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Rituximab Injection

pronounced as (ri tux' i mab)

Notice:

Rituximab injection, rituximab-abbs injection, and rituximab-pvvr injection are biologic medications (medications made from living organisms). Biosimilar rituximab-abbs injection and rituximab-pvvr injection are highly similar to rituximab injection and work the same way as rituximab injection in the body. Therefore, the term rituximab products will be used to represent these medications in this discussion.

IMPORTANT WARNING:

You may experience a serious reaction while you receive or within 24 hours after receiving a dose of a rituximab injection product. These reactions usually happen during the first dose of a rituximab injection product and may cause death. You will receive each dose of a rituximab injection product in a medical facility, and a doctor or nurse will monitor you carefully while you are receiving the medication. You will receive certain medications to help prevent an allergic reaction before you receive each dose of a rituximab injection product. Tell your doctor if you have ever had a reaction to a rituximab product or if you have or have ever had an irregular heartbeat, chest pain, other heart problems, or lung problems. If you experience any of the following symptoms, tell your doctor or other healthcare provider immediately: hives; rash; itching; swelling of the lips, tongue, or throat; difficulty breathing or swallowing; dizziness; fainting; shortness of breath, wheezing; headache; pounding or irregular heartbeat; fast or weak pulse; pale or bluish skin; pain in the chest that may spread to other parts of the upper body; weakness; or heavy sweating.

Rituximab injection products have caused severe, life-threatening skin and mouth reactions. If you experience any of the following symptoms, tell your doctor immediately: painful sores or ulcers on the skin, lips, or mouth; blisters; rash; or peeling skin.

You may already be infected with hepatitis B (a virus that infects the liver and may cause severe liver damage) but not have any symptoms of the disease. In this case, receiving a rituximab injection product may increase the risk that your infection will become more serious or life-threatening and you will develop symptoms. Tell your doctor if you have or ever had a severe

infection, including hepatitis B virus infection. Your doctor will order a blood test to see if you have an inactive hepatitis B infection. If necessary, your doctor may give you medication to treat this infection before and during your treatment with a rituximab injection product. Your doctor will also monitor you for signs of hepatitis B infection during and for several months after your treatment. If you experience any of the following symptoms during or after your treatment, call your doctor immediately: excessive tiredness, yellowing of the skin or eyes, loss of appetite, nausea or vomiting, muscle aches, stomach pain, or dark urine.

Some people who received a rituximab injection product 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: new or sudden changes in thinking or confusion; difficulty talking or walking; loss of balance; loss of strength; new or sudden changes in vision; or any other unusual symptoms that develop suddenly.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to a rituximab injection product.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with rituximab injection and each time you receive the medication. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of using a rituximab injection product.

Why is this medication prescribed?

Rituximab injection products are used alone or with other medications to treat various 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 injection products are also used with other medications to treat chronic lymphocytic leukemia (CLL; a type of cancer of the white blood cells). Rituximab injection (Rituxan) is also used with methotrexate (Otrexup, Rasuvo, Xatmep, others) 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 adults who have already been treated with a certain type of medication called a tumor necrosis factor (TNF) inhibitor. Rituximab injection (Rituxan, Ruxience) is also used in adults and children 2 years of age and older along with other medications to treat granulomatosis with polyangiitis (Wegener's Granulomatosis) and microscopic polyangiitis, which are conditions in which the body attacks its own veins and other blood vessels, which causes damage to organs, such as the heart and lungs. Rituximab injection (Rituxan) is used to treat pemphigus vulgaris (a condition that causes painful blisters on the skin and the lining the mouth, nose, throat and genitals). Rituximab injection products are in a class of medications called monoclonal antibodies. They treat the various types of NHL and CLL by

killing cancer cells. Certain rituximab injection products also treat rheumatoid arthritis, granulomatosis with polyangiitis, microscopic polyangiitis, and pemphigus vulgaris by blocking the activity of the part of the immune system that may damage the joints, veins, and other blood vessels.

How should this medicine be used?

Rituximab injection products come as a solution (liquid) to be injected into a vein. Rituximab injection products are administered by a doctor or nurse in a medical office or infusion center. 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 injection products must be given slowly into a vein. It may take several hours or longer to receive your first dose of a rituximab injection product, so you should plan to spend most of the day at the medical office or infusion center. After the first dose, you may receive a rituximab injection product 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 a rituximab product, 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 will tell you to take these medications before you receive each dose of a rituximab product.

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 receiving a rituximab injection product,

- tell your doctor and pharmacist if you are allergic to rituximab, rituximab-abbs, rituximab-pvvr, any other medications, or any of the ingredients in rituximab injection products. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- 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 any of the following: adalimumab (Humira); certolizumab (Cimzia); etanercept (Enbrel); golimumab (Simponi); infliximab (Remicade); other medications for rheumatoid arthritis; and medications that suppress the immune system such as azathioprine (Azasan, Imuran), cyclosporine (Gengraf, Neoral, Sandimmune), sirolimus (Rapamune, Torisel), and tacrolimus (Envarsus, Prograf). 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 C or other viruses such as chicken pox, herpes (a virus that may cause cold sores or outbreaks of blisters in the genital area), shingles, West Nile virus (a virus that is spread through mosquito bites and may cause serious symptoms), parvovirus B19 (fifth disease; a common virus in children that usually only causes serious problems in some adults), or cytomegalovirus (a common virus that usually only causes serious symptoms in people who have

weakened immune systems or who are infected at birth), or kidney disease. 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 if you plan to become pregnant. You should use birth control to prevent pregnancy during your treatment with a rituximab injection product and for 12 months after your final dose. Talk to your doctor about types of birth control that will work for you. If you become pregnant while using a rituximab injection product, call your doctor. Rituximab may harm the fetus.
- tell your doctor if you are breastfeeding. You should not breastfeed during your treatment with a rituximab injection product and for 6 months after your final dose.
- ask your doctor whether you should receive any vaccinations before you begin your treatment with a rituximab injection product. 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 a rituximab injection product, call your doctor right away.

What side effects can this medication cause?

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

- diarrhea
- back or joint pain
- flushing
- night sweats
- feeling unusually anxious or worried

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:

- unusual bruising or bleeding
- sore throat, runny nose, cough, fever, chills, or other signs of infection
- earache
- painful urination
- redness, tenderness, swelling or warmth of area of skin
- chest tightness

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

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Rituxan[®] (rituximab)
- Ruxience[®] (rituximab-pvvr)
- Truxima[®] (rituximab-abbs)

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