

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

Rituxan®
(Rituximab)

Manufactured by: 4835500

Genentech, Inc. Initial US Approval November 26, 1997

1 DNA Way

South San Francisco, CA 94080-4990

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Patient Information

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Rituxan® (ri-tuk'-san)

1051

(Rituximab)

1052 Read this patient information leaflet when you have been prescribed

1053 Rituxan and each time you are scheduled to receive a Rituxan infusion.

1054 This information does not take the place of talking to your doctor about

1055 your medical condition or your treatment. Talk with your doctor if you

1056 have any questions about your treatment with Rituxan.

1057 **What is the most important safety information I should know about**

1058 **Rituxan?**

1059 **Rituxan can cause the following serious side effects, some of which**

1060 **could be life-threatening:**

1061 • **Infusion reactions.** Tell your doctor or get medical treatment right
1062 away if you get hives, swelling, dizziness, blurred vision, drowsiness,
1063 headache, cough, wheezing, or have trouble breathing while receiving
1064 or after receiving Rituxan.

1065 • **Tumor Lysis Syndrome (TLS).** TLS is caused by the fast
1066 breakdown of certain blood cancers. TLS can cause kidney failure
1067 and the need for dialysis treatment. Patients receiving Rituxan for
1068 non-Hodgkin's lymphoma may get TLS.

1069 • **Severe skin reactions.** Tell your doctor or get medical treatment
1070 right away if you get painful sores, ulcers, blisters, or peeling skin
1071 while receiving or after receiving Rituxan.

- 1072 • **Progressive Multifocal Leukoencephalopathy (PML).** PML is a
1073 rare brain infection that usually causes death or severe disability.
- 1074 • PML has been reported in patients during or after their treatment with
1075 Rituxan.
- 1076 • There is no known treatment, prevention, or cure for PML.
- 1077 • Call your doctor right away if you notice any new or worsening
1078 medical problems, such as a new or sudden change in thinking,
1079 walking, strength, vision, or other problems that have lasted over
1080 several days.

1081 Also, see “What are possible side-effects with Rituxan?” for other serious
1082 side effects, some of which could be life-threatening.

1083 **What is Rituxan?**

1084 Rituxan is a biologic medicine used in adults:

- 1085 • alone or with other anti-cancer medicines to treat certain types of
1086 non-Hodgkin’s lymphoma (NHL).
- 1087 • with another medicine called methotrexate to reduce the signs and
1088 symptoms of Rheumatoid Arthritis (RA) after at least one other
1089 medicine called a tumor necrosis factor (TNF) inhibitor has been used
1090 and did not work well.

1091 Rituxan has not been studied in children.

1092 **How does Rituxan work?**

1093 Rituxan works by getting rid of certain B-cells in the blood. B-cells are a
1094 type of white blood cell found in the blood. B-cells usually help the body
1095 fight infection. B-cells play an important role in diseases such as NHL
1096 and RA. Rituxan may also get rid of healthy B-cells and this can give you
1097 a higher chance for getting infections.

1098 **Who should not receive Rituxan?**

1099 Do not receive Rituxan if you ever had an allergic reaction to Rituxan.

1100 **What should I tell my doctor before treatment with Rituxan?**

1101 Tell your doctor about all of your medical conditions, including if you:

- 1102 • have an infection or have an infection that will not go away or that
1103 keeps coming back.
- 1104 • are scheduled to have surgery.
- 1105 • have had hepatitis B virus infection or are a carrier of hepatitis B
1106 virus. Your doctor should check you closely for signs of a hepatitis
1107 infection during treatment with Rituxan and for several months after
1108 treatment ends.
- 1109 • have any scheduled vaccinations. It is not known if Rituxan affects
1110 your ability to respond to vaccines.
- 1111 • have heart or lung problems.
- 1112 • are pregnant or planning to become pregnant. It is not known if
1113 Rituxan can harm your unborn baby.
- 1114 • are breastfeeding. It is not known if Rituxan passes into human breast
1115 milk. You should not breastfeed while being treated with Rituxan.

1116 Tell your doctor about all the other medicines you take, including
1117 prescription and nonprescription medicines, vitamins, or herbal
1118 supplements. If you have RA, tell your doctor if you are taking or took
1119 another biologic medicine called a TNF inhibitor or a DMARD (disease
1120 modifying anti-rheumatic drug).

1121 **How do I receive Rituxan?**

- 1122 • Rituxan is given through a needle placed in a vein (IV infusion), in
1123 your arm. Rituxan therapy is given in different ways for NHL and
1124 RA. Talk to your doctor about how you will receive Rituxan.
- 1125 • Your doctor may prescribe other medicines before each infusion of
1126 Rituxan to prevent or reduce pain, or to reduce fever and allergic
1127 reactions.
- 1128 • Your doctor should do regular blood tests to check for side effects or
1129 reactions to Rituxan.

1130 **What are possible side effects with Rituxan?**

1131 Rituxan can cause the following serious side effects, some of which could
1132 be life-threatening side effects, including (See “What is the most
1133 important safety information I should know about Rituxan?”)

- 1134 • Infusion reactions
- 1135 • Tumor Lysis Syndrome (TLS)
- 1136 • Severe skin reactions
- 1137 • **Progressive Multifocal Leukoencephalopathy (PML)**

1138 **Other serious side effects with Rituxan include:**

- 1139 • **Hepatitis B virus reactivation.** Tell your doctor if you had
1140 Hepatitis B virus or are a carrier of Hepatitis B virus. Rituxan may
1141 make you sick with Hepatitis B virus again and cause serious liver
1142 problems. People with active liver disease due to Hepatitis B should
1143 stop receiving Rituxan.
- 1144 • **Heart Problems.** Tell your doctor about any heart problems you
1145 have including chest pain (angina) and irregular heart beats. Rituxan
1146 can cause chest pain and irregular heart beats which may require
1147 treatment.
- 1148 • **Infections.** Rituxan can increase your chances for getting infections.
1149 Call your doctor right away if you have a persistent cough, fever,
1150 chills, congestion, or any flu-like symptoms while receiving Rituxan.
1151 These symptoms may be signs of a serious infection.
- 1152 • **Stomach and bowel problems.** Serious stomach and bowel
1153 problems have been seen when Rituxan has been used with
1154 anti-cancer medicines in some patients with non-Hodgkin’s
1155 lymphoma. Call your doctor right away if you have any stomach area
1156 pain during treatment with Rituxan.

1157 **Common side effects with Rituxan include:**

1158 Fever, chills, shakes, itching, hives, sneezing, swelling, throat irritation or
1159 tightness, and cough. These usually occur within 24 hours after the first
1160 infusion. Other common side effects include headache, nausea, upper

1161 respiratory tract infection, and aching joints. If you have any of these
1162 symptoms, tell your doctor or nurse.

1163 **What if I still have questions?**

1164 If you have any questions about Rituxan or your health, talk with your
1165 doctor. You can also visit the Rituxan internet sites at www.Rituxan.com
1166 or the companies' internet sites at www.Gene.com or
1167 www.Biogenidec.com or call 1-877-4-Rituxan (877-474-8892).

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