

810 **17.2 Medication Guide**

811 **MEDICATION GUIDE**
812 **RITUXAN[®] (ri-tuk'-san)**
813 **(rituximab)**

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

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

819 Rituxan can cause serious side effects including:

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

838 See **“What are possible side effects with Rituxan?”** for other serious side effects.

839 **What is Rituxan?**

840 Rituxan is a prescription medicine used in adults:

- 841 • alone or with other anti-cancer medicines to treat certain types of NHL.
- 842 • with another medicine called methotrexate to reduce the signs and symptoms of moderately to
843 severely active Rheumatoid Arthritis (RA) after at least one other medicine called a Tumor
844 Necrosis Factor (TNF) antagonist has been used and did not work well.

845 Rituxan has not been studied in children.

846 **What should I tell my doctor before treatment with Rituxan?**

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

- 848 • had a severe infusion reaction to Rituxan in the past.
- 849 • have an infection or have an infection that will not go away or that keeps coming back.
- 850 • have or had hepatitis (liver) infection. See **“What are the possible side effects of Rituxan?”** If
851 so, your doctor should check you closely for signs of hepatitis infection during treatment with
852 Rituxan and for several months after treatment ends.

- 853 • are scheduled to receive any vaccinations. You should not receive live vaccines after you
854 receive Rituxan.
- 855 • have heart or lung problems.
- 856 • are pregnant or planning to become pregnant. It is not known if Rituxan can harm your unborn
857 baby.
- 858 • are breastfeeding. It is not known if Rituxan passes into human breast milk. You should not
859 breastfeed while being treated with Rituxan and after finishing treatment, until blood tests show
860 that there is no Rituxan in your blood.

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

865 **How do I receive Rituxan?**

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

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

874 **What are the possible side effects of Rituxan?**

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

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

892 **Common side effects during Rituxan infusions include:**

- 893 • fever • headache
- 894 • chills and shakes • nausea
- 895 • itching • hives
- 896 • cough • sneezing
- 897 • throat irritation or tightness

898 Other side effects with Rituxan include:

- 899 • aching joints
- 900 • upper respiratory tract infection
- 901 • decreased blood cell counts
- 902 • lung problems

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

905 **General Information about Rituxan**

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

911 **What are the ingredients in Rituxan?**

912 Active ingredient: rituximab

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

915
916 Jointly Marketed by: Biogen Idec Inc. and Genentech USA, Inc.

917
918 Manufactured by:

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