

## **RITUXIMAB (Rituxan)**

Rituximab is FDA approved for the treatment of low-grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma (NHL); treatment of diffuse large B-cell CD20-positive NHL; treatment of rheumatoid arthritis (RA) in combination with methotrexate.

Rituximab has not been approved for any neurologic use. There are published reports suggesting that Rituxan may be beneficial in several autoimmune neurologic diseases. You should discuss why your doctor is suggesting Rituxan with your doctor.

Rituximab is given intravenously. It is common for you to be given acetaminophen (Tylenol®), and diphenhydramine HCl (Benadryl®) before the Rituximab to reduce side-effects.

There is a chance that you will experience an allergic reaction to Rituximab. Allergic reactions may be mild, such as skin rash or hives or severe, such as breathing difficulties or shock. A severe allergic reaction would require immediate medical treatment and could result in permanent disability or death.

There are some specific risks that you need to be aware of associated with taking Rituximab, acetaminophen (Tylenol®), and diphenhydramine HCl (Benadryl®). It is possible that you might experience these same side effects.

A small portion of the Rituximab antibody is mouse protein, but the majority of the Rituximab antibody is human protein. When you take Rituximab, there is a small chance that your immune system might develop special antibodies against the small portion of mouse protein. If you develop these special antibodies, it may affect your body's ability to respond to other drugs made with antibodies.

Rituximab use has been shown to cause a decrease in the levels of certain antibodies. Some antibodies which could be responsible for helping your body fight infection may be reduced. This means your body may be vulnerable to infections. While on Rituximab, you would not receive any vaccinations that contain live organisms (e.g., measles, mumps, rubella, or polio). If you believe that it is necessary to have a vaccination, you will need to wait at least 30 days after the vaccination to receive the first dose of Rituximab. In addition, it is possible that any vaccinations you receive that do not contain live organisms (e.g., flu or tetanus) may not be effective while you are being treated with Rituximab. Your doctor will review your immunization records before you receive Rituximab to determine if you should receive any immunizations before getting Rituximab.

Before your infusions of Rituximab, you will get acetaminophen (Tylenol®) and diphenhydramine HCl (Benadryl®) pills by mouth to help prevent side effects. Rare side effects of acetaminophen include rash, hives and liver damage. In general, side effects of diphenhydramine HCl have been primarily associated with drowsiness. Taking diphenhydramine HCl may interfere with your daily routine. You should use

caution when driving a motor vehicle or operating machinery. Because of possible sedating effects of this pre medication, you should arrange a ride home from the infusion center on the day the Rituximab is given. In addition it is not recommended that you drive any motor vehicle for up to 24 hours following a dose of diphenhydramine.

Rituximab can cause side effects that occur while it is being given. These side effects seen in cancer patients are called infusion related reactions. These reactions usually involve fever and chills. Other side effects commonly seen with Rituximab include skin rash and itching, flushing, nausea, vomiting, fatigue, and headache; cold like symptoms; sensation of tongue or throat swelling; and difficulty breathing, including shortness of breath. These conditions occur from 30 minutes to 2 hours after the start of a Rituximab infusion. These symptoms are more commonly seen during the first infusion of Rituximab. If you experience these symptoms, your doctor may slow down, interrupt, or even stop the infusion. Your doctor may also give you some drugs to treat these symptoms.

In people who have ever been infected with hepatitis B virus, there is a risk that Rituximab can cause hepatitis B to flare up. This could lead to liver failure or even death. The risk continues for more than a month after you stop taking rituximab. If you become jaundiced (yellowing of the skin and eyes) or develop viral hepatitis while taking rituximab, you should tell your doctor immediately. Even if you have stopped taking rituximab the risk goes on for at least several months (it is unknown for exactly how long). Your doctor will discuss this risk with you and explain what testing is recommended to check for hepatitis.

A mild to moderate change in blood pressure may also occur during infusion. In a previous study of rheumatoid arthritis subjects, a quarter of the subjects had a decrease in blood pressure, whereas a mild to moderate increase in blood pressure was also common.

