

New Zealand Consumer Medicine Information

MABTHERA[®]

Rheumatoid Arthritis & Granulomatosis with polyangiitis and Microscopic polyangiitis

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 rheumatoid arthritis (RA), granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA). RA is an inflammatory disease of the joints. GPA and MPA are inflammatory diseases of the blood vessels.

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. B lymphocytes play a role in the inflammation observed for RA, GPA and MPA. By binding to the antigen MABTHERA reduces the ability of B lymphocytes to cause inflammation.

Your doctor, however, may have prescribed MABTHERA for another purpose. (If you have been prescribed MABTHERA for the treatment of non-Hodgkin's lymphoma (NHL) please read the Consumer Medicine Information for NHL.)

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

MABTHERA may pass into breast milk. Breast feeding is not recommended while you are being treated with MABTHERA and for 6 months following the end of MABTHERA treatment.

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 when to take 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 (e.g. angina, irregular heart rhythm, heart failure or heart attacks)

6. you have an infection, or a history of a recurring or long-term infection

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)

MABTHERA may 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 from a pharmacy, supermarket or health food 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.

MABTHERA may 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 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. Before the infusion is given you will receive medicines to reduce the chance of any reactions to MABTHERA.

The dose of MABTHERA for treatment of rheumatoid arthritis (RA) is 1000 mg followed by a second dose of 1000 mg two weeks later. For RA MABTHERA should be used together with methotrexate.

Your doctor may decide to re-treat your RA with an additional course of MABTHERA. Depending on the circumstances of your disease or response to the medicine, this may be months from now. Your doctor will decide when you should receive more MABTHERA.

The dose of MABTHERA for GPA and MPA patients is 375 mg/m² body surface area once a week for 4 weeks. For GPA or MPA MABTHERA should be used together with glucocorticoids.

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 many people with rheumatoid arthritis 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 and chills
- headache
- a temporary drop in blood pressure (you may feel this as dizziness or fainting)
- high blood pressure
- rapid heart beat
- swelling and/or pain of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing; throat irritation
- swelling of the feet and legs
- shortness of breath or cough
- nausea (feeling as if you may vomit) and/or vomiting
- flushing
- a runny nose, sneezing
- skin rash and/or redness of the skin, itchiness
- feeling tired

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:

- pain in stomach area
- aching and/or painful muscles
- painful and/or swollen joints
- indigestion, heartburn
- severe headache
- high cholesterol
- tingling, numbness of feet and hands or decreased sensitivity
- infections e.g. urinary tract infections, colds, or chest infections including pneumonia
- mouth ulcers
- Athlete's foot
- hair loss
- anxiety
- depression
- diarrhoea
- feeling faint
- insomnia (inability to sleep)

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
- severe stomach pain, nausea, vomiting
- 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.

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. MABTHERA should be stored away from light.

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 109113
Newmarket
Auckland 1149
NEW ZEALAND

Customer enquiries: 0800 276 243

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