PATIENT INFORMATION LEAFLET FOR RITUXIMAB CIPLA

SCHEDULING STATUS:

S4

RITUXIMAB CIPLA (100 mg/10 mL concentrate for solution for infusion)

RITUXIMAB CIPLA (500 mg/50 mL concentrate for solution for infusion)

Rituximab

RITUXIMAB CIPLA 100 mg/10 mL: Contains 90 mg of sodium chloride and 73,5 mg of sodium citrate dihydrate.

RITUXIMAB CIPLA 500 mg/50 mL: Contains 450,0 mg of sodium chloride and 367,5 mg of sodium citrate dihydrate.

Sugar free.

Read all of this leaflet carefully before you are given RITUXIMAB CIPLA:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- RITUXIMAB CIPLA 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 RITUXIMAB CIPLA is and what it is used for

RITUXIMAB CIPLA contains the active substance “rituximab”. Rituximab is an antibody which is a type of protein. Rituximab binds to the surface of a type of white blood cell, the B lymphocytes. When rituximab binds to the surface of this cell it causes the cell to die.

RITUXIMAB CIPLA may be used for the treatment of several different conditions. Your doctor may prescribe RITUXIMAB CIPLA for the treatment of:

a) Non-Hodgkin’s Lymphoma (NHL)

Non-Hodgkin’s Lymphoma is a disease of the lymphatic system, and B lymphocytes are involved in the cause of some of the symptoms you may have. RITUXIMAB CIPLA can be used alone or with other medicines your doctor may prescribe to induce remission of your disease. RITUXIMAB CIPLA may be used as a continuous (maintenance) treatment for 2 years in patients who have responded to induction treatment.

b) Chronic Lymphocytic Leukaemia (CLL)

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 high number of these abnormal B lymphocytes is the cause of symptoms you may have. RITUXIMAB CIPLA in combination with chemotherapy destroys these cells which are then gradually removed from the body by biological processes.

c) Rheumatoid Arthritis (RA)

RITUXIMAB CIPLA 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 CIPLA is used to treat rheumatoid arthritis in people who have already tried some other medicines which have either stopped working or have not worked well enough. RITUXIMAB CIPLA is usually taken together with another medicine called methotrexate.
RITUXIMAB CIPLA slows down the damage to your joints caused by rheumatoid arthritis and improves your ability to do normal daily activities.

d) Granulomatosis with polyangiitis (Wegener's) (GPA) and Microscopic polyangiitis (MPA):

RITUXIMAB CIPLA is used for inducing remission in Granulomatosis with polyangiitis (formerly called Wegener's granulomatosis) (GPA) or Microscopic polyangiitis (MPA), taken in combination with corticosteroids. GPA and MPA are two forms of inflammation of 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 receive RITUXIMAB CIPLA:

RITUXIMAB CIPLA should not be administered to you:

- If you are hypersensitive (allergic) to rituximab, to other similar proteins, or any of the ingredients of RITUXIMAB CIPLA (listed in **section 6**).
- If you have an active, severe infection or have a severely decreased immune system function.
- If you have severe heart failure or severe uncontrolled heart disease and have RA, GPA or MPA.
- If you are pregnant or breast-feeding your baby.

Do not receive RITUXIMAB CIPLA if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or health care professional before you are given RITUXIMAB CIPLA.

Warnings and precautions

Tell your doctor before being given RITUXIMAB CIPLA:

- If you think you have hepatitis infection now or have had it in the past. In a few cases, patients who have had hepatitis B might have a repeat attack of hepatitis. Patients with a history of hepatitis B infection will be carefully checked by their doctor for signs of active hepatitis B.
- If you are taking treatment for high blood pressure. You may be asked not to take your medicines 12 hours before your infusion of RITUXIMAB CIPLA. Some people have a fall in their blood pressure during the infusion.
- If you have ever had heart disease (i.e. angina, palpitations, or heart failure) or a history of breathing problems. Your doctor will take special care of you during your treatment with RITUXIMAB CIPLA (in any of the above cases).
- Tell your doctor if you are taking or have previously taken medicines which may affect your immune system, such as chemotherapy or immune-suppressive agents.
- Tell your doctor if you have been diagnosed or having treatment for Tuberculosis or HIV.

If you have RA, GPA or MPA 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 CIPLA help to fight infection and you should wait until the infection has passed before you are given RITUXIMAB CIPLA. Also please tell your doctor if you had a lot of infections in the past or suffer from severe infections.
- 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 CIPLA or in the months after you receive RITUXIMAB CIPLA. Your doctor will check if you should have any vaccines before you receive RITUXIMAB CIPLA.

Children and adolescents

At present, there is not much information about RITUXIMAB CIPLA treatment in children and adolescents; if you are under 18 years of age, you or your parent should ask your doctor if RITUXIMAB CIPLA is right for you.

