SCHEDULING STATUS: S4

BLITZIMA 100 mg concentrate for solution for infusion
BLITZIMA 500 mg concentrate for solution for infusion
Rituximab
Sugar free

Read all of this leaflet carefully before you start receiving BLITZIMA
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **BLITZIMA** 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 **BLITZIMA** is and what it is used for
2. What you need to know before you use **BLITZIMA**
3. How to use **BLITZIMA**
4. Possible side effects
5. How to store **BLITZIMA**
6. Contents of the pack and other information

1. What BLITZIMA is and what it is used for
BLITZIMA 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 **BLITZIMA** sticks to the surface of this cell, it destroys the cell. **BLITZIMA** may be used for the treatment of several different conditions in adults.
Your doctor may prescribe **BLITZIMA** for the treatment of:
- *Non-Hodgkin's Lymphoma (NHL)*
  This is a disease of the lymph tissue (part of the immune system) that affects B-Lymphocytes. **BLITZIMA** can be given alone or with other medicines called "chemotherapy".
  If the treatment is working, **BLITZIMA** may be continued for 2 years after completing the initial treatment.
- *Chronic lymphocytic leukaemia (CLL)*
  Chronic lymphocytic leukaemia (CLL) is the most common form of adult leukaemia. CLL affects B-lymphocytes, which originate in the bone marrow and develop 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. **BLITZIMA** in combination with chemotherapy destroys these cells.
- *Rheumatoid arthritis (RA)*
  BLITZIMA 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. **BLITZIMA** 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. **BLITZIMA** is usually taken together with another medicine called methotrexate.
  BLITZIMA slows down the damage to your joints caused by rheumatoid arthritis and improves your ability to do normal daily activities.
- *Granulomatosis with polyangiitis (GPA) or Microscopic polyangiitis (MPA)*
  BLITZIMA 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.
- *Pemphigus vulgaris (PV)*
  BLITZIMA is used for the treatment of patients with moderate to severe pemphigus vulgaris (PV). PV is an autoimmune condition that causes painful blisters on the skin and lining of the mouth, nose, throat and genitals.

2. What you need to know before you use BLITZIMA

You should not be administered with BLITZIMA if:

- you are hypersensitive (allergic) to rituximab, other proteins which are like rituximab or any of the other ingredients of **BLITZIMA** (listed in section 6).
- you have a severe active infection at the moment, infection with tuberculosis (TB), or have recently been in close contact with someone who has a tuberculosis (TB) infection.
- you have a weak immune system.
- you have severe heart failure or severe uncontrolled heart disease and have rheumatoid arthritis, granulomatosis with polyangiitis or microscopic polyangiitis.

Do not use **BLITZIMA** if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before you use **BLITZIMA**.

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before you use **BLITZIMA** if:

- you have ever been diagnosed with or might currently have a tuberculosis (TB) infection. This is because **BLITZIMA** could cause the tuberculosis infection to become active again. For this reason, your doctor may test for tuberculosis and indicate that you require preventative treatment for tuberculosis infection before using **BLITZIMA**. If the test is negative your doctor may monitor and periodically test for TB infection during your treatment with **BLITZIMA**.
- you are infected with HIV.
- you have ever had or might now have a hepatitis infection. This is because in a few cases, **BLITZIMA** could cause hepatitis B to become active again, which can be fatal in very rare cases. 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.
- you are taking treatment for high blood pressure. You may be asked not to take your medicines for 12 hours before your infusion of **BLITZIMA**. Some people experience a drop in their blood pressure during the infusion.

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

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

- you have taken or are taking medicines such as chemotherapy or immunosuppressive medicines which may affect your immune system.
- if you think you may have an infection, even a mild one like a cold. The cells that are affected by **BLITZIMA** help to fight infection and you should wait until the infection has passed before you use **BLITZIMA**. Also tell your doctor if you have 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 for travel to other countries. Some vaccines should not be given at the same time as **BLITZIMA** or in the months after you receive **BLITZIMA**. Your doctor will check if you should have any vaccines before you use **BLITZIMA**.

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 **BLITZIMA** in children and young people.

Other medicines and BLITZIMA

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

Tell your doctor or pharmacist if you are currently using:

- 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 **BLITZIMA**. This is because some people have a fall in their blood pressure while they are being given **BLITZIMA**.
- if you have ever taken medicines which affect your immune system, such as chemotherapy or immune-suppressive medicines.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **BLITZIMA.**

You must tell your doctor or nurse if you are pregnant, think that you might be pregnant or are planning to become pregnant. This is because **BLITZIMA** can transfer across 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 **BLITZIMA**. You must also do this for 12 months after your last treatment with **BLITZIMA**.

