# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:**

S4

**MabThera SC 1400 mg –** Solution for Subcutaneous Injection

Active substance: Rituximab

Sugar Free

**Read all of this leaflet carefully before you start receiving MabThera SC 1400 mg**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse, pharmacist or other healthcare provider.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
- MabThera SC 1400 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**

1. What MabThera SC 1400 mg is and what it is used for
2. What you need to know before you use MabThera SC 1400 mg
3. How to use MabThera SC 1400 mg
4. Possible side effects
5. How to store MabThera SC 1400 mg
6. Contents of the pack and other information

## 1. What MabThera SC 1400 mg is and what it is used for

MabThera contains the active substance “rituximab”. This is a type of protein called a “monoclonal

antibody". It sticks to the surface of a type of white blood cell called "B-Lymphocyte". When rituximab sticks to the surface of this cell, the cell dies. MabThera is available as a medicine for injection under your skin (called MabThera 1400 mg solution for subcutaneous injection).

MabThera SC 1400 mg is used to treat Non-Hodgkin's lymphoma in adults.This is a disease of the lymph tissue (part of the immune system) that affects a type of white blood cell called B-Lymphocytes.

MabThera SC 1400 mg can be given alone or with other medicines called "chemotherapy".

You will always be given MabThera as a drip (intra-venous infusion) at the start of your treatment. After this, you will be given MabThera as an injection under your skin. Your doctor will decide when to start MabThera injections.

In patients where the treatment is working, MabThera may be used as a maintenance treatment for 2 years after completing the initial treatment.

## 2. What you need to know before you use MabThera SC 1400 mg

**MabThera SC 1400 mg should not be administered to you:**

- If you are hypersensitive (allergic) to rituximab, other proteins which are like rituximab, or any of the other ingredients of this medicine
- If you are allergic to hyaluronidase (an enzyme that helps to increase the absorption of injected active substance)
- If you have a severe active infection at the moment
- If you have a weak immune system
- Severe heart failure (New York Heart Association Class IV) or severe, uncontrolled cardiac disease
- If you are pregnant or breastfeeding your baby

Do not have MabThera SC 1400 mg if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before you are given MabThera SC 1400 mg.

**Warnings and precautions**

Tell your doctor or health care provider before being given the injection:

- If you have ever had or might now have a hepatitis infection. This is because in a few cases, MabThera SC 1400 mg could cause hepatitis B to become active again, which can be fatal. Patients who have ever had hepatitis B infection will be carefully checked by their doctor for signs of this infection.
- you have ever had heart problems (such as angina, palpitations or heart failure) or breathing problems.
- If you have had tuberculosis, tell your doctor. Your doctor will check for signs and symptoms of tuberculosis before starting MabThera SC 1400 mg. If symptoms of tuberculosis (persistent cough, weight loss, listnessness, mild fever) or any other infection appear during or after therapy tell your doctor immediately. Your doctor will give you medicine to prevent you getting tuberculosis before you start treatment with MabThera SC 1400 mg and will monitor you throughout your treatment with MabThera SC 1400 mg.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given MabThera SC 1400 mg.

Your doctor may need to take special care of you during your treatment with MabThera.

**Children and adolescents**

Talk to your doctor, pharmacist or nurse before you are given this medicine if you, or your child, are under 18 years of age. This is because there is not much information about the use of MabThera in children and young people.

**Other medicines and MabThera SC 1400 mg**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

This is because MabThera SC 1400 mg can affect the way some other medicines work. Also some other medicines can affect the way MabThera SC 1400 mg works.

In particular, tell your doctor:

- if you are taking medicines for high blood pressure. You may be asked not to take these other

medicines 12 hours before you are given MabThera SC 1400 mg. This is because some people have a fall in their blood pressure while they are being given MabThera SC 1400 mg

- if you have ever taken medicines which affect your immune system – such as chemotherapy or immune-suppressive medicines

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given MabThera SC 1400 mg.

**Pregnancy and breastfeeding and fertility**

***Pregnancy***

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

This is because MabThera can cross the placenta and may affect your baby.

If you can get pregnant, you and your partner must use an effective method of contraception while using MabThera. You must also do this for 12 months after your last treatment with MabThera.

