

Patient Alert Card

- Your doctor should give you a copy of the Truxima® Patient Alert Card every time you have a Truxima® infusion
- The Alert Card contains important safety information that you need to be aware of before you are given Truxima® and during and after treatment with Truxima®
- Keep the Alert Card with you all the time – for example, keep it in your wallet or purse
- Show the Alert Card to any doctor, nurse, dentist or pharmacist you see – not just the specialist who prescribes your Truxima®
- You should also tell your partner or caregiver about your treatment and show them the Alert Card, as they may notice symptoms that you are not aware of
- As the effect on the immune system caused by Truxima® can last for several months, side effects may occur even after you have stopped treatment. Please therefore keep the Alert Card with you for 2 years after the last dose of Truxima®

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Please report via;

Medical Logistics Ltd.

1-4, Cantrija Complex, Triq it-Targa,
Il-Maghtab, Naxxar NXR6613 Malta
Tel: +356 2755 9990
Email: safety@medicallogisticsltd.com

Alternatively, suspected adverse reactions should be reported to:

ADR reporting

Sir Temi Zammit Buildings, Malta Life Sciences Park,
San Gwann SGN 3000, Malta
Email: postlicensing.medicinesauthority@gov.mt
Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects, you can help provide more information on the safety of this medicine

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These aids and further information can be requested from the local representative:

Medical Logistics Ltd.

Tel: +356 2755 9990

Email: safety@medicallogisticsltd.com

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What you should know about Truxima® (rituximab)


Truxima®
Rituximab


HEALTHCARE
CELLTRION

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

Important safety information for patients receiving Truxima® therapy

- This brochure contains important safety information only.
- See the Truxima® package leaflet for more information on possible side effects of Truxima®.

About this guide

This brochure is for patients who are being treated with Truxima® for **rheumatoid arthritis, granulomatosis with polyangiitis (Wegener's), microscopic polyangiitis or pemphigus vulgaris** – please read it carefully – it is important for you to know about the benefits and the risks of Truxima®.

- If you have any further questions, ask your doctor or nurse

Like all medicines, Truxima® can cause side effects, although not everybody gets them. Most side effects are mild to moderate but some may be serious and require treatment. Very rarely, some of these reactions have led to death.

This brochure focuses on important or serious side effects you should be aware of.

- See the Truxima® package leaflet for more information on possible side effects due to Truxima®
- If you are receiving Truxima® in combination with other medicines, some of the side effects you may experience may be due to the other medicine
- Please make sure you have a list of all your other medicines with you at any visit to a healthcare professional, such as a doctor, nurse or dentist
- If any of the side effects become serious, please tell your doctor, nurse or pharmacist (chemist) immediately
- The side effects listed in this brochure are not all of the possible side effects that may occur with Truxima®
- Ask your doctor for more information

Infections

- Truxima® is a drug that affects your immune system. Truxima® may make you more likely to get infections. These may be serious and require treatment – so it is very important to report any signs of infection to your doctor or nurse immediately
- The following are all possible signs of infection:
 - Fever or persistent cough
 - Weight loss
 - Pain without injuring yourself
 - Feeling generally unwell or tired/lacking energy

- **Tell your doctor or nurse immediately if you experience any of the symptoms listed above or any other side effects**

Serious Brain Infection - called Progressive Multifocal Leukoencephalopathy (PML)

- Very rarely, some patients taking Truxima® have had a serious brain infection, which can lead to very severe disability and may be life threatening.
- PML is caused by a virus. In most healthy adults, the virus remains inactive and is therefore harmless. It is not known why the virus is activated in some people, but it may be linked to having a weakened immune system.
- PML is a rare disease of the central nervous system (the brain and spinal cord). The central nervous system controls the body's actions and activities, such as movement and balance. PML can lead to severe disability and can cause death
- Symptoms can vary and may include memory loss, trouble thinking, difficulty with walking or loss of vision

You should tell your doctor or nurse immediately if you experience any of these symptoms:

- Confusion, memory loss or problems thinking
- Loss of balance or a change in the way you walk or talk
- Decreased strength or weakness on one side of your body
- Blurred vision or loss of vision

Prior to Truxima® treatment, tell your doctor or nurse if you:

- Have an active infection or serious problem with your immune system
- Are taking or have taken medicines in the past which may affect your immune system, such as chemotherapy, immunosuppressive agents or other medicines that affect the immune system
- Think you may have an infection, even a mild one like a cold. The cells that are affected by Truxima® help to fight infection and you should wait until the infection has passed before you are given Truxima®
- Have had a lot of infections in the past or suffer from severe infections
- Think you may need any vaccinations in the near future, including vaccinations needed to travel to other countries. Some vaccines should not be given at the same time as Truxima® or in the months after you receive Truxima®. Your doctor will check if you should have any vaccines before you receive Truxima®

During or after treatment with Truxima®

- If you develop symptoms of an infection, such as fever, persistent cough, sore throat, weight loss, burning pain when passing urine, pain without injuring yourself, or feeling weak or generally unwell, inform a doctor or nurse about these symptoms and about your Truxima® treatment immediately
- If you develop symptoms of PML, such as memory loss, trouble thinking, difficulty with walking or loss of vision, it is very important that you inform your doctor or nurse straight away