Do not breastfeed while you are being treated with **BLITZIMA**. Also, do not breastfeed for 12 months after your last treatment with **BLITZIMA**. This is because **BLITZIMA** may pass into breast milk.

Driving and using machines
BLITZIMA may impair your ability to drive a vehicle or use machines. Take special care before performing tasks requiring your attention, until you know how **BLITZIMA** will affect you.

BLITZIMA contains sodium
BLITZIMA contains 2,3 mmol (or 52,6 mg) sodium per 10 mL vial and 11,5 mmol (or 263,2 mg) sodium per 50 mL vial, equivalent to 2,6 % (for 10 mL vial) and 13, 2 % (for 50 mL vial) of the WHO recommended maximum daily intake of 2 g sodium for an adult. This needs to be taken into consideration by patients on a controlled sodium diet.

3. How to use BLITZIMA
Do not share medicines prescribed for you with any other person.
Always take **BLITZIMA** exactly as your doctor has instructed you.
You should check with your doctor or pharmacist if you are unsure.

How it is given
BLITZIMA 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 **BLITZIMA** as a drip (intravenous infusion).

Medicines given before each BLITZIMA administration
Before you are given **BLITZIMA**, 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 **BLITZIMA** alone*
  BLITZIMA will be given to you once a week for 4 weeks. Repeated treatment courses with **BLITZIMA** are possible.
- *If you are having **BLITZIMA** with chemotherapy*
  BLITZIMA 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 **BLITZIMA** 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 **BLITZIMA** in combination with chemotherapy, you will receive **BLITZIMA** every 28 days until you have received 6 doses. The chemotherapy should be given after the **BLITZIMA** infusion. Your doctor will decide if you should receive other treatment at the same 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 **BLITZIMA** are possible. Depending on the signs and symptoms of your disease, your doctor will decide when you should receive more **BLITZIMA**. This may be months

from the previous dose.

d) If you are being treated for granulomatosis with polyangiitis or microscopic polyangiitis
Treatment with **BLITZIMA** uses four separate infusions given at weekly intervals. A corticosteroid medicine will usually be given by injection before the start of **BLITZIMA** treatment. Corticosteroid medicine given by mouth may be started at any time by your doctor to treat your condition.

e) If you are being treated for Pemphigus vulgaris (PV)
Each course of treatment is made up of two separate infusions which are given 2 weeks apart. If you respond well to the treatment, you may be given **BLITZIMA** as a maintenance treatment. This will be administered 1 year and 18 months after the initial treatment and then every 6 months as needed or your doctor may change this, depending on how you respond to the medicine.

If you receive more BLITZIMA than you should
Since **BLITZIMA** is administered by your doctor or nurse, it is unlikely that you will be given too much. There are no known side effects of receiving too much **BLITZIMA**.

If you forget or miss your BLITZIMA infusion
If you forget or miss an appointment to receive **BLITZIMA**, make another appointment as soon as possible.

4. Possible side effects
BLITZIMA can have side effects.
Not all side effects reported for **BLITZIMA** are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking **BLITZIMA**, please consult your doctor, pharmacist or other healthcare professional for advice.

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 get pain at the infusion site, blisters, itching, sickness, tiredness, headache, breathing difficulties, 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 **BLITZIMA** 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 very rare, serious brain infection, which has been fatal (progressive multifocal leukoencephalopathy or PML)

You might get infections more easily during your treatment with **BLITZIMA**. These are often colds, but there have been cases of pneumonia or urinary infections.

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
Very rarely, 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 have any of these symptoms.**

Tell your doctor as soon as possible if you notice any of the following:

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

Very common side effects (may affect more than 1 in 10 people):

- 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 anti-bodies called "immunoglobulins" (IgG) in the blood which help protect against infection

Common side effects (may affect up to 1 in 10 people):

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

Uncommon side effects (may affect up to 1 in 100 people):

- 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

Very rare side effects (may affect up to 1 in 10 000 people):

- 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
- 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

Frequency not known:
- 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 in rare cases
- hearing loss, loss of other senses

b) If you are being treated for rheumatoid arthritis

Very common side effects (may affect more than 1 in 10 people):
- 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
- changes in blood pressure, nausea, rash, fever, feeling itchy, runny or blocked 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.

Common side effects (may affect up to 1 in 10 people):
- infections such as bronchial tube inflammation (bronchitis)
- a feeling of fullness or a throbbing pain behind the nose, cheeks and eyes (sinusitis)
- 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.

Uncommon side effects (may affect up to 1 in 100 people):
- 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

Very rare side effects (may affect up to 1 in 10,000 people):
- a complex of symptoms occurring within a few weeks of an infusion of **BLITZIMA** 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.
- recurrence of a previous Hepatitis B infection

Frequency not known:
- serious viral infection

Other rarely reported side effects due to **BLITZIMA** include fewer white cells in the blood (neutrophils) that help to fight against infection. Some infections may be severe (see information on **Infections** above).

