



INFORMED CONSENT FOR TREATMENT WITH INFLIXIMAB (REMICADE/INFLECTRA)

INFLIXIMAB (REMICADE/INFLECTRA) (infliximab) is approved by the US Food and Drug Administration for the treatment of Crohn's disease and ulcerative colitis (UC). INFLIXIMAB (REMICADE/INFLECTRA) is a synthetic antibody that blocks the activity of tumor necrosis factor (TNF), a key component in the body's inflammatory process. Because of its activity against TNF, INFLIXIMAB (REMICADE/INFLECTRA) is called an "anti-TNF antibody" (or "anti-TNF" for short). By blocking TNF, INFLIXIMAB (REMICADE/INFLECTRA) may reduce inflammation in patients with Crohn's or UC and thus improve symptoms.

WARNINGS:

INFLIXIMAB (REMICADE/INFLECTRA) may reduce symptoms from Crohn's or UC; however, the medication has been associated with serious side effects.

Infusion reactions within a few hours of infusion can include hives, difficulty breathing, and/or decrease in blood pressure. More common side effects immediately after an infusion are sinus congestion, headache, rash, cough, stomach pain, and/or fatigue; these generally resolve within about 24 hours.

Serum sickness-like reactions – with symptoms including fever, rash, headache, sore throat, muscle aches, joint pain, hand and facial swelling and/or difficulty swallowing – have been observed within a few days after infusion, especially in patients who are restarting INFLIXIMAB (REMICADE/INFLECTRA) after an extended period off the medication.

Serious infections, including tuberculosis (TB), hepatitis B, histoplasmosis, coccidioidomycosis, listeriosis, pneumocystosis, and other bacterial, fungal, and viral infections, can occur at any time in patients on anti-TNF antibodies like INFLIXIMAB (REMICADE/INFLECTRA). The medication can make you more likely to get an infection and can worsen any infection you get. The risk of serious infection is increased if you are on other immunosuppressive drugs, such as Imuran (azathioprine), 6-mercaptopurine (6-MP), or methotrexate.

Changes in body function can occur, including fluid retention (with leg swelling and/or shortness of breath), liver inflammation (with jaundice causing yellow eyes/skin or dark urine), joint and/or muscle pains (occasionally resembling systemic lupus erythematosus), rashes (including psoriasis-type lesions), or numbness/weakness.

Lymphoma, a cancer affecting blood cells, is reported in patients on medications that suppress the immune system, including INFLIXIMAB (REMICADE/INFLECTRA). The lymphoma may be associated with reactivation of a virus (Epstein-Barr virus, or EBV), but does not need to be EBV-related. The lymphoma may go into remission if immune-suppressing medications are withheld but may require chemotherapy and other therapy.

Hepatosplenic T-cell lymphoma, a rare lymphoma of the liver with a high rate of death, may have an association with anti-TNF antibodies like INFLIXIMAB (REMICADE/INFLECTRA), though the disease is more strongly associated with Imuran (azathioprine) use in younger men. As many people are on both Imuran (azathioprine) and INFLIXIMAB (REMICADE/INFLECTRA), the exact role of INFLIXIMAB (REMICADE/INFLECTRA) in the disease remains unclear.

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 prior to a decision to starting INFLIXIMAB (REMICADE/INFLECTRA).

Before starting INFLIXIMAB (REMICADE/INFLECTRA), you should inform your doctor if you have:

- A history of tuberculosis (TB) or exposure to someone with tuberculosis. Your NWGI gastroenterologist will likely check you for tuberculosis with either a skin test or a blood test (for example, QuantiFERON Gold), as well as a chest x-ray. If you have evidence of inactive tuberculosis, you will need to begin anti-tuberculosis treatment before you start INFLIXIMAB (REMICADE/INFLECTRA);
- Lived in a region where fungal infections like histoplasmosis (also known as “cave disease” or “Ohio River valley disease”) or coccidioidomycosis (aka “valley fever”) are common;
- Infections that keep returning, uncontrolled diabetes, or a problem with your immune system;
- Any type of cancer or a risk factor for developing cancer (for example, a strong family history of cancer);
- Heart failure or any serious heart condition;
- Hepatitis B virus (HBV) infection or close personal contact with HBV; or
- Nervous system disorders like multiple sclerosis (MS) or Guillan-Barre syndrome.

Vaccinations: You should not receive live vaccines (e.g., Varicella [chickenpox] vaccine, Zoster [shingles] vaccine, or live polio vaccine) while on INFLIXIMAB (REMICADE/INFLECTRA). The injected flu and pneumonia vaccines can be safely administered while on INFLIXIMAB (REMICADE/INFLECTRA). The nasal spray version of the flu vaccine is a live vaccine and SHOULD NOT be administered while on INFLIXIMAB (REMICADE/INFLECTRA). Please inform your doctor if someone in your household has received a live virus vaccine.

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 measures related to your disease and medications. DO NOT stop your Crohn's or UC medications, including INFLIXIMAB (REMICADE/INFLECTRA), without informing your gastroenterologist.

MEDICATION INTERACTIONS:

Please tell your NWGI gastroenterologist if you start new prescription or non-prescription medications, including vitamins and herbal supplements, while receiving INFLIXIMAB (REMICADE/INFLECTRA). This is especially important if you start other immune suppressants such as Humira, Cimzia, Simponi, Actemra, Enbrel, Kineret, Orencia, and Rituxan.

MEDICATION ADMINISTRATION:

INFLIXIMAB (REMICADE/INFLECTRA) is administered as a single intravenous infusion lasting approximately 2 hours. Infusion times may vary on the number of infusions you have received. Your NWGI gastroenterologist will determine the correct dose and interval of the infusions. You will see your NWGI gastroenterologist periodically to monitor your progress and response to INFLIXIMAB (REMICADE/INFLECTRA).

If you have any questions, you can contact our office at (360) 734-1420 on Monday through Friday from 8 am to 5 pm.

I certify that I have read and understand this consent form and agree to receive INFLIXIMAB (REMICADE/INFLECTRA) intravenous infusions. I have had an opportunity to discuss this treatment with my physician and have had all my questions answered.

Patient Signature

Date

Patient Printed Name