MabThera® intravenous infusion

For the treatment of Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukaemia

pronounced (mab-thir-ra)

contains the active ingredient rituximab (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MabThera intravenous 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.

What MabThera is used for

MabThera contains the active ingredient rituximab.

MabThera belongs to a group of medicines known as anti-cancer agents. There are many different classes of anti-cancer 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 non-Hodgkin's lymphoma and chronic lymphocytic leukaemia.

MabThera works by binding to a protein on the surface of certain white blood cells known as B lymphocytes. During the process of binding to the protein, the abnormal growth of the B lymphocytes is stopped.

It is the abnormally growing B lymphocytes that are responsible for certain types of non-Hodgkin's lymphoma and chronic lymphocytic leukaemia.

MabThera may be used on its own or together with chemotherapy.

If your doctor thinks it is appropriate for your circumstances you may continue to receive MabThera after the initial course of treatment.

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.

Before you are given MabThera

When you must not be given MabThera

Do not use MabThera:

- **if you have had an allergic reaction to rituximab 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 an infection, or a history of a recurring or long-term infection such as hepatitis B**
2. **you are taking or have previously taken medicines which may affect your immune system, such as chemotherapy or immunosuppressive medicines**

If you are taking or have taken medicines which affect your immune system, you may have an increased risk of infections. There have been reports of a rare, serious brain

infection called PML (progressive multifocal leuko-encephalopathy) usually affecting people with a weakened immune system. Your chance of getting PML may be higher if you are treated with MabThera and/or other medicines that weaken the immune system. PML can cause severe disability or even death.

3. **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.

4. **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.

5. **you have pre-existing lung disease**

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

6. **you intend to have or have had immunisation with any vaccine (e.g. measles, rubella, flu, vaccines for travel purposes)**

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

7. **you are allergic to any other medicines or any other substances such as foods, preservatives or dyes**
8. **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 a woman of child bearing potential, you must use effective contraceptive methods to prevent pregnancy during treatment and for 12 months after completing treatment with MabThera.

9. **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 without a prescription 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.

How MabThera is given

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

Your doctor will decide what dose and how long you will receive MabThera. The dose of MabThera depends on your body weight and body height.

MabThera may be given with or without chemotherapy. When given in combination with chemotherapy, the standard treatment with MabThera consists of 1 infusion on day 1 of each chemotherapy cycle.

Depending on the circumstances of your disease or response to the drug your doctor may decide to change your treatment.

Maintenance treatment

If you respond to initial treatment your doctor may decide to continue your treatment with MabThera for up to 2 years.

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.

While you are receiving MabThera

Things you must do

If you are a woman of child bearing potential, you must use effective contraceptive methods to prevent pregnancy during treatment with MabThera and for 12 months after completing treatment.

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.

Tell your partner or caregiver you are receiving MabThera and ask them to tell you if they notice any changes in your movement or behaviour. If they notice any changes you should tell your doctor about them immediately.

Your doctor may need to perform some tests and alter your treatment.

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.

Side effects

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 who have either non-Hodgkin's lymphoma or chronic lymphocytic leukaemia 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)
- swelling of the tongue, face, lips, mouth or throat which may cause difficulty breathing or swallowing
- itchy rash and/or pinkish, itchy swellings on the skin
- difficulty breathing and/or shortness of breath
- wheezing or coughing
- dizziness or lightheadedness, especially on standing up
- nausea (feeling sick) or vomiting
- headache
- fatigue (feeling tired) and/or feeling weak
- rhinitis (a runny nose)
- flushing
- fast heart beat
- chest pain which may spread to the neck and shoulders
- pain where the cancer is located
- 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 other common side effects. Tell your doctor if you notice any of the following and they worry you:

- sore mouth or mouth ulcers
- bleeding or bruising more easily than normal
- shingles (herpes zoster infection)
- 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
- weight loss
- ear pain and/or buzzing, hissing, whistling, ringing or other persistent noise in the ears
- constipation
- a general feeling of being unwell
- unusual hair loss or thinning

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

- vision loss associated with headaches, confusion and seizures
- one or a combination of the following: confusion, disorientation or memory loss, changes in the way you move, walk or talk, decreased strength or progressive weakness in your body, blurred or loss of vision.
- yellowing of skin and eyes, light coloured bowel motions, dark coloured urine

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

In combination with chemotherapy

If you have been given MabThera in combination with chemotherapy, as well as the side effects listed above, the following additional side effect may also occur:

- bronchitis (inflammation in the lungs)

If you are 65 years of age or over and have been given MabThera in combination with chemotherapy, the following side effects may occur more commonly:

- frequent infections with symptoms such as fever, severe chills, sore throat or mouth ulcers

These events may be related to MabThera, but you may get other side effects from your chemotherapy.

Please consult your doctor for possible side effects that may be caused by your chemotherapy.

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.

After receiving MabThera

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°C. It should not be frozen.

MabThera should be stored away from light.

Product Description

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.

MabThera is also available as a 1400 mg/11.7mL solution for subcutaneous injection in a single dose vial for the treatment of non Hodgkin's lymphoma only.

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

Distributor

MabThera is distributed by:

Roche Products Pty Limited

ABN 70 000 132 685

4-10 Inman Road

Dee Why NSW 2099

Medical 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 10 March 2016