
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Rituximab 100 Equity, concentrate for solution for infusion

Rituximab 500 Equity, concentrate for solution for infusion

Rituximab

Sugar free

Read all of this leaflet carefully before you are given Rituximab Equity

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse 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. See section 4.

What is in this leaflet

1. What Rituximab Equity is and what it is used or
2. What you need to know before Rituximab Equity is given to you
3. How Rituximab Equity will be given
4. Possible side effects
5. How to store Rituximab Equity
6. Contents of the pack and other information

1. What Rituximab Equity is and what it is used for

What Rituximab Equity is

Rituximab Equity 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.

What Rituximab Equity is used for

Rituximab Equity may be used for the treatment of several different conditions. Your doctor may prescribe Rituximab Equity for the treatment of:

a) Non-Hodgkin's lymphoma

This is a disease of the lymph tissue (part of the immune system) that affects a type of white blood cell called B-Lymphocytes. Rituximab Equity can be given alone or with other medicines called “chemotherapy”. If the treatment is working, Rituximab Equity may be used as maintenance treatment for 2 years after completing the initial treatment.

b) Chronic lymphocytic leukaemia

Chronic lymphocytic leukaemia (CLL) is the most common form of adult leukaemia. CLL affects a particular lymphocyte, the B cell, which originates from the bone marrow and develops in the lymph nodes. Patients with CLL have too many abnormal lymphocytes, which accumulate mainly in the bone marrow and blood. The spread of these abnormal B-lymphocytes is the cause of symptoms you may have. Rituximab Equity in combination with chemotherapy destroys these cells.

c) Rheumatoid arthritis

Rituximab Equity is used for the treatment of rheumatoid arthritis. Rheumatoid arthritis is a disease of the joints. B-lymphocytes are involved in the cause of some of the symptoms you have. Rituximab Equity is used to treat rheumatoid arthritis in people who have already tried other medicines which have either stopped working, have not worked well enough or have caused unacceptable side effects. Rituximab Equity is usually taken together with another medicine called methotrexate.

Rituximab Equity slows down the damage to your joints caused by rheumatoid arthritis and improves your ability to do normal daily activities.

The best responses to Rituximab Equity are seen in those who have a positive blood test to rheumatoid factor (RF) and/or anti-Cyclic Citrullinated Peptide (anti-CCP). Both tests are commonly positive in rheumatoid arthritis and aid in confirming the diagnosis.

d) Granulomatosis with polyangiitis or microscopic polyangiitis

Rituximab Equity is used for inducing remission in granulomatosis with polyangiitis (formerly called Wegener's granulomatosis) or microscopic polyangiitis, taken in combination with corticosteroids. Granulomatosis with polyangiitis and microscopic polyangiitis are two forms of inflammation of the blood vessels which mainly affects the lungs and kidneys but may affect other organs as well. B-lymphocytes are involved in the cause of these conditions.

2. What you need to know before you use Rituximab Equity

Rituximab Equity 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 Rituximab Equity (listed in section 6)
- if you have a severe active infection at the moment
- if you have a weak immune system
- if you have severe heart failure or severe uncontrolled heart disease and have rheumatoid arthritis, granulomatosis with polyangiitis or microscopic polyangiitis.

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

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

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- if you have ever had or might now have a hepatitis infection. This is because in a few cases, Rituximab Equity 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.
 - if you have ever had heart problems (such as angina, palpitations or heart failure), breathing problems or experience any breathing problems.
 - if you have or had tuberculosis (TB) infection, including latent tuberculosis infections. Treatment with Rituximab Equity may reactivate the tuberculosis disease. Your TB infection must be treated before you receive Rituximab Equity therapy. You will be tested for latent tuberculosis throughout your treatment with Rituximab Equity.
 - if you are infected with HIV.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Rituximab Equity. Your doctor may need to take special care of you during your treatment with Rituximab Equity.

Also talk to your doctor if you think you may need any vaccinations in the near future, including vaccinations needed to travel to other countries. Some vaccines should not be given at the same time as Rituximab Equity or in the months after you receive Rituximab Equity. Your doctor will check if you should have any vaccines before you receive Rituximab Equity.

