. The diagnosis must be based on laboratory tests. **Administration:** Each IV iron administration is associated with a risk of a hypersensitivity reaction. Thus, to minimise risk, the number of single IV iron administrations should be kept to a minimum. The iron need can be determined using either the Simplified Table, or the Ganzoni formula, or a fixed dose of 1,000 mg can be given to patients ≥50 kg body weight followed by re-evaluation for further iron need, please consult full Summary of Product Characteristics. Monover® may be administered as an IV bolus injection of up to 500 mg at an administration rate of up to 250 mg iron/minute up to three times a week, during a haemodialysis session directly into the venous limb of the dialyser under the same procedures as outlined for IV bolus injection, or as an up to 20 mg iron per kg body weight infusion. If the iron need exceeds 20 mg iron per kg body weight, the dose must be split into two administrations with an interval of at least one week. It is recommended whenever possible to give 20 mg iron/kg body weight in the first administration. Dependent on clinical judgement the second administration could await follow-up laboratory tests. Doses up to 1,000 mg must be administered over >15 minutes; doses above 1,000 mg must be administered over ≥30 minutes. In case of infusion, Monover® should be infused undiluted or diluted in 0.9% sodium chloride. For stability, Monover® should not be diluted to concentrations less than 1 mg iron/ml and never diluted in more than 500 ml. **Contraindications:** Non-iron deficiency anaemia, iron overload or disturbances in utilisation of iron, hypersensitivity to any of the ingredients, decompensated liver disease, or known serious hypersensitivity to other parenteral iron products. **Warnings/Precautions:** Parenterally

administered iron preparations can cause hypersensitivity reactions including potentially fatal anaphylactic/anaphylactoid reactions. The risk is enhanced for patients with known allergies, a history of severe asthma, eczema or other atopic allergy, and in patients with immune or inflammatory conditions. Monover® should only be administered in the presence of staff trained to manage anaphylactic reactions where full resuscitation facilities are available (including 1:1000 adrenaline solution). Each patient should be observed for at least 30 minutes following administration. If hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately. In patients with compensated liver dysfunction, parenteral iron should only be administered after careful benefit/risk assessment. Careful monitoring of iron status is recommended to avoid iron overload. Parenteral iron should be used with caution in case of acute or chronic infection. Monover® should not be used in patients with ongoing bacteraemia. Hypotensive episodes may occur if intravenous injection is administered too rapidly. Caution should be exercised to avoid paravenous leakage when administering Monover®. **Pregnancy:** Monover® use during pregnancy requires a careful risk/benefit evaluation. The treatment should be confined to second and third trimester only. In rare cases, foetal bradycardia has been observed in pregnant women with hypersensitivity reactions. The unborn baby should be carefully monitored during intravenous administration of parenteral irons in pregnant women. **Undesirable effects:** No very common (≥10 %) undesirable effects listed. Common undesirable effects (1 % to 10 %): nausea; rash; injection site reactions. For information on other undesirable effects, please consult full Summary of Product Characteristics. **Legal Category:** POM. **Package Quantities:** 5 vials of 1 ml; 5 vials of 5 ml; 2 vials of 10 ml. **Marketing Authorisation Number/Holder:** PA 0982/002/002, Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark. **Date of preparation:** July 2022. Further information is available on request to Pharmacosmos UK.

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to Pharmacosmos UK Ltd E: pvuk@pharmacosmos.co.uk T: +44 1844 269 007 Pharmacosmos UK Ltd | The White Building | 33 Kings Road | Reading | RG1 3AR | W: www.pharmacosmos.co.uk