

## 1 INFUSION KEPT JIM'S CALENDAR OPEN



**JIM** | 50 years old

Diagnosed with iron deficiency anemia due to his colon cancer

### WHY MONOFERRIC WAS RIGHT FOR JIM

- Has a history of oral iron intolerance and is waiting for surgery in the near future
- Loves the freedom of being a freelance photographer and creating his own schedule
- Lives in a rural community without close access to an infusion center
- Due to the long distance, he preferred to only travel for 1 infusion

MonoFerric is covered under most insurance plans

Could your  
long-distance patients  
benefit from just 1  
MonoFerric infusion?

*The adults shown in the photos  
are not real patients.*

### INDICATIONS

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

OR

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.

## **IMPORTANT SAFETY INFORMATION (*continued*)**

### **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  $\geq 1\%$  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](http://www.fda.gov/medwatch) or 1-800-FDA-1088.

**Please see Full Prescribing Information.**

