

# MabThera(R)

## Rheumatoid Arthritis

pronounced (mab-thir-ra)

*contains the active ingredient rituximab (rch)*

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## Consumer Medicine Information

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### What is in this leaflet

This leaflet answers some common questions about MabThera infusion. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given MabThera against the benefits they expect it will have for you.

**If you have any concerns about being given this medicine, ask your doctor or pharmacist.**

**Keep this leaflet.**

You may need to read it again.

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### What MabThera is used for

MabThera contains the active ingredient rituximab.

MabThera belongs to a group of medicines known as anti-rheumatic agents. There are many different classes of anti-rheumatic agents. MabThera belongs to a class called monoclonal antibodies.

Monoclonal antibodies are proteins which specifically recognise and bind to other unique proteins in the body.

MabThera is used to treat rheumatoid arthritis. Rheumatoid arthritis is a disease of the joints.

MabThera works by binding to a protein on the surface of certain white blood cells known as B lymphocytes. It is the B lymphocytes that are causing the inflammation responsible for rheumatoid arthritis. By binding to the protein MabThera reduces the ability of B lymphocytes to cause inflammation.

MabThera should be used together with methotrexate.

Your doctor may have prescribed MabThera for another reason.

**Ask your doctor if you have any questions why MabThera has been prescribed for you.**

This medicine is available only with a doctor's prescription.

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### Before you are given MabThera

***When you must not be given MabThera***

**Do not use MabThera:**

- \* **if you have had an allergic reaction to MabThera or any of the ingredients listed at the end of this leaflet**

- \* **if you have had an allergic reaction to any other proteins that are of mouse origin**  
Some of the symptoms of an allergic reaction may include severe skin rash, itching, hives, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, swelling of the hands, feet or ankles.

**If you are not sure if you should start receiving MabThera, talk to your doctor.**

***Before you are given MabThera***

**Your doctor must know about all the following before you are given MabThera.**

### **Tell your doctor if:**

**1) you have a history of heart disease with:**

- \* angina
- \* cardiac arrhythmias (abnormal beating of the heart)
- \* congestive heart failure

Your doctor will supervise you closely during treatment with MabThera.

**2) you are taking medicine to control blood pressure**

MabThera may cause a reduction in blood pressure at the beginning of treatment. Because MabThera may cause a temporary drop in your blood pressure, your doctor may advise you to temporarily stop taking your blood pressure medicine before you are given MabThera.

**3) you have pre-existing lung disease**

You may have a greater chance of breathing difficulties during treatment with MabThera.

**4) you have an infection, or a history of a recurring or long-term infection such as Hepatitis B**

**5) you intend to have or have had immunisation with any vaccine (eg measles, rubella, flu, vaccines for travel purposes)**

It is not known if MabThera will affect your normal response to a vaccine.

**6) you are allergic to any other medicines or any other substances such as foods, preservatives or dyes**

**7) you are pregnant or intend to become pregnant**

It is not known whether MabThera is harmful to an unborn baby. It is not recommended that you are given MabThera while you are pregnant.

If you are of child bearing potential, it is recommended that you do not become pregnant for 12 months following the end of treatment with MabThera.

If you are of child bearing potential, it is recommended that you use effective contraceptive methods during treatment and for up to 12 months following the end of treatment with MabThera.

**8) you are breast feeding or plan to breast feed.**

It is not known if MabThera passes into breast milk. It is recommended that you discontinue breast feeding while you are treated with MabThera.

**If you have not told your doctor about any of the above, tell them before you are given MabThera.**

### ***Use in children***

The safety and effectiveness of MabThera have not been established in children.

### ***Taking other medicines***

**Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop.**

As MabThera may cause a temporary drop in your blood pressure at the beginning of treatment, your doctor may advise you to temporarily stop taking your blood pressure medicine before you are given MabThera.

It is not known if MabThera will affect your normal response to a vaccine.

It is possible that after treatment with MabThera you may experience allergic reactions if you are treated with other medications containing monoclonal antibodies.

Your doctor and pharmacist will have more information on medicines to be careful with or to avoid while undergoing treatment with MabThera.

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## **How MabThera is given**

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MabThera is given by slow infusion into a vein (intravenous infusion) by a healthcare professional.

The dose of MabThera for treatment of rheumatoid arthritis is 1000 mg followed by a second dose of 1000 mg 2 weeks later.

