

When should I not have MabThera?

Do not have MabThera if you have an active infection or a serious problem with your immune system.

Tell your doctor or nurse if you are taking or have previously taken medicines which may affect your immune system; this includes chemotherapy.

What are the signs of getting an infection?

Look out for the following possible signs of infection:

- Fever or cough all the time
- Weight loss
- Pain without injuring yourself
- Feeling generally unwell or listless.

If you get any of these, tell a doctor or nurse straight away. You should also tell them about your MabThera treatment.

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. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Please report side effects to:

Post: The Drug Surveillance Centre,
Roche Products (Ireland) Limited, 3004 Lake Drive,

Citywest, Naas Road, Dublin 24, Ireland

Telephone: 00 353 (0)1 4690700

Email: ireland.drug_surveillance_centre@roche.com

Alternatively, suspected adverse reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at:

<http://www.medicinesauthority.gov.mt/adrportal>,
and sent by post or email to:

Post: Pharmacovigilance Section at
Post-Licensing Directorate, Medicines Authority,
Sir Temi Żammit Buildings,

Malta Life Sciences Park,
San Ġwann SĠN 3000, Malta

Email: postlicensing.medicinesauthority@gov.mt



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FOR USE IN MALTA

**MabThera[®] (rituximab) in
non-oncology indications
Patient Alert Card**

- For patients (or for parents/legal guardians of paediatric patients) who are being given MabThera
- Keep this card with you at all times
- Present this card to every healthcare professional involved in your healthcare.

Please read this material along with the Package Leaflet supplied with this medicine or also available on www.medicines.ie and www.ema.europa.eu before taking this medicine.

Why have I been given this card?

This medicine may make you more likely to get infections. This card tells you:

- What you need to know before having MabThera
- What the signs of an infection are
- What to do if you think you might be getting an infection.

It also includes your name and doctor's name and phone number on the back.

What should I do with this card?

- Keep this card with you all the time - such as in your wallet or purse
- Show this card to any doctor, nurse or dentist you see - not just the specialist who prescribes your MabThera.

Keep this card with you for 2 years after your last dose of MabThera. This is because side effects can develop several months after you have had treatment.

Where can I get more information?

See the MabThera package leaflet for more information.

Treatment start date and contact details

Date of most recent infusion: _____

Date of first infusion: _____

Patient's Name: _____

Doctor's Name: _____

Doctor's contact details: _____

Make sure you have a list of all your medicines when you see a healthcare professional.

Please talk to your doctor or nurse if you have any questions about the information in this card.

What else do I need to know?

Very rarely MabThera can cause a serious brain infection, called "Progressive Multifocal Leukoencephalopathy" or PML. This can be fatal.

Signs of PML include:

- 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.

If you get any of these, tell a doctor or nurse straight away. You should also tell them about your MabThera treatment.