MEDICATION GUIDE

RITUXAN® (ri tuk san)
(rituximab)
injection

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

RITUXAN can cause serious side effects that can lead to death including:

- **Infusion-related reactions.** Infusion-related reactions are very common side effects of RITUXAN treatment. Serious infusion-related reactions can happen during your or your child's infusion or within 24 hours after your or your child's infusion of RITUXAN. Your healthcare provider should give you or your child medicines before your or your child's infusion of RITUXAN to decrease your or your child's chance of having a severe infusion-related reaction.

  Tell your healthcare provider or get medical help right away if you or your child 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

- **Severe skin and mouth reactions.** Tell your healthcare provider or get medical help right away if you or your child get any of these symptoms at any time during your treatment with RITUXAN:

  - painful sores or ulcers on your skin, lips or in your mouth
  - blisters
  - peeling skin
  - rash
  - pustules

- **Hepatitis B virus (HBV) reactivation.** Before you or your child receive RITUXAN treatment, your healthcare provider will do blood tests to check for HBV infection. If you or your child have had hepatitis B or are a carrier of hepatitis B virus, receiving RITUXAN could cause the virus to become an active infection again. Hepatitis B reactivation may cause serious liver problems including liver failure, and death. You or your child should not receive RITUXAN if you or your child have active hepatitis B liver disease. Your healthcare provider will monitor you or your child for hepatitis B infection during and for several months after you or your child stop receiving RITUXAN.

  Tell your healthcare provider right away if you or your child get worsening tiredness, or yellowing of your or your child's skin or white part of your eyes, during treatment with RITUXAN.

- **Progressive Multifocal Leukoencephalopathy (PML).** PML is a rare, serious brain infection caused by a virus that can happen in people who receive RITUXAN. People with weakened immune systems can get PML. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML.

  Tell your healthcare provider right away if you or your child have any new or worsening symptoms or if anyone close to you notices these symptoms:

  - confusion
  - dizziness or loss of balance
  - difficulty walking or talking
  - decreased strength or weakness on one side of your body
  - vision problems

See **"What are the possible side effects of RITUXAN?"** for more information about side effects.

What is RITUXAN?

RITUXAN is a prescription medicine used to treat:

- Adults with Non-Hodgkin's Lymphoma (NHL): alone or with other chemotherapy medicines.
- Children 6 months of age and older with mature B-cell Non-Hodgkin's Lymphoma (NHL) and mature B-cell acute leukemia (B-AL): in combination with chemotherapy medicines.
- Adults with Chronic Lymphocytic Leukemia (CLL): with the chemotherapy medicines fludarabine and cyclophosphamide.
- Adults with Rheumatoid Arthritis (RA): with another prescription medicine called methotrexate, to reduce the signs and symptoms of moderate to severe active RA in adults, after treatment with at least one other medicine called a Tumor Necrosis Factor (TNF) antagonist has been used and did not work well
- Adults and children 2 years of age and older with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA): with glucocorticoids, to treat GPA and MPA.
- Adults with Pemphigus Vulgaris (PV): to treat moderate to severe PV.

RITUXAN is not indicated in children less than 2 years of age with GPA or MPA, in children less than 6 months of age with mature B-cell NHL and B-AL, or in children with conditions other than GPA, MPA, B-cell NHL and B-AL.

Before you or your child receive RITUXAN, tell your healthcare provider about all of your or your child's medical conditions, including if you or your child:

- have had a severe reaction to RITUXAN or a rituximab product
- have a history of heart problems, irregular heart beat or chest pain
- have lung or kidney problems
- have an infection or weakened immune system
- have or have had any severe infections including:
  - Hepatitis B virus (HBV)
  - Hepatitis C virus (HCV)
  - Cytomegalovirus (CMV)
  - Herpes simplex virus (HSV)
  - Parvovirus B19
  - Varicella zoster virus (chickenpox or shingles)
  - West Nile Virus
- have had a recent vaccination or are scheduled to receive vaccinations. You or your child should not receive certain vaccines before or during treatment with RITUXAN.
- are pregnant or plan to become pregnant. Talk to your healthcare provider about the risks to your or your child's unborn baby if you or your child receive RITUXAN during pregnancy.

  Females who are able to become pregnant:

  - Your healthcare provider should do a pregnancy test to see if you or your child are pregnant before starting RITUXAN.
  - You or your child should use effective birth control (contraception) during treatment with RITUXAN and for **12 months** after your or your child's last dose of RITUXAN. Talk to your healthcare provider about effective birth control.
  - Tell your healthcare provider right away if you or your child become pregnant or think that you or your child are pregnant during treatment with RITUXAN.
- are breastfeeding or plan to breastfeed. RITUXAN may pass into your breast milk. Do not breastfeed during treatment and for **6 months** after your or your child's last dose of RITUXAN.