Non-Hodgkin's lymphoma

RITUXIMAB CIPLA can be used for the treatment of children and adolescents, 6 months of age and older, with non-Hodgkin's lymphoma, specifically CD20 positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL)/Burkitt leukaemia (mature B-cell acute leukaemia) (BAL) or Burkitt-like lymphoma (BLL).

Granulomatosis with polyangiitis or microscopic polyangiitis

RITUXIMAB CIPLA can be used for treatment of children and adolescents, 2 years of age and older, with granulomatosis with polyangiitis (formerly called Wegener's granulomatosis) or microscopic polyangiitis. There is not much information about the use of rituximab in children and adolescents with other diseases.

Other medicines with RITUXIMAB CIPLA

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines). This is because RITUXIMAB CIPLA can affect the way some other medicines work. Also, some other medicines can affect the way RITUXIMAB CIPLA works.

- 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 RITUXIMAB CIPLA. This is because some people have a fall in their blood pressure while they are being given RITUXIMAB CIPLA.
- 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 healthcare professional before you are given RITUXIMAB CIPLA.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving RITUXIMAB CIPLA.

Pregnancy

You must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant. This is because RITUXIMAB CIPLA is an antibody and can cross the placenta and affect your baby. You should not receive RITUXIMAB CIPLA when you are pregnant.

If you can get pregnant, you must use an effective method of birth control during therapy with RITUXIMAB CIPLA and for 12 months after your last treatment with RITUXIMAB CIPLA.

Breastfeeding

RITUXIMAB CIPLA might also get into breast milk and so you should not breastfeed your baby during treatment with RITUXIMAB CIPLA and for 12 months after your last treatment with RITUXIMAB CIPLA.

Driving and using machines

It is not known whether RITUXIMAB CIPLA has an effect on your ability to drive a car or operate machinery. You should first note how RITUXIMAB CIPLA affects you before drive or use machines.

RITUXIMAB CIPLA contains sodium

RITUXIMAB CIPLA contains 163,5 mg sodium per 10 mL vial and 817,5 mg sodium per 50 mL vial, equivalent to 8,18 % (for 10 mL vial) and 40,875 % (for 50 mL vial) of the of the

recommended maximum daily dietary intake of sodium for an adult.

3. How to receive RITUXIMAB CIPLA:

RITUXIMAB CIPLA is administered by a healthcare professional after dilution as an intravenous infusion ("drip"). Your doctor will give you a medicine to prevent or reduce pain and/or fever and allergy before each infusion of RITUXIMAB CIPLA.

You will be observed by a healthcare professional while you are being given RITUXIMAB CIPLA in case you have any side effects during the infusion.

Before the infusion is given, you will be given medicines to prevent or reduce possible reactions to RITUXIMAB CIPLA.

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

If you are treated with RITUXIMAB CIPLA alone you will receive infusions at weekly intervals for a total of four infusions (days 1, 8, 15 and 22), so that a course of treatment usually lasts for 22 days. Repeated treatment courses with RITUXIMAB CIPLA are possible. If you are treated with RITUXIMAB CIPLA in combination with other medicines, you will receive an infusion of RITUXIMAB CIPLA on the same day as the other medicines, which are usually given 8 times at 3-week intervals. If you have responded to treatment and are further treated with RITUXIMAB CIPLA as continuous (maintenance) treatment, you will receive one infusion of RITUXIMAB CIPLA every 2 or 3 months (as directed by your doctor) for two years. Your doctor may change the number of infusions depending on your disease.

If you are less than 18 years of age, you will be given RITUXIMAB CIPLA with chemotherapy. You will receive RITUXIMAB CIPLA up to 6 times over a 3.5 – 5.5 month period.

b) If you are being treated for chronic lymphocytic leukaemia

When you are treated with RITUXIMAB CIPLA in combination with chemotherapy, you will receive RITUXIMAB CIPLA 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 CIPLA 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 CIPLA are possible. Depending on the signs and symptoms of your disease, your doctor will decide when you should receive more RITUXIMAB CIPLA. This may be months from now.

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

Treatment with RITUXIMAB CIPLA uses four separate infusions given at weekly intervals. Corticosteroids will usually be given by injection before the start of RITUXIMAB CIPLA treatment. Corticosteroids given by mouth may be started at any time by your doctor to treat your condition. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

If you are 18 years of age and older and respond well to treatment, you may be given RITUXIMAB CIPLA 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 CIPLA (up to 5 years), depending on how you respond to the medicine.

If you receive more RITUXIMAB CIPLA than you should:

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

If you forget to receive RITUXIMAB CIPLA:

Since a health care provider will administer RITUXIMAB CIPLA, it is unlikely that the dose will

be missed.