***Breastfeeding***

Do not breastfeed your baby while you receive treatment with MabThera. Also do not breastfeed for 12 months after your last treatment with MabThera. This is because MabThera may pass into breast milk.

**Driving and using machines**

It is not always possible to predict to what extent MabThera SC 1400 mg may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MabThera SC 1400 mg affects them.

**MabThera SC 1400 mg contains:** α,α-trehalose dihydrate, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, $N_2$ medical gas, polysorbate 80,recombinant human hyaluronidase (rHuPH20), water for injections.

MabThera SC contains less than 1 mmol sodium per dose, i.e. it is essentially sodium-free.

## 3. How to use MabThera SC 1400 mg

Do not share medicines prescribed for you with any other person.

Always use MabThera SC 1400 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You will not be expected to give yourself MabThera SC 1400 mg. It will be given to you by a person who is qualified to do so.

You will be receiving doses according to your treatment plan and therefore you should go to the oncology clinic according to your scheduled appointments.

MabThera SC 1400 mg will be given to you by a doctor or nurse who is experienced in the use of this treatment. They will watch you closely while you are being given this medicine. This is in case you get any side effects.

**You will always be given your first dose of MabThera IV as a drip (intravenous infusion) at the start of your treatment.**

After this, you will be given MabThera SC 1400 mg either as a second or subsequent dose, as an injection under your skin (subcutaneous injection) over approximately 5 minutes. There is a peel-off sticker on the glass vial that specifies the medication.

Your doctor or nurse will place the sticker on the syringe before injection.

Your doctor will decide when to start MabThera injections.

When injected under your skin, it is given in the stomach area, not in other sites of the body, and not into areas of the stomach where the skin is red, bruised, tender, hard or where there are moles or scars.

*Medicines given before each MabThera SC 1400 mg administration*

Before you are given MabThera SC 1400 mg, you will be given other medicines (premedication) to prevent or reduce possible side effects.

*How much and how often you will receive your treatment*

- MabThera will be given to you on the same day as your chemotherapy. This is usually given every 3 weeks up to 8 times.
- If you respond well to treatment, you may be given MabThera as a maintenance treatment every 2 or 3 months for two years.

Your doctor may change this, depending on how you respond to the medicine.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse. Your doctor will tell you how long your treatment with MabThera SC will last. If you have the impression that the effect of MabThera SC is too strong or too weak, tell your doctor or pharmacist.

**If you take more MabThera SC 1400 mg than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Since a health care provider will administer MabThera SC 1400 mg, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

**If you forget to take MabThera SC 1400 mg**

Since a health care provider will administer MabThera SC 1400 mg**,** it is unlikely that the dose will be missed.

**4. Possible side effects**

MabThera SC 1400 mg can have side effects.

Not all side effects reported for MabThera SC 1400 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MabThera SC 1400 mg, please consult your health care provider for advice.

Most side effects are mild to moderate but some may be serious and need treatment. Some of

these side effects have been fatal.

If any of the following happens, stop taking / using MabThera SC 1400 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

***Reactions that may occur where the medicine is injected***

You may get some local side effects where your healthcare professional injects the MabThera SC 1400 mg. These may include: pain, swelling, bruising, bleeding, skin redness, itching and rash.

Your doctor may decide to stop your MabThera treatment if these reactions are serious.

***Infections***

**Tell your doctor immediately if you get any of the following signs of an infection including:**

- fever, cough, sore throat, burning pain when passing urine or feeling weak or generally unwell;
- memory loss, trouble thinking, difficulty walking or sight loss – these may be due to a very rare, serious brain infection, which has been fatal (Progressive Multifocal Leukoencephalopathy or PML).

You might get infections more easily during your treatment with MabThera. These are often colds, but there have been cases of pneumonia or urinary infections, see “Other side effects” below.

