INFORMED CONSENT FOR TREATMENT WITH INJECTAFER

Iron is a mineral that human bodies need in order to produce red blood cells. If someone does not have enough iron, iron-deficiency anemia (too few red blood cells) can occur. Reasons for not having enough iron can include blood loss (most commonly from gastrointestinal bleeding or, in women, heavy menstrual cycles) or difficulty absorbing iron from the intestinal tract (for example, in people with celiac disease [gluten allergy] or Crohn's disease). INJECTAFER (ferric carboxymaltose injection) is an iron preparation delivered directly into the blood via intravenous (IV) infusion. It is approved by the United States Food and Drug Administration (FDA) for treatment of iron-deficiency anemia in adult patients who have intolerance to oral iron supplements or who have had an unsatisfactory response to oral iron supplements. INJECTAFER contains a core of iron (ferric hydroxide) stabilized within a carbohydrate shell (carboxymaltose) that allows rapid IV delivery of a high dose of iron within a short period of time. The total iron concentration within the bloodstream increases rapidly after INJECTAFER administration, providing the human body with iron to make new red blood cells (and thus improve the anemia).

WARNINGS:

INJECTAFER may improve iron-deficiency anemia; however, the medication has been associated with side effects, including serious side effects with the potential to cause death.

Anaphylactic hypersensitivity reactions – There is a potential for anaphylactic hypersensitivity reactions, including shock, loss of consciousness, and collapse. In clinical trials, these reactions occurred in 0.1% (one-tenth of one percent) of patients, or in 2 out of 1775 patients, undergoing INJECTAFER infusions.

Other hypersensitivity reactions – Either while receiving an infusion or within a few hours after an infusion, other hypersensitivity reactions can occur, including rash/itching, hives, flushed skin, wheezing/difficulty breathing, and low blood pressure. In clinical trials, these reactions occurred in 1.5% of patients, or 26 out of 1775 patients, undergoing INJECTAFER infusions.

High blood pressure – Immediately after receiving INJECTAFER, some people have a temporary rise in blood pressure, which can cause facial flushing, dizziness, or nausea. This rise in blood pressure generally resolves within 30 minutes. In clinical trials, this reaction occurred in 3.8% of patients, or 67 out of 1775 patients, undergoing INJECTAFER infusions.

Other adverse effects – The most common adverse effects from INJECTAFER infusion (in > 1% of patients in clinical trials) are nausea, high blood pressure, flushing, dizziness, discoloration of the injection site, headache, and changes in taste. INJECTAFER infusion can also temporarily elevate one of the commonly measured liver enzyme blood tests (alanine aminotransferase, or ALT).

IMPORTANT SAFETY INFORMATION:

In deciding to use a medication, the risks of taking the medicine must be weighed against its benefits. Your Northwest Gastroenterology (NWGI) gastroenterologist should discuss these risks and benefits before you decide to start INJECTAFER.

Before starting INJECTAFER, you should inform your doctor if you have:

- Hypersensitivity/reaction to previous iron infusions; or
- Plans to become pregnant (or are already pregnant) or are breastfeeding.

PREGNANCY AND BREASTFEEDING:

Please tell your NWGI gastroenterologist if you are pregnant, planning to become pregnant, or breastfeeding. This will allow you and your gastroenterologist to discuss appropriate issues. INJECTAFER is a pregnancy category C medication, meaning that studies on animal reproduction have shown an adverse effect on the animal fetus but that there are no adequate and well-controlled studies in humans; however, potential benefits may warrant use of the drug in pregnant women despite potential risks. A study on nursing mothers using either INJECTAFER or oral iron supplements showed higher average iron levels in the breast milk of the group taking INJECTAFER.

MEDICATION ADMINISTRATION:

INJECTAFER is generally administered as two 750-mg intravenous (IV) infusions separated by at least 7 days. Each infusion lasts about 30 minutes. You will see your NWGI gastroenterologist periodically to monitor your progress and response to INJECTAFER.

If you have any questions, please call NWGI at (360) 734-1420 (Monday through Friday, 8 am to 5 pm).

By signing, I indicate that I have read and understand this consent form and agree to receive INJECTAFER infusions. I have had an opportunity to discuss this treatment with my physician and have had my questions answered.

Patient Signature Date

Patient Printed Name