

Consumer Medicine Information

MABTHERA[®] *Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukaemia*

Rituximab

100 mg in 10 mL and 500 mg in 50 mL concentrate for solution for infusion

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 expected 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 is used to treat non-Hodgkin's lymphoma and chronic lymphocytic leukaemia (both are types of blood cancer).

MABTHERA belongs to a group of medicines known as monoclonal antibodies. Monoclonal antibodies are proteins which specifically recognise and bind to another unique protein called an antigen.

MABTHERA works by binding to an antigen on the surface of certain white blood cells known as B lymphocytes. It is the abnormally growing B lymphocytes that are responsible for certain types of non-Hodgkin's lymphoma and chronic lymphocytic leukaemia. During the process of binding to the antigen, the abnormal growth of the B lymphocytes is stopped.

MABTHERA may be used on its own or together with other chemotherapy.

Your doctor, however, may have prescribed MABTHERA for another purpose.

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

You should not be given MABTHERA if:

- you have had an allergic reaction to MABTHERA or any of the ingredients listed at the end of this leaflet
- 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

Tell your doctor if:

1. you are pregnant or plan to become pregnant

It is not known whether MABTHERA is harmful to an unborn baby. MABTHERA is not recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby. It is not recommended that you become pregnant during or for twelve months following the end of treatment with MABTHERA.

2. you are breast-feeding or plan to breast-feed

It is not known if MABTHERA passes into breast milk. Breast feeding is not recommended while you are being treated with MABTHERA.

3. you are taking medication to control blood pressure

MABTHERA may cause a temporary drop in blood pressure at the beginning of treatment. Your doctor will advise you about taking your blood pressure medication before you are given MABTHERA.

4. you have any disorders or conditions affecting your lungs

5. you have a history of heart disease

6. you have a history of certain types of blood disorders (e.g. low neutrophils (low white blood cells), low platelets (cells which help clot blood))

7. you have a history of hepatitis B

8. you intend to have or recently had immunisation with any vaccine (e.g. measles, rubella, flu)

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

9. you are allergic to any other medicines, foods, dyes or preservatives

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 health food shop.

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 may 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 of MABTHERA is right for you and how often and for how long you should be given MABTHERA. The dose of MABTHERA depends on your body weight and height.

The usual dose of MABTHERA when it is given on its own is 375 mg per square metre body surface area, once a week for four weeks.

For non-Hodgkin's lymphoma MABTHERA is usually given in combination with chemotherapy medicines. The usual dose of MABTHERA is 375 mg per square metre body surface area on day one of each chemotherapy cycle, for up to eight cycles depending on the type of chemotherapy.

For chronic lymphocytic leukaemia MABTHERA is given in combination with chemotherapy medicines at a dose of 375 mg per square metre body surface area on day one of the first chemotherapy cycle, followed by 500 mg per square metre body surface area for each subsequent chemotherapy cycle, for six cycles in total.

Your doctor may decide to change your treatment or give you more courses of treatment with MABTHERA, depending on your condition and your response to the medicine.

While you are receiving MABTHERA

Things you must do

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

If you are a woman of child bearing potential, you should use effective contraception during treatment with MABTHERA and for twelve months following therapy.

Tell your doctor if you become pregnant while 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

You should 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.

However, MABTHERA is not expected to affect your ability to drive or operate machinery.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are receiving MABTHERA.

MABTHERA helps most people with non-Hodgkin's lymphoma but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious. You may need medical treatment if you get some of the side effects.

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

Tell your doctor if you notice any of the following and they worry you:

The following symptoms can occur after receiving an infusion of Mabthera, often within the first few hours:

- fever, chills and severe shivering (most likely to occur)
- hypotension (temporary drop in blood pressure. You will feel this as dizziness or fainting)
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- shortness of breath
- nausea (feeling as if you may vomit) and/or vomiting
- flushing
- a runny nose
- pain at the infusion site, pain where the tumour is
- skin rash and/or redness of the skin, itchiness
- headache
- fatigue (feeling tired) and/or feeling weak

Please note:

- 1. The above events are temporary and less likely to occur with subsequent infusions.**
- 2. Your doctor may recommend that you take medication to prevent pain or allergy before you receive your MABTHERA infusion.**

Other events that may happen during or after you receive an infusion:

- dizziness
- insomnia, agitation, feeling anxious
- anaemia (symptoms may include tiredness, headaches, being short of breath when exercising, dizziness and looking pale)
- general pain, stomach, chest, back and/or neck pain
- aching muscles, muscle tenderness or weakness, muscle stiffness
- joint pain, painful swollen joints
- indigestion, constipation
- diarrhoea
- difficulty swallowing
- loss of appetite, weight loss
- cough
- sweating and night sweats
- tingling, numbness of feet and hands or decreased sensitivity
- bleeding or bruising more easily than normal
- high sugar (glucose) levels in the blood (symptoms may include passing large amounts of urine, excessive thirst, dry mouth and/or skin)
- high blood pressure

- fast and/or irregular heart beat
- throat irritation, mouth ulcers
- watering and/or itching eyes, ear pain, buzzing/ringing in ears
- infections e.g. urinary tract infections, skin infections

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

- infections with fever, severe chills, sore throat or mouth ulcers
- 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
- numbness of the face
- severe vision or hearing loss
- 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
- severe stomach pain, nausea, vomiting
- yellowing of skin and eyes, light coloured bowel motions, dark coloured urine

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

If you have been given MABTHERA in combination with chemotherapy, the following additional side effects, which may be due to MABTHERA, may occur.

- bronchitis (inflammation of the lungs)
- sinusitis (feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache)
- shingles (Herpes zoster)

You may get other side effects from your chemotherapy.

Please consult your doctor for possible side effects that may be caused by your chemotherapy. These may be quite different from all of the side effects listed above.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Medicines you have been given while you are being treated with MABTHERA may have different side effects to those for MABTHERA.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

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.

Product description

Availability

MABTHERA concentrate for solution for infusion comes in two strengths:

- Mabthera 100 mg in 10 mL vials (each vial contains 100 mg rituximab), 2 vials per pack
- Mabthera 500 mg in 50 mL vials (each vial contains 500 mg rituximab), 1 vial per pack

What MABTHERA looks like

MABTHERA is available as a clear, colourless to pale yellow, concentrated solution for intravenous infusion. It is diluted before infusion into a vein.

Ingredients

Active ingredient

- rituximab

Inactive ingredients

Each vial of MABTHERA also contains:

- sodium citrate dihydrate, polysorbate 80, sodium chloride, hydrochloric acid or sodium hydroxide, water for injection

Distributor

MABTHERA is distributed by:

Roche Products (New Zealand) Limited
P O Box 12492 Penrose
AUCKLAND 1642

Customer Enquiries: 0800 656 464

This leaflet was prepared on 14 June 2011.