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INFORMED CONSENT FOR TREATMENT WITH HUMIRA

Humira has been approved by the Food and Drug Administration (FDA) for the treatment of Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis.
Humira blocks the action of a protein called Tumor Necrosis Factor (TNF). This blockade results in decreased swelling (inflammation) and decreased immune system function (immunosuppression). Humira is effective in treating the above diseases since swelling and an overactive immune system probably play a role in these diseases.

WARNINGS:

Humira decreases immune system function (immunosuppression), which can result in serious infections including invasive fungal infections or worsening of an existing infection. Deaths from serious infections have been reported in patients receiving Humira.

Before starting treatment with Humira, you should have a tuberculosis skin test done to check for tuberculosis that may not be causing any symptoms (latent tuberculosis). If you have been diagnosed with tuberculosis, anti-tuberculosis medicines must be started before you start Humira therapy. This will reduce the likelihood of a serious tuberculosis infection. Tell your doctor if you have ever had tuberculosis or have come in contact with someone with tuberculosis. Tell your doctor if you have ever had a positive PPD (tuberculosis skin test) – this may require treatment.

Tell your doctor immediately if you have any complaints that may indicate an infection. These include but are not limited to pink eye, ear pain or drainage, sinus pain or drainage, sore throat, hoarse voice, cough, difficulty breathing, fevers, chills, sweats, vomiting, abdominal pain, diarrhea, burning with urination, increased frequency of urination, vaginal discharge, and cuts or wounds that are red, swollen or draining pus.

Tell your doctor if you have been diagnosed as having an infection, are on antibiotics or if you are prone to recurrent infections. You should not receive Humira while you have an infection or while you are on antibiotics. Humira can be restarted once you have completed your antibiotic course and your infection has resolved.

Tell your doctor if you have a planned surgery, as you will need to stop your Humira temporarily around the time of your surgery.

PRECAUTIONS:

Treatment with Humira may result in the formation of autoimmune antibodies and, rarely, may cause a lupus-like syndrome. In clinical trials, patients who developed a lupus-like syndrome have had resolution of the syndrome after treatment with Humira was stopped.
Patients with a long duration of inflammation and chronic exposure to immunosuppressant treatments are more prone to develop cancer, in particular lymphoma. The impact of Humira on this is not known. Possible long-term side effects such as the development of lymphoma or other cancers cannot be predicted.
It is not known if Humira can cause fetal harm when given during pregnancy, or if it is safe to receive Humira while breast feeding
Humira may worsen congestive heart failure. Some deaths have occurred in patients with congestive heart failure. Tell your doctor if you have been diagnosed with congestive heart failure.
Humira has been reported to cause liver test abnormalities and blood cell count abnormalities. The blood cell count abnormalities can be severe. You should let your doctor know if you notice bruising, bleeding or paleness of the skin.
Humira may cause worsening of psoriasis or the development of psoriasis.
There are rare reports of Humira causing damage to the nervous system, for eg. seizures, numbness, tingling, paralysis. Let your doctor know if you develop any such complaints.
You should not receive live vaccines (for eg. polio, smallpox) while on Humira, without speaking with your doctor. The injected flu vaccine and pneumonia vaccine can be safely administered while on Humira. The nasal spray version of the flu vaccine is a live vaccine and should not be administered while on Humira. Please let your doctor know if someone in your household has received or will receive a live virus vaccine.

ADVERSE REACTIONS:

The most common side effect from Humira is a reaction at the site of the injection. You may experience some redness, itching or hives. If a reaction occurs it is usually mild and goes away after a few weeks of continued usage of the drug. Other side effects include but are not limited to upper respiratory infections such as sinus infections, headache and nausea.

ALLERGIC REACTIONS:

In rare cases severe allergic reactions may occur, leading to difficulty breathing and low blood pressure or shock. Allergic reactions can happen after your first dose or may not happen until after you have taken Humira many times. If you develop a severe rash, swollen face or difficulty breathing while taking Humira, call your doctor right away or seek emergency care immediately.

MEDICATION ADMINISTRATION:

Humira is injected under the skin twice a month, ie. every 14 days. You will be taught how to do the injections.

EMERGENCY CONTACTS:

In case of emergency, you can contact our office at (503) 297-3384 from 8:00 am to 5:00 pm Monday – Friday, or after hours dial the above number to page your physician or call 911 or go to the emergency room.

I certify that I have read and understand this consent form and agree to receive and self administer Humira . I have had an opportunity to discuss this treatment with my physician and ask questions regarding the treatment. I will be given a signed copy of this form for my records.

_____ _____

Patient signature Date

_____ _____

Witness signature Date