

Informed Consent for Treatment with Rituximab (Rituxan, Truxima, Ruxience)

Rituximab is a monoclonal antibody that was approved in 1997 for the treatment of lymphoma (lymph node cancer) by the Food and Drug Administration (FDA). It is estimated that over 500,000 patients with lymphoma have been treated with rituximab since that time. In 2006, the FDA approved rituximab in combination with methotrexate to reduce signs and symptoms in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies (such as Enbrel, Humira and Remicade).

HOW RITUXIMAB WORKS:

B cells are a type of cell in your body that are felt to play a role in inflammation that results in joint pain and swelling in rheumatoid arthritis.

Rituximab is a protein that fits like a lock and key with a protein on certain B cells in your body. Once rituximab attaches to these B cells, it affects their ability to function normally and therefore may decrease joint pain and swelling in rheumatoid arthritis.

WARNINGS:

Fatal infusion reactions have been reported in rare patients who received rituximab for the treatment of lymphoma. Severe skin and kidney damage has also been reported in patients who have received rituximab for the treatment of lymphoma. Rare cases of death from these reactions have been reported.

SIDE EFFECTS:

Infusion reactions:

Infusion-related side effects occur in about one third of patients. These side effects usually occur within 30 minutes to 2 hours of the infusion starting. It may be necessary to slow down or interrupt your infusion, and the infusion can usually be restarted once symptoms resolve. Infusion reactions can include but are not limited to fevers, chills, shakes, swelling of the face or throat, drop in blood pressure, shortness of breath and high blood pressure. Nausea and vomiting, itching, fatigue, headache, throat irritation, hives, rash, runny nose, muscle pain and dizziness have also been reported.

Infections:

Serious infections may occur. 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 with an infection, are on antibiotics or if you are prone to recurrent infections. You should not receive rituximab while you have an infection or while you are on antibiotics.

Tell your doctor if you have planned surgery, then you should not receive rituximab around the time of the planned surgery.

Other reported events:

Reactivation of hepatitis B, abnormalities in blood counts, heart and lung abnormalities, autoimmune events, and rare cases of a serious neurological condition (progressive multifocal leukoencephalopathy).

Patients with a long duration of inflammation and chronic exposure to immunosuppressant treatments are more prone to developing cancer, particularly lymphoma. The impact of rituximab on this is unknown.

Pregnancy and breast feeding:

It is not known if rituximab can cause fetal harm when given during pregnancy, or if it is safe to receive rituximab while breast feeding. It is not known if rituximab can affect fertility.

Vaccinations:

You should not receive live vaccines (for eg. polio, smallpox) without speaking with your doctor. The injectable flu vaccine and pneumonia vaccine can be safely administered. The flu vaccine in the form of nasal spray is a live vaccine and should not be administered.

Other side effects not listed above can also occur in some patients. Tell your doctor if you have any problems.

Medication administration:

Your first infusion may take most of the day. The second infusion will usually require less time. You should arrange for someone to be available to drive you home after your infusion in case this is needed.

You will be receiving pre-medication that may cause your blood sugar to rise temporarily. If you are diabetic PLEASE discuss this with your rheumatologist.

EMERGENCY CONTACTS:

In case of an emergency, please call 911 or go to the nearest emergency room. You can contact our office at (916)677-4744 from 8.00 am to 5.00 pm Monday – Friday.

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

Patient Name

Patient DOB

Patient Signature

Date

FINANCIAL RESPONSIBILITY:

Our office will contact your insurance company and the necessary arrangements will be made for approval of the medication and administration. You may want to follow up with your insurance company also to be sure everything is covered. **Our office does NOT provide a guarantee of coverage for any of these services. If coverage is not provided, YOU WILL BE RESPONSIBLE for any charges incurred for treatment and/or follow-up care.**

Patient signature

Date