

INFORMED CONSENT FOR THE USE OF HUMIRA (ADALIMUMAB) BIOLOGIC THERAPY

Background

Biologic treatments are medications that affect the functioning of the immune system. They are helpful in treating autoimmune diseases in which the body's immune system is attacking normal tissue. Different biologic medications have different mechanisms of action, including T-cell modulators, tumor necrosis factor alpha (TNF- α) antagonists, and interleukin-12 (IL-12) and interleukin-23 (IL-23) inhibitors. These are specific steps of the immune system that are targeted to dull the immune response and therefore decrease inflammation. Humira works as a TNF- α antagonist.

Indications

Severe plaque psoriasis
Psoriatic arthritis
Rheumatoid arthritis
Polyarticular juvenile idiopathic arthritis
Ankylosing spondylitis
Crohn's Disease

Contraindications

Sepsis
Known hypersensitivity

WARNINGS AND SIDE EFFECTS: Like all medications, Humira can have side effects. Before using Humira, it is important that you are aware of these side effects. Humira may cause:

Initials

_____1. Increased risk of infections. The most common type of infections are mild upper respiratory types of infection. There have been rare cases where patients taking Humira have developed serious infections, including tuberculosis (TB) and infections caused by bacteria or fungi that have spread throughout their body (sepsis). Some patients have died from these infections. If you get infections easily or if you develop an infection while taking Humira, you should tell your doctor right away.

_____2. Injection site reaction. These occur in 30 – 40% of patients, are typically mild to moderate (redness, itching, pain, swelling) and do not necessitate discontinuation of therapy. These reactions typically last for 3-5 days and decrease in frequency with continued treatment. If you have pain, redness or swelling around the injection site that does not go away or gets worse, call your doctor.

_____4. Allergic reactions (<2% of patients). If you develop a severe rash, swollen face or difficulty breathing while taking Humira, call your doctor right away or go to the emergency room.

_____5. Nervous system diseases. There have been rare cases of disorders that affect the nervous system of people taking Humira. Signs that you could be experiencing a problem affecting your nervous system include: numbness or tingling throughout your body, problems with your vision, weakness in your arms and/or legs and dizziness. Whether Humira caused these disorders is unclear.

_____6. Blood problems. In some patients the body may fail to produce enough of the blood cells that help your body fight infections or help you stop bleeding. If you develop a fever that does not go away, bruise or bleed very easily or look very pale, call your doctor right away. Your doctor may decide to stop your treatment. Some people have also had symptoms that resemble lupus (rash on face and arms that gets worse in sun) that may go away when you stop taking Humira.

____7. Lymphoma (a type of cancer) occurs in greater frequency in patients with rheumatoid arthritis than in the general population. Since Humira has been studied in patients with rheumatoid arthritis, Humira has also been reportedly associated with an increased incidence of lymphomas. The increased rate was not greater than would be expected in patients with rheumatoid arthritis. There have been rare reports of lymphoma in patients taking Humira occurring more often than expected for people in general. The role of Humira in the development of cancer is not known.

____8. Heart problems. You should tell your doctor if you have ever been treated for heart failure. If you have, your doctor may choose not to start you on Humira, or may want to monitor you more closely.

____9. I understand Humira is a pregnancy category B drug. I understand that if I am pregnant, trying to get pregnant or breastfeeding, I will discuss this with my doctor before starting Humira. If I should become pregnant while taking Humira, I will notify my doctor promptly before taking the next dose of Humira.

____10. I understand I should not receive live virus vaccines while taking Humira, and other vaccines may be less effective.

____11. I understand exposure to someone with chicken pox or shingles (herpes zoster) is very dangerous while taking Humira and I should report any exposure to my physician immediately.

____12. I understand I should report to my doctor immediately if I develop a persistent fever, bruising, bleeding or pallor (become pale appearing).

____13. I understand that Humira is an injection type of therapy that I, or someone else properly trained, must give.

____14. I understand I must tell my doctor if I have any kind of infection including an infection that is only in one place (such as an open sore), or an infection that is in my whole body (such as the flu), a history of infections that keep coming back or other conditions like diabetes, that might increase my risk of infections.

____15. I will notify my doctor if I have ever had a positive test for tuberculosis (TB), or if I have been or will be in close contact with someone who has had, or has tuberculosis. If I develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) I will call my doctor to be examined for TB and have a skin test or chest x-ray.

____16. I will notify my doctor if I have been scheduled for major surgery or have been scheduled to be vaccinated for anything.

____17. I understand that this is a partial list of possible side effects and a more complete listing can be found in the package insert available from the pharmacist. I also understand that since Humira is a relatively new drug on the market, there may be side effects that we do not know about and sometimes are not discovered until much later.

____18. I have read and understand the information presented in the Humira patient education packet provided by Abbott Laboratories.

BLACK BOX WARNING

WARNINGS

SERIOUS INFECTIONS

Patients treated with HUMIRA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

HUMIRA should be discontinued if a patient develops a serious infection or sepsis.

Reported infections include:

- Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before HUMIRA use and during therapy. Treatment for latent infection should be initiated prior to HUMIRA use.
- Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.
- Bacterial, viral and other infections due to opportunistic pathogens.

The risks and benefits of treatment with HUMIRA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with HUMIRA, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MALIGNANCIES

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which HUMIRA is a member.

I have read the above 18 items and the black box warning. I have had the opportunity to ask any questions and received answers to my satisfaction. I have also had alternative treatments explained to me, including doing nothing.

I hereby consent to be treated with Humira.

Patient Signature

Date

Witness

Date

Physician Signature

Date