SAMPLE CMS-1500 CLAIM FORM¹ FOR MONOFERRIC | Physician office administration
(Patient Weight 50 kg or Above): Administer 1,000 mg of Monoferric as an intravenous infusion²

Note, only the 1,000 mg iron/10 mL (100 mg/mL) single-dose vial of Monoferric is available in the United States. The sample form provides information for demonstration purposes only. It provides an example of the type of information that may facilitate the claims process with a patient’s insurance provider. All coding information is for reference purposes only. Use of this template or the information in this sample form does not guarantee reimbursement or coverage.

1. For patients weighing 50 kg or above, administer 1,000 mg of Monoferric as an intravenous infusion.
2. Note: 1,000 mg iron/10 mL (100 mg/mL) single-dose vial of Monoferric is available in the United States. The sample form provides information for demonstration purposes only. 

Please see additional Important Safety Information throughout. Please click here for Full Prescribing Information.
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**WARNINGS AND PRECAUTIONS**

**IMPORTANT SAFETY INFORMATION**

**Hypersensitivity Reactions:** Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Monoferric. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after Monoferric administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Monoferric when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. Monoferric is contraindicated in patients with prior serious hypersensitivity reactions to Monoferric or any of its components. In clinical trials in patients with IDA and CKD, serious or severe hypersensitivity were reported in 0.3% (6/2008) of the Monoferric treated subjects. These included 3 events of hypersensitivity in 3 patients; 2 events of infusion-related reactions in 2 patients and 1 event of asthma in one patient.

**Note:** To facilitate accurate payment, report the exact dose administered. More information on the claims process and the CMS fee schedule can be found here.

**Sample billing units calculation:** 20 mg/kg * Y kg of body weight = 20 * Y mg administered. Then [20 * Y] * 1 billing unit/10 mg = [# Billing Units]

**IMPORTANT INFORMATION:** The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider’s responsibility to determine the appropriate health care setting, and to submit true and correct claims for those products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials are provided to assist health care providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains at all times with the provider.

**Sample CMS-1500 Claim Form**

1. Complete Box 20: Description of Service:

   - In this box, specify the procedure or procedure code, the drug, the drug description, and any modifiers that may be necessary to accurately describe the service provided. For example:
   - **Box 24D:** Enter the appropriate HCPCS code for Monoferric, J1437, Injection, ferric derisomaltose, 10 mg. Include the appropriate modifier to report the amount of the drug that is unused and after Monoferric administration for at least 30 minutes and until clinically stable following completion of the infusion. Use modifier JW to report the amount of the drug that is unused and after Monoferric administration for at least 30 minutes and until clinically stable following completion of the infusion.
   - **Box 24E:** Enter the charge for each listed service and the unit of measurement qualifier (e.g., ME for milligrams), and the unit quantity. Example: N473594931001ME1000.

2. Complete Box 23: Enter the PA number.

3. Complete Box 24A: In the nonshaded area, list the date of service. If required by the payer, in the shaded area, provide a detailed drug description: the N4 indicator, the 11-digit NDC number, the unit of measurement qualifier (e.g., ME for milligrams), and the unit quantity. Example: N473594931001ME1000.

4. Complete Box 19: If additional information is required to describe Monoferric (e.g., NDC, route of administration), this information may be captured in Box 19.

5. Complete Box 24G: Report the appropriate number of units for the procedure and the appropriate number of units for Monoferric, J1437, Injection, ferric derisomaltose, 10 mg. Include the appropriate modifier to report the amount of the drug that is unused and after Monoferric administration for at least 30 minutes and until clinically stable following completion of the infusion. Use modifier JW to report the amount of the drug that is unused and after Monoferric administration for at least 30 minutes and until clinically stable following completion of the infusion. Use modifier JW to report the amount of the drug that is unused and after Monoferric administration for at least 30 minutes and until clinically stable following completion of the infusion.

6. Complete Box 24F: Enter the charge for each listed service and the product.

**Healthcare Provider Web Resources:**

- monoferric-patient-solutions.com
- monoferricpatientsolutionsportal.com

**Patient Resources:**

- Please see additional Important Safety Information throughout. Please click here for Full Prescribing Information.
INDICATION

Monoferric is indicated for the treatment of iron deficiency anemia (IDA) in adult patients:
- who have intolerance to oral iron or have had unsatisfactory response to oral iron
- who have non-hemodialysis dependent chronic kidney disease (NDD-CKD)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Monoferric is contraindicated in patients with a history of serious hypersensitivity to Monoferric or any of its components. Reactions have included shock, clinically significant hypotension, loss of consciousness, and/or collapse.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Monoferric. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after Monoferric administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Monoferric when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. Monoferric is contraindicated in patients with prior serious hypersensitivity reactions to Monoferric or any of its components. In clinical trials in patients with IDA and CKD, serious or severe hypersensitivity were reported in 0.3% (6/2008) of the Monoferric treated subjects. These included 3 events of hypersensitivity in 3 patients; 2 events of infusion-related reactions in 2 patients and 1 event of asthma in one patient.

Iron Overload

Excessive therapy with parenteral iron can lead to excess iron storage and possibly iatrogenic hemosiderosis or hemochromatosis. Monitor the hematologic response (hemoglobin and hematocrit) and iron parameters (serum ferritin and transferrin saturation) during parenteral iron therapy. Do not administer Monoferric to patients with iron overload.

ADVERSE REACTIONS

Adverse reactions were reported in 8.6% (172/2008) of patients treated with Monoferric. Adverse reactions related to treatment and reported by ≥1% of the treated patients were nausea (1.2%) and rash (1%). Adjudicated serious or severe hypersensitivity reactions were reported in 6/2008 (0.3%) patients in the Monoferric group. Hypophosphatemia (serum phosphate <2.0 mg/dL) was reported in 3.5% of Monoferric-treated patients in Trials 1 & 2.

To report adverse events, please contact Pharmacosmos at 1-888-828-0655. You may also contact the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for Full Prescribing Information.