



Monoferric™ (ferric derisomaltose) – New drug approval

- On January 16, 2020, the [FDA approved](#) Pharmacosmos' [Monoferric \(ferric derisomaltose\)](#), 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)
- The efficacy of Monoferric was established in two randomized, open-label, actively-controlled clinical studies in a total of 3,050 patients with IDA of different etiology. Study 1 included patients with IDA who had intolerance to oral iron or who had had unsatisfactory response to oral iron or for whom there was a clinical need for rapid repletion of iron stores. Study 2 included patients with IDA who had NDD-CKD. In both studies, patients were randomized to treatment with Monoferric or iron sucrose and efficacy of Monoferric was established based upon the change in hemoglobin from baseline to week 8.
 - In study 1, noninferiority was demonstrated for change in hemoglobin from baseline to week 8. The mean difference between the two groups was 0.00 (95% CI: -0.13, 0.13).
 - Noninferiority was also met in study 2 (treatment difference: 0.08, 95% CI: -0.06, 0.23).
- Warnings and precautions for Monoferric include hypersensitivity reactions and iron overload.
- The most common adverse reactions ($\geq 1\%$) with Monoferric use were rash and nausea.
- The recommended dose of Monoferric for patients weighing 50 kg or more is 1,000 mg by intravenous (IV) infusion over at least 20 minutes as a single dose. The dose may be repeated if iron deficiency anemia reoccurs. For patients weighing less than 50 kg, the recommended dose is 20 mg/kg actual body weight by IV infusion over at least 20 minutes as a single dose. A repeat dose can be given if iron deficiency anemia reoccurs.
 - Monoferric should only be administered when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions.
- Pharmacosmos' launch plans for Monoferric are pending. Monoferric will be available as 1,000 mg/10 mL, 500 mg/5 mL, and 100 mg/mL single dose vials



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