

New Zealand Consumer Medicine Information

MABTHERA[®] SC

Rituximab

1400 mg solution for subcutaneous injection for non-Hodgkin's Lymphoma and 1600mg solution for subcutaneous injection for chronic lymphocytic leukaemia

What is in this leaflet

Please read this leaflet carefully before you start using Mabthera SC.

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 expected for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Mabthera SC is used for

Mabthera SC contains the active ingredient rituximab.

Mabthera SC 1400mg is used to treat non-Hodgkin's lymphoma. Mabthera SC 1600mg is used to treat chronic lymphocytic leukaemia. Non-Hodgkin's lymphoma and chronic lymphocytic leukaemia are types of blood cancers.

Mabthera SC 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 SC 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 SC may be used on its own or together with chemotherapy .

Your doctor may have prescribed Mabthera SC for another purpose.

Ask your doctor if you have any questions about 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

You should not be given Mabthera SC if:

- **you have had an allergic reaction to Mabthera SC, rituximab 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 SC, talk to your doctor.

Before you are given Mabthera SC

Tell your doctor if:

1. you are pregnant or plan to become pregnant

It is not known whether Mabthera SC is harmful to an unborn baby. Mabthera SC is not recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby. If you are a woman of child bearing potential, you must use effective contraception methods to prevent pregnancy during treatment and for 12 months after completing treatment with Mabthera SC.

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

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

3. you are taking medication to control blood pressure

Mabthera SC 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 SC.

4. you have any disorders or conditions affecting your lungs

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

5. you have a history of heart disease with angina, cardiac arrhythmias (abnormal beating of the heart) or congestive heart failure

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) or 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 may affect your immune system, you may have an increased risk of infections. There have been reports of a rare, serious brain infection called progressive multifocal leuko-encephalopathy (PML) in patients taking Mabthera intravenously, 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.

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

8. you have a history of hepatitis B

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

Some vaccines should not be given when you are receiving Mabthera SC . It is not known if Mabthera SC will affect your normal response to a vaccine.

10. 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 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.

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 may 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 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 injection. This means it is injected with a short needle into a fatty tissue just under the skin.

Mabthera as a subcutaneous injection is given as a fixed dose of 1400 mg or 1600mg per injection.

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 consists of 1 subcutaneous injection on day 1 of each chemotherapy cycle.

Mabthera SC must always be administered by a healthcare professional.

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

While you are receiving Mabthera SC

Things you must do

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

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

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

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 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.

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

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, tell your doctor immediately.

Side effects

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

Mabthera SC helps many people with non-Hodgkin's lymphoma or chronic lymphocytic leukaemia 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.

Your doctor may recommend that you take medication to prevent pain or allergy before you receive your Mabthera SC injection.

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
- hypotension (temporary drop in blood pressure. You will feel this as dizziness or fainting)
- nausea (feeling as if you may vomit) and/or vomiting
- flushing
- a runny nose
- pain where the tumour is
- headache
- fatigue (feeling tired) and/or feeling weak
- 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 SC in combination with chemotherapy, the following additional side effects, which may be due to Mabthera SC, 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 SC may have different side effects to those for Mabthera SC.

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 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/11.7 mL and 1600mg/13.4mL single dose vials. It is supplied as one vial per carton.

Mabthera is also available as a concentrate for intravenous infusion.

What Mabthera SC looks like

Mabthera SC is a clear to opalescent, colourless to yellowish, solution.

Ingredients

Active ingredient

- rituximab

Inactive ingredients

Each vial of Mabthera SC also contains:

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

Distributor

Mabthera SC is distributed by:

Roche Products (New Zealand) Limited
P O Box 109113
Newmarket, Auckland 1149
NEW ZEALAND

Medical enquiries: 0800 276 243

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