The iron they need in just **ONE** visit up to 20 mg/kg\(^1\)

Simplified dosing guide for intravenous iron administration

Prescribing Information is available on the last page.
A simple approach to dosing

Determine the patient’s iron need based on haemoglobin and body weight, using a simplified table*

<table>
<thead>
<tr>
<th>Haemoglobin</th>
<th>Patient body weight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;50 kg</td>
</tr>
<tr>
<td>≥100 g/l</td>
<td>500 mg</td>
</tr>
<tr>
<td>&lt;100 g/l</td>
<td>500 mg</td>
</tr>
</tbody>
</table>

*Guidance provided based on section 4.2 of the Monofer SPC. Monofer should not be used during pregnancy unless clearly necessary. The treatment should be confined to second and third trimester.†

†All patients with a body weight ≥75 kg and a Hb ≥100 g/l can be treated in just one visit.

Example dosing calculation

**Patient:** 75 kg, Hb 105 g/l

**Iron need:** 1500 mg

Remember:†

- Total dose per week should not exceed 20 mg iron/kg body weight
- A single Monofer infusion should not exceed 20 mg iron/kg body weight
- A single Monofer bolus injection should not exceed 500 mg iron
- Reassess haemoglobin no earlier than 4 weeks after last infusion

Minimise patient hospital visits with Monofer, the ONLY fast IV iron that can be administered in single doses

> 1000 mg up to 20 mg/kg†⁻³

IV, intravenous; SPC, Summary of Product Characteristics.
Monofer offers fast and simple administration

- **Injection**: 500 mg over 2 minutes
- **Infusion**: ≤1000 mg over >15 minutes, >1000 mg over ≥30 minutes

If iron need >20 mg/kg, administer maximum dose at first visit, second administration based on clinical judgement, at least one week after first visit.

For IV infusion, Monofer should be infused undiluted or diluted in sterile 0.9% sodium chloride. It should not be diluted to concentrations <1 mg/ml and never diluted in >500 ml.

For IV bolus injection, Monofer may be administered undiluted or diluted in maximum 20 ml sterile 0.9% sodium chloride.

IV iron should only be administered when trained staff are present and the patient should be observed for at least 30 minutes following each injection.

Monofer concentration: 100 mg/ml

Monofer vial sizes:
- 1 ml = 100 mg iron
- 5 ml = 500 mg iron
- 10 ml = 1000 mg iron
UK Prescribing Information

Monofer® (ferric derisomaltose) prescribing information

This medicinal product is subject to additional monitoring, and healthcare professionals are asked to report any suspected adverse reaction

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: Monofer® 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. Monofer® 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, Monofer® should be infused undiluted or diluted in 0.9% sodium chloride. For stability, Monofer® 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, uncompensated 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. Monofer® 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. In patients with immune or inflammatory conditions, Monofer® 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 Monofer®. Pregnancy: Monofer® should not be used during pregnancy unless clearly necessary. The treatment should be confined to second and third trimester. 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 iron 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 and basic Prices: 5 vials of 1 ml, £84.75; 5 vials of 5 ml, £423.75; 2 vials of 10 ml, £339.00. Marketing Authorisation Number/Holder: PL 18380/001, Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark. Date of preparation: August 2020. Further information is available on request to Pharmacosmos UK.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk. Adverse events should also be reported to Pharmacosmos UK Ltd.

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PHARMACOSMOS
Committed to Quality

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We are the UK subsidiary of Pharmacosmos, an independent pharmaceutical company based in Denmark. We specialise in iron deficiency management and help healthcare professionals in iron therapy.

Date of Preparation: September 2020
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