If you have rheumatoid arthritis, granulomatosis with polyangiitis or microscopic polyangiitis also tell your doctor

- if you think you may have an infection, even a mild one like a cold. The cells that are affected by Rituximab Equity help to fight infection and you should wait until the infection has passed before you are given Rituximab Equity. Please also tell your doctor if you have had a lot of infections in the past or suffer from severe infections or if you notice neurological symptoms or signs.

Children and adolescents

The safety and efficacy of Rituximab Equity in children and adolescents have not been established.

Other medicines and Rituximab Equity

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

This is because Rituximab Equity can affect the way some other medicines work. Also some other medicines can affect the way Rituximab Equity works.

In particular, tell your doctor:

- if you are taking medicines for high blood pressure. You may be asked not to take these medicines 12 hours before you are given Rituximab Equity. This is because some people have a fall in their blood pressure while they are being given Rituximab Equity.
- if you have ever taken medicines which affect your immune system – such as chemotherapy, immune-suppressive medicines including medicines to treat rheumatoid arthritis such as DMARD's (disease-modifying antirheumatic drugs).

If any of the above applies to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Rituximab Equity.

Pregnancy, 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 healthcare provider for advice before receiving Rituximab Equity. This is because Rituximab Equity 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 Rituximab Equity. You must also do this for 12 months after your last treatment with Rituximab Equity.

Breastfeeding:

Rituximab Equity passes into breast milk in very small amounts. Do not breastfeed while you are being treated with Rituximab Equity. Do not breastfeed for 12 months after your last treatment with Rituximab Equity.

Driving and using machines

It is not known whether Rituximab Equity has an effect on you being able to drive or use any tools or machines.

It is not always possible to predict to what extent Rituximab Equity may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which Rituximab Equity affects you.

Rituximab Equity contains sodium

Rituximab Equity contains 41,3 mg sodium (main component of the cooking/table salt) in each 10 mL vial and 205,8 mg in each 50 mL vial.

This is equivalent to 2,1 % (for 10 mL vial) and 10,3 % (for 50 mL vial) of the recommended maximum dietary intake of sodium for an adult.

3. How to use Rituximab Equity

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

You will not be expected to give yourself Rituximab Equity. It will be given to you by a person who is qualified to do so. They will watch you closely while you are being given Rituximab Equity. This is in case you get any side effects.

You will always be given Rituximab Equity through a drip (intravenous infusion).

Medicines given before each Rituximab Equity administration

Before you are given Rituximab Equity, you will be given other medicines (pre-medication) to prevent or reduce possible side effects.

How much and how often you will receive your treatment

a) If you are being treated for non-Hodgkin's lymphoma

If you are having Rituximab Equity alone

Rituximab Equity will be given to you once a week for 4 weeks. Repeated treatment courses with Rituximab Equity are possible.

If you are having Rituximab Equity with chemotherapy

Rituximab Equity 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 Rituximab Equity 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.

b) If you are being treated for chronic lymphocytic leukaemia

When you are treated with Rituximab Equity in combination with chemotherapy, you will receive Rituximab Equity infusions on day 0 (the day before chemotherapy), cycle 1 then day 1 of each cycle for 6 cycles in total. Each cycle has a duration of 28 days. The chemotherapy should be given after the Rituximab Equity infusion. Your doctor will decide if you should receive supportive therapy at that time.

c) If you are being treated for rheumatoid arthritis

Each course of treatment is made up of two separate infusions which are given 2 weeks apart. Repeated courses of treatment with Rituximab Equity are possible. Depending on the signs and symptoms of your disease, your doctor will decide when you should receive more Rituximab Equity. This may be months from now.

d) If you are being treated for granulomatosis with polyangiitis or microscopic polyangiitis

Treatment with Rituximab Equity uses four separate infusions given at weekly intervals. Corticosteroids will usually be given by injection before the start of Rituximab Equity treatment. Corticosteroids given by mouth may be started at any time by your doctor to treat your condition.

If you are 18 years of age and older and respond well to treatment, you may be given Rituximab Equity as a maintenance treatment. This will be administered as 2 separate infusions which are given 2 weeks apart, followed by 1 infusion every 6 months for at least 2 years. Your doctor may decide to treat you longer with Rituximab Equity (up to 5 years), 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.

If you receive more Rituximab Equity than you should

Since a healthcare provider will administer Rituximab Equity, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of Rituximab Equity

Since a healthcare provider will administer Rituximab Equity, it is unlikely that the dose will be missed.

