

What is Monoferric?

MONOFERRIC is a prescription iron replacement medicine used to treat iron deficiency anemia in adults who have:

- intolerance to oral iron or who have not responded well to treatment with oral iron
- non-dialysis dependent chronic kidney disease

It is not known if MONOFERRIC is safe and effective for use in children less than 18 years old.

IMPORTANT SAFETY INFORMATION

Who should not receive Monoferric?

Do not receive MONOFERRIC if you are allergic to ferric derisomaltose or any of the ingredients in MONOFERRIC.

What should I tell my doctor or healthcare provider before receiving Monoferric?

Before receiving MONOFERRIC, tell your healthcare provider about all of your medical conditions, including if you:

- have had an allergic reaction to IV iron
- are pregnant or plan to become pregnant. It is not known if MONOFERRIC will harm your unborn baby.
- are breastfeeding or plan to breastfeed. MONOFERRIC passes into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with MONOFERRIC.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

What are the possible side effects of Monoferric:

MONOFERRIC may cause serious side effects, including:

- **Allergic (hypersensitivity) reactions.** Serious life-threatening allergic reactions have happened in people who receive MONOFERRIC. Symptoms of an allergic reaction including rash, itching, hives, dizziness, lightheadedness, breathing problems and low blood pressure have also happened during treatment with MONOFERRIC. Tell your healthcare provider right away if you develop any of the above symptoms of a serious

allergic reaction or if you have ever had any unusual or allergic reaction to any IV iron in the past.

- **Too much iron stored in your body (iron overload).** Your healthcare provider should check the iron level in your blood before you start and during treatment with MONOFERRIC.

The most common side effects of MONOFERRIC include: rash and nausea.

These are not all the possible side effects of Monoferric. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information including information for patients.