Tell your healthcare provider about all the medicines you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you or your child take or have taken:

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

If you are not sure if your or your child's medicine is one listed above, ask your healthcare provider.

How will I receive RITUXAN?

- RITUXAN is given by infusion through your or your child's central catheter or through a needle placed in a vein (intravenous infusion), in your or your child's arm. Talk to your healthcare provider about how you or your child will receive RITUXAN.
- Your healthcare provider may prescribe medicines before each infusion of RITUXAN to reduce infusion side effects such as fever and chills.
- Your healthcare provider should do blood test regularly to check for side effects to RITUXAN.
- Before each RITUXAN treatment, your healthcare provider or nurse will ask you questions about your or your child's general health. Tell your healthcare provider or nurse about any new symptoms.

What are the possible side effect of RITUXAN?

RITUXAN can cause serious side effects, including:

- See "What is the most important information I should know about RITUXAN?"
- **Tumor Lysis Syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. TLS can cause you or your child to have:
  - kidney failure and the need for dialysis treatment
  - abnormal heart rhythm

  TLS can happen within 12 to 24 hours after an infusion of RITUXAN. Your healthcare provider may do blood tests to check you or your child for TLS. Your healthcare provider may give you or your child medicine to help prevent TLS.

  Tell your healthcare provider right away if you or your child have any of the following signs or symptoms or TLS:
  - nausea
  - vomiting
  - diarrhea
  - lack of energy
- **Serious infections.** Serious infections can happen during and after treatment with RITUXAN, and can lead to death. RITUXAN can increase your or your child's risk of getting infections and can lower the ability of your or your child's immune system to fight infections. Types of serious infections that can happen with RITUXAN include bacterial, fungal, and viral infections. After receiving RITUXAN, some people have developed low levels of certain antibodies in their blood for a long period of time (longer than 11 months). Some of these people with low antibody levels developed infections. People with serious infections should not receive RITUXAN. Tell your healthcare provider right away if you or your child have any symptoms of infection:
  - fever
  - cold symptoms, such as runny nose or sore throat that do not go away
  - flu symptoms, such as cough, tiredness, and body aches
  - earache or headache
  - pain during urination
  - cold sores in the mouth or throat
  - cuts, scrapes or incisions that are red, warm, swollen or painful
- **Heart problems.** RITUXAN may cause chest pain, irregular heartbeats, and heart attack. Your healthcare provider may monitor your or your child's heart during and after treatment with RITUXAN if you or your child have symptoms or heart problems or have a history of heart problems. Tell your healthcare provider right away if you or your child have chest pain or irregular heartbeats during treatment with RITUXAN.
- **Kidney problems**, especially if you or your child are receiving RITUXAN for NHL. RITUXAN can cause severe kidney problems that lead to death. Your healthcare provider should do blood tests to check how well your or your child's kidneys are working.
- **Stomach and Serious bowel problems that can sometimes lead to death**. Bowel problems, including blockage or tears in the bowel can happen if you or your child receive RITUXAN with chemotherapy medicines. Tell your healthcare provider right away if you or your child have any severe stomach-area (abdomen) pain or repeated vomiting during treatment with RITUXAN.

Your healthcare provider will stop treatment with RITUXAN if you have severe, serious or life-threatening side effects.

The most common side effects of RITUXAN include:

- infusion-related reactions (see **"What is the most important information I should know about RITUXAN?"**)
- infections (may include fever, chills)
- body aches
- tiredness
- nausea

In adults with GPA or MPA the most common side effects of RITUXAN also include:

- low white and red blood cells
- swelling
- diarrhea
- muscle spasms

In children with B-cell NHL or B-AL who receive RITUXAN with chemotherapy, the most common side effects include:

- decreased white blood cells with fever
- mouth sores
- inflammation of the upper intestine
- serious infection throughout the body and organs (sepsis)

- changes in liver function blood tests
- low level of potassium in the blood

Other side effects with RITUXAN include:

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

These are not all of the possible side effects with RITUXAN.

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

General information about the safe and effective use of RITUXAN.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about RITUXAN that is written for healthcare providers.

What are the ingredients in RITUXAN?

Active ingredient: rituximab

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

Manufactured by: Genentech, Inc., A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990
Jointly Marketed by Biogen and Genentech USA, Inc.
U.S. License Number: 1048

For more information, go to www.RITUXAN.com or call 1-877-436-3683.

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