4. Possible side effects

Rituximab Equity can have side effects.

Not all side effects reported for Rituximab Equity are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being treated with Rituximab Equity, please consult your healthcare provider for advice.

Most side effects are mild to moderate but some may be serious and require treatment. Less frequently, some of these reactions have been fatal.

Infusion reactions

During or within the first 24 hours of the first infusion you may develop fever, chills and shivering. Less frequently, some patients may get pain at the infusion site, blisters, itching, hives, rash, sickness (nausea), tiredness, headache, breathing difficulties, blood pressure raised, wheezing, throat discomfort, tongue or throat swelling, itchy or runny nose, vomiting, flushing or palpitations, heart attack or low number of platelets. If you have heart disease or angina, these infusion reactions might get worse. **Tell the person giving you the infusion immediately** if you develop any of these symptoms, as the infusion may need to be slowed down or stopped. You may require additional treatment such as an antihistamine or paracetamol. When these symptoms go away, or improve, the infusion can be continued. These reactions are less likely to happen after the second infusion. Your doctor may decide to stop your Rituximab Equity treatment if these reactions are serious.

Infections

Tell your doctor immediately if you get 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 serious brain infection, which has been fatal (Progressive Multifocal Leukoencephalopathy or PML)
- fever, headache and stiff neck, incoordination (ataxia), personality change, hallucinations, altered consciousness, seizures or coma – these may be due to a serious brain infection (enteroviral meningoencephalitis), which can be fatal

You might get infections more easily during your treatment with Rituximab Equity.

These are often colds, but there have been cases of pneumonia, urinary infections and serious viral infections. These are listed below under “Other side effects”.

If you are being treated for rheumatoid arthritis, granulomatosis with polyangiitis or microscopic polyangiitis, you will also find this information in the Patient Alert Card you have been given by your doctor. It is important that you keep this Alert Card and show it to your partner or caregiver.

Skin reactions

Less frequently, severe blistering skin conditions that can be life-threatening may occur. Redness, often associated with blisters, may appear on the skin or on mucous membranes, such as inside the mouth, the genital areas or the eyelids, and fever may be present. **Tell your doctor immediately if you experience any of these symptoms.**

Other side effects include:

a) If you are being treated for non-Hodgkin's Lymphoma or chronic lymphocytic leukaemia

Frequent side effects:

- bacterial or viral infections, bronchitis
- low number of white blood cells sometimes with fever, or low number of blood cells called "platelets"
- feeling sick (nausea)
- bald spots on the scalp, chills, headache
- lower immunity – because of lower levels of antibodies called "immunoglobulins" (IgG) in the blood which help protect 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 lactate dehydrogenase (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)

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- ringing sound in the ears, ear pain
 - heart problems – such as heart attack and 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 (bronchospasm), inflammation, irritation in the lungs, throat or sinuses, being 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.

Less frequent side effects:

- severe virus infections, fungus infections
- 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
- allergic reaction, tumour lysis syndrome, cytokine release syndrome, serum sickness
- short-term increase in the amount of some types of antibodies 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

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- 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. Redness, often associated with blisters, may appear on the skin or on mucous membranes, such as inside the mouth, the genital areas or the eyelids, and fever may be present
 - kidney failure
 - severe vision loss

Not known (it is not known how often these side effects happen):

- 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
- lung infiltration
- brain and meningeal infection/inflammation (enteroviral meningoencephalitis)

b) If you are being treated for rheumatoid arthritis

Frequent side effects:

- infections such as pneumonia (bacterial)
- pain on passing water (urinary tract infection)
- allergic reactions that are most likely to occur during an infusion, but can occur up to 24-hours after infusion
- changes in blood pressure, nausea, rash, fever, feeling itchy, runny or blocked nose and sneezing, shaking, rapid heartbeat, and tiredness
- headache
- changes in laboratory tests carried out by your doctor. These include a decrease in the amount of some specific proteins in the blood (immunoglobulins) which help protect against infection.
- infections such as bronchial tube inflammation (bronchitis)

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- a feeling of fullness or a throbbing pain behind the nose, cheeks and eyes (sinusitis), pain in the abdomen, vomiting and diarrhoea, breathing problems
 - fungal foot infection (athlete's foot)
 - high cholesterol levels in the blood
 - abnormal sensations of the skin, such as numbness, tingling, pricking or burning, sciatica (pain that runs down one or both legs from the lower back), migraine, dizziness
 - loss of hair
 - anxiety, depression
 - indigestion, diarrhoea, acid reflux, irritation and/or ulceration of the throat and the mouth
 - pain in the tummy, back, muscles and/or joints

