



PROJECT SUBMISSION FORM

Project Information (for help press F1 when cursor is in the text box)

Item Name: Medication Guide

Brand Name: Rituxan

Item Owner: Kimberly Crichton

Item Vendor:
AT

Partner Code:

Agency Job #:
200-13323

Item Description: 8.5x11 black and white, 2-sided standalone version of the Medication Guide information

Derived from previous item(s)?

No Yes - If yes, enter item(s) code: 7141417 LJ1240

Replace existing item(s)?

No Yes - If yes, enter item(s) code:

Estimated first use: February 2008

Warehouse code needed?

No Yes - If yes, enter anticipated warehouse date: February 2008

Target Audience: Consumer

Distribution: Sales Rep

Date: February 2008
To: RITUXAN COS
Cc: RM, DM, RPM, TLL, CTD
From: Kimberly Crichton
Subject: Medication Guide

PRC APPROVED FOR PROMOTIONAL USE

Description

- 8.5x11 black and white, 2-sided standalone version of the Medication Guide information

Audience

- Patients

Objectives

- To communicate the FDA-approved Medication Guide

Overall Brand Message(s)

- N/A

Key Message(s)

- N/A

Distribution

- These PIs will be distributed by COSs to HCPs for distribution to patients with promotional pieces. They will be available for order on the GOLF ordering system. They will be listed as LJ2876.

Any questions from your HCPs regarding off-label product use are to be referred to the Medical Communications department in the "Contact Us" section of the Genentech corporate website (<http://www.gene.com/gene/contact/inquiries-info.html>) or 1-800-821-8590 for a response.

Rituxan
Rituximab

Medication Guide
RITUXAN (ri-tu-xan)
(rituximab)

Read the Medication Guide given to you before you start Rituxan and before each Rituxan infusion. The information may have changed. This Medication Guide does not take the place of talking to your doctor about your medical condition or your treatment. Talk with your doctor if you have any questions about your treatment with Rituxan.

What is the most important information I should know about Rituxan?

Rituxan can cause serious side effects including:

- **Progressive Multifocal Leukoencephalopathy (PML)**
PML is a rare brain infection. PML usually causes death or severe disability.
• Call your doctor right away if you notice any new or worsening medical problems, such as a new or sudden change in thinking, walking, strength, vision, or other problems that have lasted over several days.
• PML usually happens in patients with weakened immune systems.
• PML can occur during treatment with Rituxan or after treatment has finished.
• There is no known treatment, prevention, or cure for PML.
- **Infection reactions.** Tell your doctor or get medical treatment right away if you get fevers, swelling, dizziness, blurred vision, drowsiness, headache, cough, wheezing, or have trouble breathing while receiving or after receiving Rituxan.
- **Tumor Lysis Syndrome (TLS).** TLS is caused by the fast breakdown of certain types of cancer cells. TLS can cause kidney failure and the need for dialysis treatment. Patients receiving Rituxan for non-Hodgkin's lymphoma (NHL) may get TLS. Your doctor will check you for TLS.
- **Serious skin reactions.** Tell your doctor or get medical treatment right away if you get any of these symptoms: painful sores on your skin or in your mouth, sores, blisters, or peeling skin while receiving or after receiving Rituxan.

See "What are the possible side effects of Rituxan?" for other serious side effects.

What is Rituxan?

Rituxan is a prescription medicine used in adults:

- alone or with other anti-cancer medicines to treat certain types of NHL.
- with another medicine called methotrexate to reduce the signs and symptoms of Rheumatoid Arthritis (RA) after at least one other medicine called a tumor necrosis factor (TNF) inhibitor has been used and did not work well.

Rituxan has not been studied in children.

What should I tell my doctor before treatment with Rituxan?

Tell your doctor about all of your medical conditions, including if you:

- had a severe infusion reaction to Rituxan in the past.
- have an infection or have an infection that will not go away or that keeps coming back.
- have or had hepatitis (liver) infection. See "What are the possible side effects of Rituxan?" If so, your doctor should check you closely for signs of hepatitis infection during treatment with Rituxan and for several months after treatment ends.
- are scheduled to receive any vaccinations. You should not receive live vaccines after you receive Rituxan.
- have had or long problems.
- are pregnant or planning to become pregnant. It is not known if Rituxan can harm your unborn baby.
- are breastfeeding. It is not known if Rituxan passes into human breast milk. You should not breastfeed while being treated with Rituxan and after finishing treatment, and blood tests show that there is no Rituxan in your blood.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, or herbal supplements. If you have RA, especially tell your doctor if you take or have taken another medicine called a TNF inhibitor or a DMARD (disease modifying anti-rheumatic drug).

How do I receive Rituxan?

- Rituxan is given through a needle placed in a vein (IV or intravenous infusion), in your arm. Talk to your doctor about how you will receive Rituxan.
- Your doctor may prescribe medicines before each infusion of Rituxan to reduce side effect of infusions (such as fever and chills).
- Your doctor should do regular blood tests to check for side effects to Rituxan.

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- Your doctor should do regular blood tests to check for side effects to Rituxan.

Before each Rituxan treatment, your doctor or nurse will ask you questions about your general health to make sure that Rituxan is still right for you. Tell your doctor or nurse about any new symptoms and symptoms that get worse over a few days or that will not go away.

What are the possible side effects of Rituxan?

The “**What is the most important information I should know about Rituxan?**” section lists certain serious and life-threatening side effects with Rituxan. Rituxan can cause other serious and life-threatening side effects, including:

- **Hepatitis B virus reactivation.** Tell your doctor if you had hepatitis B virus or are a carrier of hepatitis B virus. Receiving Rituxan could cause the hepatitis B virus to become an active infection again. This may cause serious liver problems and death. People with active liver disease due to hepatitis B should stop receiving Rituxan.
- **Heart problems.** Tell your doctor about any heart problems you have including chest pain (angina) and irregular heart beats. Rituxan can cause chest pain and irregular heart beats which may require treatment.
- **Infections.** Rituxan can increase your chances for getting infections. Call your doctor right away if you have a cough that will not go away, fever, chills, congestion, or any flu-like symptoms while receiving Rituxan. These symptoms may be signs of a serious infection.
- **Stomach and bowel problems.** Serious stomach and bowel problems have been seen when Rituxan has been used with anti-cancer medicines in some patients with non-Hodgkin’s lymphoma. Call your doctor right away if you have any stomach area pain during treatment with Rituxan.

Common side effects during Rituxan infusions include:

- fever
- headache
- chills and shakes
- nausea
- itching
- hives
- cough
- sneezing
- throat irritation or tightness

Other side effects with Rituxan include:

- aching joints
- upper respiratory tract infection
- decreased blood cell counts
- lung problems

Tell your doctor about any side effect that bothers you or that does not go away. These are not all of the possible side effects with Rituxan. Ask your doctor for more information.

General Information about Rituxan

This Medication Guide provides a summary of the most important information about Rituxan. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information or have any questions, talk with your doctor. You can ask your doctor for information about Rituxan that is written for healthcare professionals. You can also visit www.Rituxan.com or call 1-877-474-8892.

What are the ingredients in Rituxan?

Active ingredient: rituximab

Inactive ingredients: sodium chloride, sodium citrate dihydrate, polysorbate 80, and water for injection.

Jointly Marketed by: Biogen Idec Inc. and Genentech USA, Inc.

Manufactured by:

Genentech, Inc.

1 DNA Way

South San Francisco, CA 94080-4990



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This Medication Guide has been approved by the U.S. Food and Drug Administration.