

What you should know about MabThera[®] (rituximab)

Important safety information for patients receiving MabThera therapy

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

This educational material is provided by Roche Products (Ireland) Limited and is mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks.

About this brochure

The information in this brochure is for patients who are being given MabThera for Rheumatoid Arthritis, Granulomatosis with Polyangiitis or Microscopic Polyangiitis, or Pemphigus Vulgaris. Please read this brochure carefully – it is important for you to know about the benefits and the risks of MabThera.

This brochure will:

- answer questions you may have about the potential risks with MabThera – this will help you and your doctor decide if it is the right treatment for you
- tell you about MabThera
- tell you what you need to know before having MabThera
- tell you about important side effects that you need to be aware of – this includes a rare but serious brain infection called ‘Progressive Multifocal Leukoencephalopathy’ or PML
- tell you what the signs of an infection and PML are
- tell you what to do if you think you are getting an infection or PML
- tell you about the Patient Alert Card.

What you should know about MabThera

About MabThera

MabThera affects your immune system, it may make you more likely to get an infection. Some infections may be serious and require treatment.

What MabThera is used for

MabThera is used to treat people with:

- **Severe Active Rheumatoid Arthritis (RA)** – it is used when other medicines have either stopped working, not worked well enough or have caused side effects. You will usually also be given another medicine called methotrexate.
- **Granulomatosis with Polyangiitis (GPA or Wegener’s) or Microscopic Polyangiitis (MPA)** – it is used to reduce or get rid of the signs and symptoms. You will usually also be given daily steroids.
- **Pemphigus Vulgaris (PV)** – it is used to treat moderate to severe pemphigus vulgaris, usually in combination with steroids.
- **Specific blood cancers** – information about this use is not included in this brochure.

About having MabThera

MabThera is given as an infusion into the vein.

Like all medicines, MabThera can cause side effects, although not everybody gets them and most are not serious.

- If you are given MabThera in combination with other medicines, some of the side effects you may experience may be due to the other medicines.
- Some side effects may be serious and require treatment. Rarely, some side effects may be life threatening.

If any of the side effects get serious, please tell your doctor, pharmacist or nurse immediately. If you have any further questions, ask your doctor, pharmacist or nurse.

Keep a list of all of your other medicines with you. You should show them to anyone who is giving you medical care, such as a doctor, pharmacist, nurse or dentist.

Before treatment with MabThera

Tell your doctor, pharmacist or nurse before taking MabThera if you have or have ever had any of the following:

Infections

Tell your doctor, pharmacist or nurse before having MabThera if you:

- currently have an infection (even a mild one like a cold). Your doctor, pharmacist or nurse may tell you to wait until the infection has gone before you are given MabThera
- get a lot of infections or have been getting many in the past
- have or have had a severe infection such as tuberculosis, blood poisoning (sepsis) or any other condition that weakens your immune system
- have a condition which may make you more likely to get a serious infection that needs treatment.

Other conditions

Tell your doctor, pharmacist or nurse before having MabThera if you:

- have heart disease
- have breathing problems
- are pregnant, trying to become pregnant, or are breastfeeding
- have or have ever had viral hepatitis or any other liver disease
- have had any abnormal results from your blood or urine lab tests.

Medicines

Tell your doctor, pharmacist or nurse before having MabThera if you:

- are taking medicines for high blood pressure
- are having or have ever had medicines that may affect your immune system – such as medicines that suppress your immune system called “immuno-suppressants” or a type of cancer treatment called chemotherapy
- have had chemotherapy that affects your heart (cardiotoxic chemotherapy)
- are taking or have recently taken any other medicines. This includes medicines bought from a pharmacy, supermarket or health store.

Vaccinations

Tell your doctor, pharmacist or nurse before having MabThera if you:

- think you may need to have a vaccination in the near future, including any vaccinations needed to travel to other countries.

Some vaccines should not be given at the same time as MabThera or for several months after you receive MabThera. Your doctor will check if you should have any vaccinations before you are given MabThera.

Tell your doctor, pharmacist or nurse if any of the above applies to you. If you are not sure, talk to your doctor, pharmacist or nurse before you are given MabThera.

During or after treatment with MabThera

MabThera affects your immune system and may make you more likely to get an infection. Some infections may be serious and require treatment.

Infections

Tell your doctor, pharmacist or nurse straight away if you get any of the following possible signs of infection:

- a high temperature (fever) with or without chills
- a cough which will not go away
- weight loss
- pain when you have not hurt yourself
- feeling generally unwell, tired or low in energy
- burning pain when passing urine.

Tell your doctor, pharmacist or nurse straight away if you get any of the signs of infection above.

Serious brain infection – called Progressive Multifocal Leukoencephalopathy (PML)

Rarely MabThera can cause a serious brain infection called 'Progressive Multifocal Leukoencephalopathy' or PML. This 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 weak immune system.

Tell your doctor, pharmacist or nurse straight away if you get any of the following signs of PML:

- confusion, memory loss or problems thinking straight
- loss of balance or a change in the way you walk or talk
- loss of strength or weakness on one side of the body
- blurred vision or loss of vision.

Tell your doctor, pharmacist or nurse straight away if you get any of the signs of PML above during treatment or for up to 2 years after your last dose of MabThera.

Patient Alert Card

The Patient Alert Card contains important safety information that you need to know before, during and after treatment with MabThera.

- Your doctor, pharmacist or nurse should give you a MabThera Patient Alert Card every time you have a MabThera infusion.
- Keep the Patient Alert Card with you all the time – you can keep it in your wallet or purse.
- Show the Patient Alert Card to anyone who is giving you medical care. This includes **any** doctor, pharmacist, nurse or dentist you see – not just the specialist who prescribes your MabThera.
- Tell your partner or caregiver about your treatment and show them the Patient Alert Card because they may notice side effects that you are not aware of.
- Keep the Patient Alert Card with you for 2 years after your last dose of MabThera. This is because the effects of MabThera on the immune system can last for several months, so side effects can occur even when you are no longer being treated with MabThera.

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 MabThera 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 it to:

The Drug Surveillance Centre, Roche Products (Ireland) Limited,
3004 Lake Drive, Citywest, Naas Road, Dublin 24, Ireland.

Tel: 00 353 (0)1 4690700; Fax: 00 353 (0)1 4690793

Email: ireland.drug_surveillance_centre@roche.com

Alternatively, report to:

Pharmacovigilance Section at Post-Licensing Directorate Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.

Reporting forms and information can be found at
www.medicinesauthority.gov.mt/adrportal