These are all very serious side effects. If you have them, you may have had a serious reaction to MabThera SC 1400 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

**Other side effects include:**

*Frequent*:

- bacterial or viral infections, bronchitis
- low number of white blood cells with or without fever or blood cells called “platelets”
- feeling sick (nausea)
- bald spots on the scalp, chills, headache

- lower immunity – because of lower levels of anti-bodies called “immunoglobulins” (IgG) in the blood which help protect you against infection
- infections of the blood (sepsis), pneumonia, shingles, cold, bronchial tube infections, fungal infections, infections of unknown origin, sinus inflammation, hepatitis B
- low number of red blood cells (anaemia), low number of all blood cells
- allergic reactions (hypersensitivity)
- high blood sugar level, weight loss, swelling in the face and body, high levels of the enzyme “LDH” in the blood, low calcium levels in the blood
- unusual feelings of the skin - such as numbness, tingling, pricking, burning, a creeping skin feeling, reduced sense of touch
- feeling restless, problems falling asleep
- becoming very red in the face and other areas of the skin as a consequence of dilation of the blood vessels
- feeling dizzy or anxious
- producing more tears, tear duct problems, inflamed eye (conjunctivitis)
- ringing sound in the ears, ear pain
- heart problems – such as heart attack, uneven or fast heart rate
- high or low blood pressure (low blood pressure especially when standing upright)
- tightening of the muscles in the airways which causes wheezing being (bronchospasm), inflammation, irritation in the lungs, throat or sinuses, short of breath, runny nose
- being sick (vomiting), diarrhoea, pain in the stomach, irritation or ulcers in the throat and mouth, problems swallowing, constipation, indigestion
- eating disorders, not eating enough, leading to weight loss
- hives, increased sweating, night sweats
- muscle problems – such as tight muscles, joint or muscle pain, back and neck pain
- tumour pain

- general discomfort or feeling uneasy or tired, shaking, signs of flu
- multiple-organ failure.

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

Tell your doctor if you notice any of the following:

*Less frequent*:

- blood clotting problems, decrease of red blood cell production and increase of red blood cell destruction (aplastic haemolytic anaemia), swollen or enlarged lymph nodes
- low mood and loss of interest or enjoyment in doing things, feeling nervous
- taste problems – such as changes in the way things taste
- heart problems – such as reduced heart rate or chest pain (angina)
- asthma, too little oxygen reaching the body organs
- swelling of the stomach.
- short term increase in the amount of some types of anti-bodies in the blood (called immunoglobulins – IgM), chemical disturbances in the blood caused by break-down of dying cancer cells
- nerve damage in arms and legs, paralysed face
- heart failure
- inflammation of blood vessels including those leading to skin symptoms
- respiratory failure
- damage to the intestinal wall (perforation)
- severe skin problems causing blisters that can be life-threatening
- kidney failure
- severe vision loss (sign of brain nerves damage).

*Other side effects include:*

- a reduction in white blood cells which does not happen straight away
- reduced platelets number just after the infusion – this can be reversed, but can be fatal

- hearing loss, loss of other senses.

MabThera may also cause changes in laboratory tests carried out by your doctor.

If you are having MabThera with other medicines, some of the side-effects you may get may be due to the other medicines.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MabThera SC 1400 mg.

## 5. How to store MabThera SC 1400 mg

Store all medicines out of reach of children.

Store at 2 °C - 8 °C (in a refrigerator). Do not freeze. Keep the container in the outer carton in order to protect from light.

Do not use this medicine after the date has passed or after the medicine has expired which is stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

**What MabThera SC 1400 mg contains**

Each vial contains 1400 mg/11,7 mL of rituximab supplied as a solution for subcutaneous (SC) injection. Each mL contains 120 mg of rituximab.

The other ingredients are: α,α-trehalose dihydrate, L-histidine, L-histidine hydrochloride, monohydrate, L-methionine, $N_2$ medical gas,polysorbate 80,recombinant human hyaluronidase

(rHuPH20), water for injections.

MabThera SC 1 400 mg contains less than 1 mmol sodium per dose, i.e. it is essentially sodium-free.

**What MabThera SC 1400 mg looks like and contents of the pack**

- Pack of 1 vial. Colourless 15 mL type 1 glass vial with a grey butyl rubber stopper with aluminium over seal and a pink plastic flip-off disc.
- MabThera SC 1400 mg is a ready to use, clear to opalescent, colourless to yellowish liquid provided in sterile, preservative-free, non-pyrogenic, single dose vials.

**Holder of Certificate of Registration**

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