Less frequent side effects:

- reactivation of hepatitis B
- excess fluid retention in the face and body
- inflammation, irritation and/or tightness of the lungs and throat, coughing
- skin reactions including hives, itching and rash
- allergic reactions including wheezing or shortness of breath, swelling of the face and tongue, collapse
- a complex of symptoms occurring within a few weeks of an infusion of Rituximab Equity including allergic like reactions such as rash, itching, joint pain, swollen lymph glands and fever
- severe blistering skin conditions that can be life-threatening. Redness, often associated with blisters, may appear on the skin or on mucous membranes, such as inside the mouth, the genital areas or the eyelids, and fever may be present.

Not known (it is not known how often these side effects happen):

- serious viral infection
- brain and meningeal infection/inflammation (enteroviral meningoencephalitis)

Other less frequently reported side effects due to Rituximab Equity include a decreased number of white cells in the blood (neutrophils) that help to fight against infection. Some infections may be severe (please see information on ***Infections*** within this section).

c) If you are being treated for granulomatosis with polyangiitis or microscopic polyangiitis

Frequent side effects:

- infections, such as chest infections, urinary tract infections (pain on passing water), colds and herpes infections
- allergic reactions that are most likely to occur during an infusion, but can occur up to 24-hours after infusion
- diarrhoea
- coughing or shortness of breath
- nose bleeds
- raised blood pressure
- painful joints or back
- muscle twitches or shakiness
- feeling dizzy
- tremors (shakiness, often in the hands)
- difficulty sleeping (insomnia)
- swelling of the hands or ankles
- indigestion
- constipation
- skin rashes, including acne or spots
- flushing or redness of the skin
- fever
- blocked or runny nose
- tight or painful muscles
- pain in the muscles or in the hands or feet

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- low number of red blood cells (anaemia)
 - low numbers of platelets in the blood
 - an increase in the amount of potassium in the blood
 - changes in the rhythm of the heart, or the heart beating faster than normal

Less frequent side effects:

- severe blistering skin conditions that can be life-threatening. Redness, often associated with blisters, may appear on the skin or on mucous membranes, such as inside the mouth, the genital areas or the eyelids, and fever may be present.
- recurrence of a previous Hepatitis B infection

Not known (it is not known how often these side effects happen):

- serious viral infection
- brain and meningeal infection/inflammation (enteroviral meningoencephalitis)

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

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Rituximab Equity.

5. How to store Rituximab Equity

- Store all medicines out of reach of children.
- Store in a refrigerator (2 °C - 8 °C).
- Keep the container in the outer carton in order to protect from light.

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- Do not freeze.
 - Do not use this medicine after the expiry date which is stated on the carton and the vial.
 - Return all unused medicine to your pharmacist.
 - Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Content of the pack and other information

What Rituximab Equity contains

The active substance is rituximab.

Each mL of concentrate contains 10 mg of rituximab.

Each 10 mL vial contains 100 mg of rituximab.

Each 50 mL vial contains 500 mg of rituximab.

The other ingredients are sodium citrate dihydrate, polysorbate 80, sodium chloride, hydrochloric acid and water for injection.

What Rituximab Equity looks like and contents of the pack

Rituximab Equity is a clear or slightly opalescent, colourless to light yellow liquid free of visible particles, with a pH of 6,2 – 6,8 and osmolality of 324 – 396 mOsmol/g.

Rituximab 100 Equity: Clear Type I glass vial sealed with a grey bromobutyl rubber stopper crimped with aluminium seal with grey plastic flip-off cap. Pack of 2 vials.

Rituximab 500 Equity: Clear Type I glass vial sealed with a grey bromobutyl stopper crimped with aluminium seal with grey plastic flip-off cap. Pack of 1 vial.

Holder of Certificate of Registration

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RITUXIMAB 500 EQUITY: 56/30.1/0485

Access to the corresponding Professional Information

An electronic copy of the translated Patient Information Leaflet (PIL) is available on the Equity website

<http://www.equitypharmaceuticals.co.za> or <http://www.sahpra.org.za>.