

DRUG INFORMATION: RITUXIMAB (ri tux' i mab) INJECTION

IMPORTANT WARNING: Some people who received rituximab experienced severe reactions to the medication. Some of these people died within 24 hours after they received a dose of rituximab. Most of these deaths happened after the first dose of rituximab. Tell your doctor if you have or have ever had chronic lymphocytic leukemia (CLL; a type of cancer that begins in the white blood cells), mantle cell lymphoma (a fast-growing cancer that begins in the cells of the immune system), an irregular heartbeat, or heart or lung disease. If you have any of these conditions, or if you are female, there is a greater chance that you will experience a serious reaction to rituximab. If you experience any of the following symptoms, tell your doctor or other health care provider immediately: hives; swelling of the lips, tongue, or throat; difficulty breathing or swallowing; dizziness; fainting; shortness of breath, wheezing; blurred vision; headache; pounding or irregular heartbeat; fast or weak pulse; loss of consciousness, fast breathing; pale or bluish skin; pain in the chest that may spread to other parts of the upper body; weakness; excessive tiredness; sweating; or anxiety. When rituximab is used to treat non-Hodgkin's lymphoma (NHL; a type of cancer that begins in a type of white blood cells that normally fight infection) it may cause a condition called tumor lysis syndrome (TLS; a group of symptoms caused by the fast breakdown of cancer cells). TLS may cause kidney failure and the need for dialysis treatment. Tell your doctor if you are also receiving cisplatin (Platinol). If you notice that you need to urinate less often than usual or that you produce less urine than usual, tell your doctor immediately. Rituximab has caused severe skin reactions. These reactions have caused death. If you experience any of the following symptoms, tell your doctor immediately: painful sores, ulcers, blisters, rash, or peeling skin. Some people who received rituximab developed progressive multifocal leukoencephalopathy (PML; a rare infection of the brain that cannot be treated, prevented, or cured and that usually causes death or severe disability) during or after their treatment. If you experience any of the following symptoms, call your doctor immediately: difficulty thinking clearly or walking, loss of strength, vision problems, or any other unusual symptoms that develop suddenly. Talk to your doctor about the risks of using rituximab.

Why is this medication prescribed?

Rituximab is used alone or with other medications to treat certain types of non-Hodgkin's lymphoma (NHL; a type of cancer that begins in a type of white blood cells that normally fights infection). Rituximab is also used with another medication to treat the symptoms of rheumatoid arthritis (RA; a condition in which the body attacks its own joints, causing pain, swelling, and loss of function) in people who have already been treated with a certain type of medication called a tumor necrosis factor (TNF) inhibitor. Rituximab is in a class of medications called biologic antineoplastic agents. It treats NHL by causing the death of blood cells that have multiplied abnormally. It treats rheumatoid arthritis by causing the death of certain blood cells that may cause the immune system to attack the joints.

How should this medicine be used?

Rituximab comes as a solution (liquid) to be injected into a vein. Rituximab is administered by a doctor or nurse in a medical office or infusion center. When rituximab is used to treat rheumatoid arthritis, it is usually given as 2 doses spaced 2 weeks apart. When rituximab is used to treat NHL it is either given once a week for 4-8 weeks or on the first day of each chemotherapy cycle. Your dosing schedule will depend on the condition that you have, the other medications you are using, and how well your body responds to treatment.

Rituximab must be given slowly. It may take several hours or longer to receive your first dose of rituximab, so you should plan to spend most of the day at the medical office or infusion center. After the first dose, you may receive your medication more quickly, depending on how you respond to treatment.

You may experience symptoms such as fever, shaking chills, tiredness, headache, or nausea while you are receiving a dose of rituximab, especially the first dose. Tell your doctor or other healthcare provider if you experience these symptoms while you are receiving your medication. Your doctor may prescribe other medications to help prevent or relieve these symptoms. Your doctor may tell you to take these medications before you receive each dose of rituximab. Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before using rituximab,

- tell your doctor and pharmacist if you are allergic to rituximab or any other medications.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medication in the IMPORTANT WARNING section and either of the following: medications for high blood pressure and other medications for rheumatoid arthritis. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have any of the conditions mentioned in the IMPORTANT WARNING section and if you have or have ever had hepatitis B or other viruses such as chicken pox, herpes (a virus that may cause cold sores or outbreaks of blisters in the genital area), West Nile virus (a virus that is spread through mosquito bites and may cause serious symptoms), or cytomegalovirus (a common virus that usually only causes serious symptoms in people who have weakened immune systems or who are infected at birth). Also tell your doctor if you have any type of infection now or if you have or have ever had an infection that would not go away or an infection that comes and goes.
- tell your doctor if you are pregnant or plan to become pregnant. Rituximab may harm the fetus. You should use birth control to prevent pregnancy during your treatment with rituximab and for up to 12 months after your treatment. Talk to your doctor about types of birth control that will work for you. If you become pregnant while using rituximab, call your doctor.
- tell your doctor if you are breast-feeding. You should not breast-feed during your treatment with rituximab or for some time after your treatment
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are using rituximab.
- you should know that you may be drowsy or dizzy after you receive a dose of rituximab. Do not drive a car or operate machinery until you know how this medication affects you. Plan to have someone else drive you home from the medical office or infusion center after you receive your treatment.
- ask your doctor whether you should receive any vaccinations before you begin your treatment with rituximab. Do not have any vaccinations during your treatment without talking to your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you miss an appointment to receive rituximab, call your doctor right away.

What side effects can this medication cause?

Rituximab may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- vomiting
- diarrhea
- heartburn
- weight gain
- muscle or back pain
- flushing
- night sweats
- tiredness
- weakness
- numbness, burning or tingling in the hands or feet
- runny nose

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- stomach area pain
- unusual bruising or bleeding
- sore throat, fever, chills, or other signs of infection
- chest tightness
- joint pain or soreness

Rituximab may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

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