

MEDICATION GUIDE

RIABNI™ (re AB nee)

(rituximab-arrx)

injection

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

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

- **Infusion-related reactions.** Infusion-related reactions are very common side effects of RIABNI treatment. Serious infusion-related reactions can happen during your infusion or within 24 hours after your infusion of RIABNI. Your healthcare provider should give you medicines before your infusion of RIABNI to decrease your chance of having a severe infusion-related reaction.
Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an infusion of RIABNI:
 - 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 get any of these symptoms at any time during your treatment with RIABNI:
 - painful sores or ulcers on your skin, lips or in your mouth
 - blisters
 - peeling skin
 - rash
 - pustules
- **Hepatitis B virus (HBV) reactivation.** Before you receive your RIABNI treatment, your healthcare provider will do blood tests to check for HBV infection. If you have had hepatitis B or are a carrier of hepatitis B virus, receiving RIABNI could cause the virus to become an active infection again. Hepatitis B reactivation may cause serious liver problems including liver failure, and death. You should not receive RIABNI if you have active hepatitis B liver disease. Your healthcare provider will monitor you for hepatitis B infection during and for several months after you stop receiving RIABNI.
Tell your healthcare provider right away if you get worsening tiredness, or yellowing of your skin or white part of your eyes, during treatment with RIABNI.
- **Progressive Multifocal Leukoencephalopathy (PML).** PML is a rare, serious brain infection caused by a virus that can happen in people who receive RIABNI. 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 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 RIABNI?” for more information about side effects.

What is RIABNI?

RIABNI is a prescription medicine used to treat:

- Adults with Non-Hodgkin’s Lymphoma (NHL): alone or with other 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 with Granulomatosis with Polyangiitis (GPA) (Wegener’s Granulomatosis) and Microscopic Polyangiitis (MPA): with glucocorticoids, to treat GPA and MPA.

RIABNI is not indicated for treatment of children.

Before you receive RIABNI, tell your healthcare provider about all of your medical conditions, including if you:

- have had a severe reaction to RIABNI or another 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 should not receive certain vaccines before or during treatment with RIABNI.
- are pregnant or plan to become pregnant. Talk to your healthcare provider about the risks to your unborn baby if you receive RIABNI during pregnancy.

Females who are able to become pregnant:

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

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you 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 medicine is one listed above, ask your healthcare provider.

How will I receive RIABNI?

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

What are the possible side effects of RIABNI?

RIABNI can cause serious side effects, including:

- See “**What is the most important information I should know about RIABNI?**”
- **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

TLS can happen within 12 to 24 hours after an infusion of RIABNI. Your healthcare provider may do blood tests to check you for TLS. Your healthcare provider may give you medicine to help prevent TLS. Tell your healthcare provider right away if you 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 RIABNI, and can lead to death. RIABNI can increase your risk of getting infections and can lower the ability of your immune system to fight infections. Types of serious infections that can happen with RIABNI include bacterial, fungal, and viral infections. After receiving RIABNI, 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 RIABNI. Tell your healthcare provider right away if you 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.** RIABNI may cause chest pain, irregular heartbeats, and heart attack. Your healthcare provider may monitor your heart during and after treatment with RIABNI if you have symptoms of heart problems or have a history of heart problems. Tell your healthcare provider right away if you have chest pain or irregular heartbeats during treatment with RIABNI.
- **Kidney problems,** especially if you are receiving RIABNI for NHL. RIABNI can cause severe kidney problems that lead to death. Your healthcare provider should do blood tests to check how well your 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 receive RIABNI with chemotherapy medicines. Tell your healthcare provider right away if you have any severe stomach-area (abdomen) pain or repeated vomiting during treatment with RIABNI.

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

The most common side effects of RIABNI include:

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

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

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

Other side effects with RIABNI 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 RIABNI.

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 RIABNI.

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 RIABNI that is written for healthcare providers.

What are the ingredients in RIABNI?

Active ingredient: rituximab-arrx

Inactive ingredients: polysorbate 80, sodium chloride, sodium citrate dihydrate, and Water for Injection, USP.

Hydrochloric acid is used to adjust the buffer solution pH.

Manufactured by: Amgen, Inc., One Amgen Center Drive, Thousand Oaks, CA 91320-1799

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For more information, go to www.RIABNI.com or call 1-805-447-1000.

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