

MEDICATION GUIDE
TRUXIMA® (trux-ee'-mah)
(rituximab-abbs)
injection

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

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

- **Infusion-related reactions.** Infusion-related reactions are very common side effects of TRUXIMA treatment. Serious infusion-related reactions can happen during your infusion or within 24 hours after your infusion of TRUXIMA. Your healthcare provider should give you medicines before your infusion of TRUXIMA 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 TRUXIMA:
 - 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 TRUXIMA:
 - 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 TRUXIMA 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 TRUXIMA 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 TRUXIMA 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 TRUXIMA. 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 TRUXIMA.
- **Progressive Multifocal Leukoencephalopathy (PML).** PML is a rare, serious brain infection caused by a virus that can happen in people who receive TRUXIMA. 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 TRUXIMA?**” for more information about side effects.

What is TRUXIMA?

TRUXIMA is a prescription medicine used to treat adults with:

- 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 enough.
- Adults with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA): with glucocorticoids, to treat GPA and MPA.

TRUXIMA is not indicated for treatment of children.

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

- have had a severe reaction to TRUXIMA 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

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- have had a recent vaccination or are scheduled to receive vaccinations. You should not receive certain vaccines before or during treatment with TRUXIMA.
- are pregnant or plan to become pregnant. Talk to your healthcare provider about the risks to your unborn baby if you receive TRUXIMA during pregnancy.
Females who are able to become pregnant should use effective birth control (contraception) during treatment with TRUXIMA and for **12 months** after the last dose of TRUXIMA. 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 TRUXIMA.
- are breastfeeding or plan to breastfeed. It is not known if TRUXIMA passes into your breast milk. Do not breastfeed during treatment and for **at least 6 months** after your last dose of TRUXIMA.
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 TRUXIMA?

- TRUXIMA is given by infusion through a needle placed in a vein (intravenous infusion), in your arm. Talk to your healthcare provider about how you will receive TRUXIMA.
- Your healthcare provider may prescribe medicines before each infusion of TRUXIMA to reduce infusion side effects such as fever and chills.
- Your healthcare provider should do blood tests regularly to check for side effects to TRUXIMA.
- Before each TRUXIMA 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 TRUXIMA?

TRUXIMA can cause serious side effects, including:

• See “What is the most important information I should know about TRUXIMA?”

- **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 TRUXIMA. 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 of TLS:

- nausea
- vomiting
- diarrhea
- lack of energy

- **Serious infections.** Serious infections can happen during and after treatment with TRUXIMA, and can lead to death. TRUXIMA 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 TRUXIMA include bacterial, fungal, and viral infections. After receiving TRUXIMA, 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 TRUXIMA. 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.** TRUXIMA may cause chest pain, irregular heartbeats, and heart attack. Your healthcare provider may monitor your heart during and after treatment with TRUXIMA 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 TRUXIMA.

- **Kidney problems,** especially if you are receiving TRUXIMA for NHL. TRUXIMA 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 TRUXIMA with chemotherapy medicines. Tell your healthcare provider right away if you have any severe stomach-area (abdomen) pain or repeated vomiting during treatment with TRUXIMA.

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

The most common side effects of TRUXIMA include:

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

In adult patients with GPA or MPA the most common side effects of TRUXIMA also include:

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

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| <p>Other side effects with TRUXIMA include:</p> <ul style="list-style-type: none"> ◦ aching joints during or within hours of receiving an infusion ◦ more frequent upper respiratory tract infection <p>These are not all of the possible side effects with TRUXIMA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p> |
| <p>General information about the safe and effective use of TRUXIMA. 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 TRUXIMA that is written for healthcare professionals.</p> |
| <p>What are the ingredients in TRUXIMA? Active ingredient: rituximab-abbs Inactive ingredients: polysorbate 80, sodium chloride, tri-sodium citrate dihydrate, and Water for Injection, USP.</p> |
| <p>Manufactured by: CELLTRION, Inc. 20, Academy-ro 51 beon-gil, Yeonsu-gu, Incheon, 22014 Republic of Korea U.S. License Number 1996 Marketed by: Teva Pharmaceuticals USA, Inc, North Wales, PA 19454 For more information, go to www.TRUXIMA.com or call 1-888-483-8279.</p> |

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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