In the non Hodgkin's lymphoma population, rare (about 1 in 1000), very serious (even occasionally causing death; 1 in 10,000), infusion related side effects have occurred with the use of rituximab. These serious infusion related side effects include the following:

- Chest pain (approximately 1 in 1,000)
- Abnormal heartbeat (approximately 1 in 1,000)
- Death (approximately 1 in 10,000)
- Severe shortness of breath (approximately 1 in 10,000)
- Severe skin rash (approximately 1 in 10,000)
- Lung inflammation (swelling and redness inside the lungs, approximately 1 in 10,000)
- Heart failure (approximately 1 in 10,000)
- Kidney failure from rapid killing of tumor cells (approximately 1 in 10,000; seen only in cancer patients)

Other uncommon side effects, not necessarily occurring during the rituximab infusion, may include the following:

- Severe skin rash (approximately 1 in 10,000)
- o Blistering skin reactions, some with fatal outcome, have been reported in patients treated with rituximab for non Hodgkin's lymphoma. The onset of these skin reactions has varied from 1 to 13 weeks following rituximab exposure.
- Anemia (low blood count, which may cause tiredness and lack of energy)
- Low platelet count (clotting cells in your blood) (uncommon), which may cause bleeding
- Joint pain
- Infection
- o In cancer patients, some patients with hepatitis B have experienced worsening of the hepatitis.
- Flu like symptoms
- Decreased appetite
- Fatigue
- Sleep problems
- High blood pressure

Your doctor will monitor you for these events. For example, you will have your blood pressure, pulse rate, and temperature taken every 15 minutes for the first hour and then each half hour while you are receiving Rituximab. If you experience a reaction that could be related to Rituximab, your doctor may stop the infusion. There may be unknown and potentially serious or life threatening side effects that could occur with Rituximab.

More information can be found at [www.rituxan.com](http://www.rituxan.com)

**RITUXIMAB (Injection)**  
**Rituximab (ri-TUK-si-mab)**

**Treats non-Hodgkin's lymphoma.**

**Brand Name(s): Rituxan**

There may be other brand names for this medicine.

**When This Medicine Should Not Be Used:**

You should not receive this medicine if you have had an allergic reaction to rituximab or other murine (mice or rats) proteins. You should not use this medicine if you are breast feeding.

**How to Use This Medicine:**

**Injectable**

- Medicines used to treat cancer are very strong and can have many side effects. Before receiving this medicine, make sure you understand all the risks and benefits. It is important for you to work closely with your doctor during your treatment.
- A nurse or other trained health professional will give you this medicine.
- Your doctor will prescribe your exact dose and tell you how often it should be given. This medicine is given through a needle placed in one of your veins.
- Rituximab must be given slowly, so the needle will remain in place a few hours. You may also receive medicines to help prevent possible allergic reactions to the injection.
- You will be watched closely for unwanted side effects while you are receiving this medicine.

**If a dose is missed:**

- Call your doctor or pharmacist for instructions.

**Drugs and Foods to Avoid:**

**Ask your doctor or pharmacist before using any other medicine, including over-the-counter medicines, vitamins, and herbal products.**

- Make sure your doctor knows if you are also receiving cisplatin (Platinol®).
- Talk to your doctor before getting flu shots or other vaccines while you are receiving this medicine. Vaccines may not work as well, or they could make you ill while you are using this medicine.

**Warnings While Using This Medicine:**

- Make sure your doctor knows if you are pregnant, or if you have hepatitis B. Tell your doctor if you have kidney disease, heart disease, or heart rhythm problems.
- Tell your doctor if you have ever had a reaction to murine (mice or rats) proteins. Murine proteins are also used in other medicines.
- Your doctor will need to check your blood at regular visits while you are using this medicine. Be sure to keep all appointments.

**Possible Side Effects While Using This Medicine:**

**Call your doctor right away if you notice any of these side effects:**

- Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing.

- Blistering, peeling, red skin rash.
- Chest pain, uneven heartbeat, sudden fainting.
- Confusion, weakness, uneven heartbeat, shortness of breath, or numbness or tingling in your hands, feet, or lips.
- Dark-colored urine or pale stools.
- Decrease in how much or how often you urinate.
- Fever, chills, cough, sore throat, and body aches.
- Nausea, vomiting, loss of appetite, pain in your upper stomach.
- Unusual bleeding, bruising, weakness, or lightheadedness.
- Yellowing of your skin or the whites of your eyes.

**If you notice these less serious side effects, talk with your doctor:**

- Headache, sore throat, runny or stuffy nose.
- Mild skin rash or itching.
- Muscle or joint pain.
- Problems with your vision.

**If you notice other side effects that you think are caused by this medicine, tell your doctor.**

 © 1974-2007 Thomson MICROMEDEX. All rights reserved.