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

If you stop receiving RITUXIMAB CIPLA

Do not stop receiving RITUXIMAB CIPLA unless your doctor tells you to do so. If you stop receiving RITUXIMAB CIPLA, your original complaints may return or worsen. If you have further questions on the use of RITUXIMAB CIPLA, ask your doctor or pharmacist.

4. Possible side effects

RITUXIMAB CIPLA can have side effects.

Not all side effects reported for RITUXIMAB CIPLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving RITUXIMAB CIPLA, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop receiving RITUXIMAB CIPLA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RITUXIMAB CIPLA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pain,
- Angina,

- Changes in the way your heart beats e.g. if you notice it beating faster,
- Difficulty in breathing,
- Less urine than is normal for you,
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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

Infusion reactions

During or within the first 2 hours of the first infusion you may develop fever, chills and shivering. Less frequently, some patients may experience blisters, itching, sickness, tiredness, headache, breathing difficulties, tongue or throat swelling, itchy, runny nose, vomiting, flushing or palpitations, heart attack or low number of platelets. If you have heart disease or angina, these 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 for a while. 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 not to continue with RITUXIMAB CIPLA treatment if you have a serious infusion-related reaction.

Infections

Tell your doctor after your RITUXIMAB CIPLA treatment if you get any symptoms of an infection, for example fever, cough, sore throat, burning pain when passing urine, or you start to feel weak or generally unwell. You might get infections more easily following RITUXIMAB CIPLA therapy. Often these are colds, but there have been cases of pneumonia or urinary infections.
There have been patients being treated with RITUXIMAB CIPLA who had experienced a serious

brain infection, which was fatal. Tell your doctor immediately if you have memory loss, trouble thinking, difficulty with walking or loss of vision.

Skin Reactions

Severe blistering skin conditions that can be life-threatening have occurred, including Stevens-Johnson Syndrome. 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 reactions

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

The following side effects have frequently been reported:

- Infections such as pneumonia (bacterial) and herpes (viral) or bronchial tube inflammation (bronchitis),
- Low number of white blood cells, with or without fever, low number of platelets in the blood,
- Allergic reactions after infusion,
- Skin rashes, itching, bald spots on the scalp, fever, chills, physical weakness, headache,
- Infections such as sepsis and pneumonia (bacterial), herpes and hepatitis B (viral) or candidal (fungal) bronchial tube and sinuses inflammation, or other general infections of unknown origin',
- Low number of red blood cells, low number of red and white blood cells and platelets,
- Allergic reactions (hypersensitivity),
- High sugar level in the blood, weight loss, excess fluid in the face and the body, increased blood levels of the enzyme (LDH), low blood level of calcium,
- Abnormal sensations of the skin, such as numbness, tingling, pricking, burning, a

creeping skin sensation, decreased sense of touch. Feeling restless, difficulty falling asleep, becoming red in the face and bruising of the skin as a consequence of dilation of the blood vessels, dizziness, anxiety,

- An increased production of tears, secretion and shedding disorders, inflammation of the eye (conjunctivitis),
- Ringing sound in the ears, ear pain,
- Heart disorders (heart attack, irregular heart rate, abnormally fast heart rate),
- High or low blood pressure, a decrease in blood pressure upon assuming an upright posture,
- Inflammation, irritation and / or tightness of the lungs, throat and / or sinuses, shortness of breath, too little oxygen reaching the body organs, coughing,
- Vomiting, diarrhoea, pain in the abdomen, irritation and /or ulceration of the throat and the mouth, difficulties in swallowing, constipation, indigestion. Eating disorders: decrease in the amount of food eaten with a consequential dangerous loss in weight,
- Skin disorders, burning sensation of the skin, itching, increased perspiration, night sweats,
- Musculoskeletal disorders, abnormal increase in tightness of muscle tone, pain, joint pain, muscle pain, back and neck pain,
- General disorders, tumour pain, becoming markedly red in the face and other areas of the skin, general discomfort or uneasiness, flu syndrome, fatigue, shaking, multi-organ dysfunction.

The following side effects have been reported less frequently:

- Abnormal clotting, decrease of blood cells production, auto-immune decrease of red blood cells, swollen/enlarged lymph nodes,
- Low mood and loss of interest or pleasure in usual activities, nervousness,
- Taste changes,

- Heart disorder (heart attack, abnormal fast heart rate, reduced heart rate, irregular heart rate, chest pain) inflammation, irritation and/or tightness of the lungs, asthma, shortness of breath,
- Enlargement of the abdomen,
- Pain at the infusion site,
- Temporary increased immunoglobulins, chemical disturbances in blood caused by the breakdown of dying cancer cells, which can also lead to kidney failure,
- Nerve damage in arms and legs, paralysis of the face,
- Heart failure,
- Inflammation of blood vessels including those leading to skin symptoms,
- Perforation of the bowel wall,
- Kidney failure,
- 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,
- Infection caused by a fungus called *Pneumocystis jirovecii.*

The following side effects have been reported with unknown frequency:

- Delayed reduction of white blood cells,
- Infusion-related immediate reduction of platelets (reversible), can be fatal in rare cases,
- Hearing loss,
- Loss of other senses.

