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MEDICATION GUIDE
Rituxan® (ri-tuk-san)
(rituximab)
for injection

Read this Medication Guide before you start Rituxan and before each Rituxan infusion. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or your treatment.

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

Rituxan can cause serious side effects that can lead to death, including:

- 1. Infusion reactions.** Infusion reactions are the most common side effect of Rituxan treatment. Serious infusion reactions can happen during your infusion or within 24 hours after your infusion of Rituxan. Your doctor should give you medicines before your infusion of Rituxan to decrease your chance of having a severe infusion reaction.

Tell your doctor or get medical help right away if you get any of these symptoms during or after an infusion of Rituxan:

- hives (red itchy welts) or rash
- itching
- swelling of your lips, tongue, throat or face
- sudden cough
- shortness of breath, difficulty breathing, or wheezing
- weakness
- dizziness or feel faint
- palpitations (feel like your heart is racing or fluttering)
- chest pain

- 2. Progressive Multifocal Leukoencephalopathy (PML).** PML is a rare, serious brain infection caused by a virus. People with weakened immune systems can get PML. Your chance of getting PML may be higher if you are treated with Rituxan alone or with other medicines that weaken your immune system. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML.

Tell your doctor right away if you have any of the following symptoms or if anyone close to you notices these symptoms:

- confusion or problems thinking
- loss of balance
- change in the way you walk or talk
- decreased strength or weakness on one side of your body
- blurred vision or loss of vision

- 3. Tumor Lysis Syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. TLS can cause you to have:

- kidney failure and the need for dialysis treatment
- abnormal heart rhythm

1059 Your doctor may do blood tests to check you for TLS. Your doctor may give you medicine to
1060 help prevent TLS.

1061 **4. Severe skin and mouth reactions.** Tell your doctor or get medical help right away if you get
1062 any of these symptoms at anytime during your treatment with Rituxan:

- 1063 • painful sores or ulcers on your skin, lips or in your mouth
- 1064 • blisters
- 1065 • peeling skin
- 1066 • rash
- 1067 • pustules

1068 See “**What are possible side effects of Rituxan?**” for more information about side effects.

1069 **What is Rituxan?**

1070 Rituxan is a prescription medicine used to treat:

- 1071 • **Non-Hodgkin’s Lymphoma (NHL):** alone or with other chemotherapy medicines.
- 1072 • **Chronic Lymphocytic Leukemia (CLL):** with the chemotherapy medicines fludarabine and
1073 cyclophosphamide.
- 1074 • **Rheumatoid Arthritis (RA):** with another prescription medicine called methotrexate, to reduce
1075 the signs and symptoms of moderate to severe active RA in adults, after treatment with at least
1076 one other medicine called a Tumor Necrosis Factor (TNF) antagonist has been used and did not
1077 work well enough.
- 1078 • **Wegener’s Granulomatosis (WG) and Microscopic Polyangiitis (MPA):** with
1079 glucocorticoids, to treat WG and MPA.

1080 People with serious infections should not receive Rituxan.

1081 It is not known if Rituxan is safe or effective in children.

1082

1083 **What should I tell my doctor before receiving Rituxan?**

1084 Before receiving Rituxan, tell your doctor if you:

- 1085 • have had a severe infusion reaction to Rituxan in the past
- 1086 • have a history of heart problems, irregular heart beat or chest pain
- 1087 • have lung or kidney problems
- 1088 • have an infection or weakened immune system.
- 1089 • have or have had any severe infections including:
 - 1090 • Hepatitis B virus (HBV)
 - 1091 • Hepatitis C virus (HCV)
 - 1092 • Cytomegalovirus (CMV)
 - 1093 • Herpes simplex virus (HSV)
 - 1094 • Parvovirus B19
 - 1095 • Varicella zoster virus (chickenpox or shingles)
 - 1096 • West Nile Virus

- 1097 • have had a recent vaccination or are scheduled to receive vaccinations. You should not receive
1098 certain vaccines before or after you receive Rituxan. Tell your doctor if anyone in your
1099 household is scheduled to receive a vaccination. Some types of vaccines can spread to people
1100 with a weakened immune system, and cause serious problems.
- 1101 • have taken Rituxan for WG or MPA in the past.
- 1102 • have any other medical conditions
- 1103 • are pregnant or planning to become pregnant. Rituxan may affect the white blood cell counts of
1104 your unborn baby. It is not known if Rituxan may harm your unborn baby in other ways.
1105 Women who are able to become pregnant should use effective birth-control (contraception)
1106 while using Rituxan and for 12 months after you finish treatment. Talk to your doctor about
1107 effective birth control.
- 1108 • are breast-feeding or plan to breast-feed. It is not known if Rituxan passes into your breast milk.
1109 You and your doctor should decide the best way to feed your baby if you receive Rituxan.

1110 Tell your doctor about all the medicines you take, including prescription and nonprescription
1111 medicines, vitamins, and herbal supplements. Especially tell your doctor if you take or have taken:

- 1112 • a Tumor Necrosis Factor (TNF) inhibitor medicine
- 1113 • a Disease Modifying Anti-Rheumatic Drug (DMARD)

1114 If you are not sure if your medicine is one listed above, ask your doctor or pharmacist.

1115 Know the medicines you take. Keep a list of them to show to your doctor and pharmacist when you
1116 get a new medicine. Do not take any new medicine without talking with your doctor.

