

MabThera® SC subcutaneous injection

For the treatment of Non-Hodgkin's Lymphoma (1400 mg strength) and Chronic Lymphocytic Leukaemia (1600 mg strength)

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 SC for subcutaneous (under the skin) injection. 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 SC 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 SC is used for

MabThera SC contains the active ingredient rituximab.

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

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

MabThera SC is used to treat non-Hodgkin's lymphoma and chronic lymphocytic leukaemia. MabThera SC in chronic lymphocytic leukaemia was approved building on data from both the intravenous form of MabThera and MabThera SC in non-Hodgkin's lymphoma.

MabThera SC 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 SC 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 SC after the initial course of treatment.

Your doctor may have prescribed MabThera SC for another reason.

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

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

Before you are given MabThera SC

When you must not be given MabThera SC

Do not use MabThera SC:

- **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 SC, talk to your doctor.

Before you are given MabThera SC

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

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 leukoencephalopathy) usually affecting people with a weakened immune system. Your chance of getting PML may be higher if you are treated with MabThera SC 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 failureYour doctor will supervise you closely during treatment with MabThera SC.

4. **you are taking medicine to control blood pressure**

MabThera SC may cause a reduction in blood pressure at the beginning of treatment. Because MabThera SC 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 SC.

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

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

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 SC or in the months after you receive MabThera SC. Your doctor will check if you should have any vaccines before you receive MabThera SC.

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 SC is harmful to an unborn baby. It is not recommended that you are given MabThera SC 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 SC.

9. **you are breast feeding or plan to breast feed.**

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

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

Use in children

The safety and effectiveness of MabThera SC 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.

As MabThera SC 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 SC.

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

It is possible that after treatment with MabThera SC 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 SC.

How MabThera SC is given

Your treatment with MabThera SC will always begin with an infusion of MabThera intravenous formulation into a vein. If the infusion is tolerated, then further treatment with MabThera SC can be given by subcutaneous injection. This means it is injected with a short needle into the fatty tissue just under the skin.

MabThera SC is given as a fixed dose of 1400 mg per injection over approximately 5 minutes for treatment of non-Hodgkin's lymphoma.

MabThera SC is given as a fixed dose of 1600 mg per injection over approximately 7 minutes for treatment of chronic lymphocytic leukaemia.

Your doctor will decide on the frequency of injections.

MabThera SC may be given with or without chemotherapy. When given in combination with chemotherapy, the standard treatment

with MabThera SC consists of 1 subcutaneous injection on day 1 of each chemotherapy cycle.

MabThera SC must always be administered by a healthcare professional.

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 SC. for up to 2 years.

Overdose

As MabThera SC 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 SC, 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 SC and for 12 months after completing treatment.

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

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

Tell your partner or caregiver you are receiving MabThera SC 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 SC.

It is not known whether MabThera SC 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 SC affects you.

MabThera SC generally does not cause any problems with your ability to drive or operate machinery. However, as with many other medicines, MabThera SC 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 SC.

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

You may not experience any of them.

MabThera SC helps many people who have 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. Your doctor may recommend that you take medication to prevent pain or allergy before you receive your MabThera SC injection.

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

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

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

- side effects at the injection site including pain, swelling, bruising, bleeding, skin redness, itching and rash
 - 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)
 - 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
 - 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 SC 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 SC 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 SC, 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 SC

Storage

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

MabThera SC should be kept in a refrigerator at 2 to 8°C. It should not be frozen.

MabThera SC should be stored away from light.

Product Description

Availability

MabThera SC is available as a solution for subcutaneous injection in 1400 mg/11.7mL and 1600 mg/13.4mL as single dose vials. It is supplied as one vial per carton.

MabThera is also available as a concentrate for intravenous infusion in 100 mg/10 mL and 500 mg/50 mL single dose vials.

What MabThera SC looks like

MabThera SC is available as a clear to opalescent, colourless to yellowish solution.

Ingredients

MabThera SC contains the active ingredient rituximab (rch). Each vial of MabThera SC

also contains the following inactive ingredients:

- vorhyaluronidase alfa
- histidine
- histidine hydrochloride
- trehalose dihydrate
- methionine
- polysorbate 80
- water for injection

Distributor

MabThera SC is distributed by:

Roche Products Pty Limited

ABN 70 000 132 685

4-10 Inman Road

Dee Why NSW 2099

Medical enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Number:

- AUST R 207334 (1400mg)
- AUST R 235147 (1600mg)

This leaflet was prepared on 23 September 2016