Children and adolescents with non-Hodgkin's lymphoma:

In general, side effects in children and adolescents with non-Hodgkin's lymphoma were similar to those in adults with non-Hodgkin's lymphoma or chronic lymphocytic leukaemia. The most frequent side effects seen were fever associated with low levels of a type of white blood cell (neutrophil), inflammation or sores in the lining of the mouth, and allergic reactions

(hypersensitivity).

b) If you are being treated for rheumatoid arthritis

The following side effects have frequently been reported:

- 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 block nose and sneezing, shaking, rapid heart-beat, 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),
- 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, 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.

The following side effects have been reported less frequently:

- 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 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,

Other reported side effects due to rituximab 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

The following side effects have frequently been reported:

- 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,
- Blocked nose,
- Tight or painful muscles,
- Pain in the muscles or in the hands or feet,
- 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.

The following side effects have been reported less frequently:

- 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.

Children and adolescents with granulomatosis with polyangiitis or microscopic polyangiitis

In general, side effects in children and adolescents with granulomatosis with polyangiitis or

microscopic polyangiitis were of a similar type to those in adults with granulomatosis with polyangiitis or microscopic polyangiitis. Most common side effects seen were infections, allergic reactions and feeling sick (nausea).

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

RITUXIMAB CIPLA may also cause changes in laboratory tests carried out by your doctor. These include a decreased number of white cells in the blood (neutrophils) that help to fight against infection and a decrease in the amount of some specific proteins in the blood (immunoglobulins) which help protect against infection.
If you are receiving RITUXIMAB CIPLA in combination with other medicines, some of the side affects you may experience may be due to the other medicine.

If any of the side effects gets serious, or, if you notice any side effects not listed in this leaflet, please inform your doctor, nurse or pharmacist immediately.

Reporting of side effects

If you get side effects, talk to your doctor 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 or by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of RITUXIMAB CIPLA.

5. How to store RITUXIMAB CIPLA:

- **Store all medicines out of reach of children.**
- Always store the vials in the closed original pack between 2 °C to 8 °C (in the refrigerator). Keep the container in the outer carton in order to protect from sunlight.

- Do not use after the expiry date dated on the outer pack and on the vial label. The expiry date refers to the last day of that month.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What RITUXIMAB CIPLA contains

The active ingredient in RITUXIMAB CIPLA is called rituximab.

The other ingredients are: Polysorbate 80 (Tween 80), sodium chloride, sodium citrate dihydrate and water for injection.

What RITUXIMAB CIPLA looks like and contents of the pack

What RITUXIMAB CIPLA looks like:

RITUXIMAB CIPLA 100 mg/10mL is a clear or slightly opalescent, colourless or slightly yellow liquid, free of visible particles.

RITUXIMAB CIPLA 500 mg/50mL is a clear or slightly opalescent, colourless or slightly yellow liquid, free of visible particles.

Contents of the pack:

RITUXIMAB CIPLA 100 is supplied in a single-use vials containing a sterile, non-pyrogenic concentrate for solution for infusion. The vial consists of a type I borosilicate glass vial sealed with a chlorobutyl stopper with FluroTec® and a blue plastic/aluminium flip-off cap.

RITUXIMAB CIPLA 500 is supplied in a single-use vials containing a sterile, non-pyrogenic concentrate for solution for infusion. The vial consists of a type I borosilicate glass vial sealed with a chlorobutyl stopper with FluroTec® and a dark blue plastic/aluminium flip-off cap.

RITUXIMAB CIPLA (100 mg/10 mL concentrate for solution for infusion)

RITUXIMAB CIPLA 100 mg/10 mL presentation contains two labelled vials of 10 mL each, properly conditioned in a suitable plastic tray placed in a carton box.

RITUXIMAB CIPLA (500 mg/50 mL concentrate for solution for infusion)

RITUXIMAB CIPLA 500 mg/50 mL presentation contains one labelled vial of 50 mL, properly conditioned in a suitable plastic tray placed in a carton box.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Customer Care: 080 222 6662.

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Registration number(s)

RITUXIMAB 100 CIPLA: 57/26/0217

RITUXIMAB 500 CIPLA: 57/26/0218

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR Code to be generated and included after approval.