1117 **How will I receive Rituxan?**

- 1118 • Rituxan is given by infusion through a needle placed in a vein (intravenous infusion), in
1119 your arm. Talk to your doctor about how you will receive Rituxan.
- 1120 • Your doctor may prescribe medicines before each infusion of Rituxan to reduce side effects
1121 of infusions such as fever and chills.
- 1122 • Your doctor should do regular blood tests to check for side effects to Rituxan.

1123 Before each Rituxan treatment, your doctor or nurse will ask you questions about your general
1124 health. Tell your doctor or nurse about any new symptoms.

1125 **What are the possible side effects of Rituxan?**

1126 Rituxan can cause serious and life-threatening side effects, including:

1127 See **“What is the most important information I should know about Rituxan?”**

- 1128 • **Hepatitis B virus (HBV) reactivation.** If you have had hepatitis B or are a carrier of hepatitis B
1129 virus, receiving Rituxan could cause the virus to become an active infection again. Hepatitis B
1130 reactivation may cause serious liver problems including liver failure, and death. You should not
1131 receive Rituxan if you have active hepatitis B liver disease. Your doctor should monitor you for
1132 hepatitis B infection during and for several months after you stop receiving Rituxan.
1133
- 1134 • **Serious infections.** Serious infections can happen during and after treatment with Rituxan, and
1135 can lead to death. Rituxan can lower the ability of your immune system to fight infections.
1136 Types of serious infections that can happen with Rituxan include bacterial, fungal, and viral
1137 infections. After receiving Rituxan, some patients have developed low levels of certain
1138 antibodies in their blood for a long period of time (longer than 11 months). Some of these

1139 patients with low antibody levels developed infections. Call your doctor right away if you have
1140 any symptoms of infection:

- 1141 o fever
- 1142 o cold symptoms, such as runny nose or sore throat that do not go away
- 1143 o flu symptoms, such as cough, tiredness, and body aches
- 1144 o earache or headache
- 1145 o pain during urination
- 1146 o white patches in the mouth or throat
- 1147 o cuts, scrapes or incisions that are red, warm, swollen or painful
- 1148 • **Heart problems.** Rituxan may cause chest pain and irregular heart beats which may need
1149 treatment, or your doctor may decide to stop your treatment with Rituxan.
- 1150 • **Kidney problems,** especially if you are receiving Rituxan for NHL. Your doctor should do
1151 blood tests to check how well your kidneys are working.
- 1152 • **Stomach and Serious bowel problems that can sometimes lead to death.** Bowel problems,
1153 including blockage or tears in the bowel can happen if you receive Rituxan with chemotherapy
1154 medicines to treat non-Hodgkin’s lymphoma. Tell your doctor right away if you have any
1155 stomach area pain during treatment with Rituxan.
- 1156 • **Low blood cell counts.** Your doctor may do blood tests during treatment with Rituxan to check
1157 your blood cell counts.
 - 1158 o **White blood cells.** White blood cells fight against bacterial infections. Low white
1159 blood cells can cause you to get infections, which may be serious. See “Increased
1160 risk of infections” above for a list of symptoms of infection.
 - 1161 o **Red blood cells.** Red blood cells carry oxygen to your body tissues and organs.
 - 1162 o **Platelets.** Platelets are blood cells that help your blood to clot.

1163 **Common side effects during Rituxan treatment include:**

- 1164 • infusion reactions (see What is the most important information I should know about Rituxan?)
- 1165 • chills
- 1166 • infections
- 1167 • body aches
- 1168 • tiredness
- 1169 • low white blood cells

1170 Other side effects with Rituxan include:

- 1171 • aching joints during or within hours of receiving an infusion
- 1172 • more frequent upper respiratory tract infection

1173 Tell your doctor about any side effect that bothers you or that does not go away.

1174 These are not all of the possible side effects with Rituxan. For more information, ask your doctor or
1175 pharmacist.

1176 Call your doctor for medical advice about side effects. You may report side effects to FDA at
1177 1-800-FDA-1088.

1178 **General information about Rituxan**

1179 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This
1180 Medication Guide provides a summary of the most important information about Rituxan. If you
1181 would like more information, talk with your doctor. You can ask your doctor for information about
1182 Rituxan that is written for healthcare professionals.

1183 For more information, go to www.Rituxan.com or call 1-877-474-8892.

1184 **What are the ingredients in Rituxan?**

1185 Active ingredient: rituximab

1186 Inactive ingredients: sodium chloride, sodium citrate dihydrate, polysorbate 80, and water for
1187 injection.

1188 This Medication Guide has been approved by the U.S. Food and Drug Administration.

1189 Jointly Marketed by: Biogen Idec Inc. and Genentech USA, Inc.
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RITUXAN[®] [rituximab]

Manufactured by:

10134808

Genentech, Inc.

Initial US Approval: November 1997

A Member of the Roche Group

Med Guide Revision Date: February 2012

1 DNA Way

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