Depending on the circumstances of your disease or response to the drug, your doctor may decide to re-treat with an additional course of MabThera.

### ***Overdose***

**As MabThera is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given MabThera, tell your doctor immediately.**

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## **While you are receiving MabThera**

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### ***Things you must do***

**If you are of child bearing potential, you should use an effective contraceptive method during treatment with MabThera and for 12 months following therapy.**

**Tell your doctor if you become pregnant while receiving MabThera.**

**Tell all doctors, dentists and pharmacists who are treating you that you are receiving MabThera.**

**Be sure to keep all your appointments with your doctor so that your progress can be checked. Your doctor will perform regular blood tests.**

## **Things you must not do**

### **Do not breast feed your infant during treatment with MabThera.**

It is not known whether MabThera crosses into human milk.

**Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.**

## **Things to be careful of**

### **Be careful driving or operating machinery until you know how MabThera affects you.**

MabThera generally does not cause any problems with your ability to drive or operate machinery. However, as with many other medicines, MabThera may cause dizziness in some people.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving MabThera.**

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

MabThera helps many people with rheumatoid arthritis but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

The following is a list of the more common side effects.

## **During or after an infusion**

**Tell your doctor if you notice any of the following during or after receiving an infusion (particularly during the first 2 hours of receiving the first infusion) and they worry you:**

- \* fever, chills and severe shivering (most likely to occur)
- \* nausea (feeling sick)
- \* vomiting
- \* headache
- \* skin rash and/or redness of the skin
- \* fatigue (feeling tired) and/or feeling weak
- \* difficulty breathing
- \* shortness of breath
- \* swelling of the tongue, which may cause difficulty breathing or swallowing
- \* rhinitis (a runny nose)
- \* dizziness on standing up
- \* flushing
- \* fast heart beat
- \* chest pain
- \* muscle and joint pain
- \* stomach pain or discomfort
- \* throat irritation

These side effects are temporary and less likely to occur after the first infusion.

Your doctor may recommend that you take medication to prevent pain or allergy before you receive your MabThera infusion.

**The following is a list of less common side effects. Tell your doctor if you notice any of the following and they worry you:**

- \* diarrhoea
- \* increased blood pressure
- \* indigestion
- \* loss of appetite
- \* muscle stiffness
- \* nervousness, feeling anxious or agitated
- \* increased cough
- \* inability to sleep
- \* pins and needles, or decreased feeling in the skin

- \* stuffy nose or chest
- \* sweating or night sweats
- \* watery, itchy or crusty eyes
- \* changes to sense of taste

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:**

- \* severe skin rash, itching, hives
- \* swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, swelling of the hands, feet or ankles
- \* one or a combination of the following: severe shortness of breath, severe difficulty breathing, severe wheezing, severe coughing.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Your doctor or pharmacist has a more complete list. Others may occur in some people and there may be some side effects not yet known.

**Tell your doctor if you notice anything else that is making you feel unwell.**

**Ask your doctor or pharmacist if you don't understand anything in this list.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## **After receiving MabThera**

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### **Storage**

MabThera should be stored in the pharmacy or on the hospital ward.

The concentrated solution for infusion should be kept in a refrigerator at 2-8 degrees C. It should not be frozen.

MabThera should be stored away from light.

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## Product Description

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### **Availability**

MabThera is available as 100 mg/10 mL and 500 mg/50 mL single dose vials.

MabThera comes in packs of two vials for the 100 mg/10 mL presentation and packs of one vial for the 500 mg/50 mL presentation.

### **What MabThera looks like**

MabThera is available as a clear, colourless, concentrated solution for intravenous infusion. It is diluted before infusion into a vein.

### **Ingredients**

MabThera contains the active ingredient rituximab (rch). MabThera comes in two strengths, 100 mg and 500 mg. Each vial of MabThera also contains the following inactive ingredients:

- \* sodium citrate
- \* polysorbate 80
- \* sodium chloride
- \* sodium hydroxide and/or
- \* hydrochloric acid

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## Distributor

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MabThera is distributed by:  
Roche Products Pty Limited  
ABN 70 000 132 685  
4-10 Inman Road  
Dee Why NSW 2099

Customer enquiries: 1 800 233 950  
Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers:

- \* 100 mg vial: AUST R 60318
- \* 500 mg vial: AUST R 60319

This leaflet was prepared on 13 July 2009.