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

Very common side effects (may affect more than 1 in 10 people):
- 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

Common side effects (may affect up to 1 in 10 people):
- 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

Very rare side effects (may affect up to 1 in 10 000 people):
- 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

d) If you are being treated for pemphigus vulgaris

Very common side effects (may affect more than 1 in 10 people):
- allergic reactions that are most likely to occur during an infusion, but can occur up to 24 hours after infusion
- headache
- infections such as chest infections
- long lasting depression
- loss of hair

Common side effects (may affect up to 1 in 10 people):
- infections such as common cold, herpes infections, eye infection, oral thrush and urinary tract infections (pain on passing urine)
- mood disorders such as irritability and depression
- skin disorders such as itching, hives, and benign lumps
- feeling tired or dizzy
- fever
- painful joints or back
- pain in the tummy
- pain in the muscles
- heart beating faster than normal

Frequency not known (frequency cannot be estimated from the available data):
- serious viral infection

BLITZIMA 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 **BLITZIMA**.
You may also report to Adcock Ingram Limited using the following e-mail address: Adcock.AEReports@adcock.com.

5. How to store BLITZIMA
Storage of unopened vials
- Store vials in a refrigerator between at 2 °C to 8 °C.
- Keep the vial in the outer carton in order to protect from light.

Storage of diluted product
- The prepared infusion solution of rituximab is physically and chemically stable for 24 hours at 2 °C to 8 °C and subsequently 12 hours at room temperature (not more than 30 °C).
- From a microbiological point of view, the prepared infusion solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 °C to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What BLITZIMA contains
Each vial of **BLITZIMA** 100 contains 100 mg (in 10 ml) of rituximab concentrate for solution for infusion.
Each vial of **BLITZIMA** 500 contains 500 mg (in 50 ml) of rituximab concentrate for solution for infusion.
The other ingredients are polysorbate 80, sodium chloride, tri-sodium citrate dihydrate, water for injections.

What BLITZIMA looks like and contents of the pack
BLITZIMA is a clear to opalescent, colourless to pale yellow solution, with pH of 6,3 – 6,8 and osmolality of 342 – 371 mOsmol/kg.
BLITZIMA 100 mg: Clear, colourless, type I glass vial with a chlorobutyl rubber stopper and an aluminium seal with a yellow flip-off cap containing 100 mg of rituximab in 10 mL. Pack of 2 vials.

BLITZIMA 500 mg: Clear, colourless, type I glass vial with a chlorobutyl rubber stopper and an aluminium seal with a dark grey flip-off cap containing 500 mg of rituximab in 50 mL. Pack of 1 vial.

Holder of Certificate of Registration
Adcock Ingram Limited
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Customer Care: 0860 ADCOCK / 232625

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Registration number
BLITZIMA 100 mg: 53/26/0506
BLITZIMA 500 mg: 53/26/0507

SKEDULERINGSTATUS: S4

BLITZIMA 100 mg konsentraat vir oplossing vir infusie
BLITZIMA 500 mg konsentraat vir oplossing vir infusie
Rituximab
Suikervry

Lees hierdie hele biljet noukeurig deur voordat u BLITZIMA begin ontvang
- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter of u apteker.
- **BLITZIMA** is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie biljet
1. Wat **BLITZIMA** is en waarvoor dit gebruik word
2. Wat u moet weet voordat u **BLITZIMA** gebruik
3. Hoe om **BLITZIMA** te gebruik
4. Moontlike newe-effekte
5. Hoe om **BLITZIMA** te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat is BLITZIMA en waarvoor word dit gebruik
BLITZIMA bevat die aktiewe bestanddeel rituximab. Dit is 'n tipe proteïen wat 'n monoklonale teenliggaam genoem word. Dit kleef aan die oppervlak van 'n tipe witbloedsel, genaamd B-limfosiet, vas. Wanneer **BLITZIMA** aan die oppervlak van hierdie sel kleef, vernietig dit die sel. **BLITZIMA** kan gebruik word vir die behandeling van verskeie verskillende toestande by volwassenes.
U dokter kan **BLITZIMA** voorskryf vir die behandeling van:
- *Non-Hodgkin se Limfoom (NHL)*
  Dit is 'n siekte van die limfweefsel (deel van die immuunstelsel) wat B-limfosiete beïnvloed. **BLITZIMA** kan alleen of saam met ander medisyne genaamd "chemoterapie" gegee word.
  Indien die behandeling werk, kan **BLITZIMA** vir 2 jaar voortgesit word ná voltooiing van die aanvanklike behandeling.
- *Chroniese limfositiese leukemie (CLL)*
  Chroniese limfositiese leukemie (CLL) is die mees algemene vorm van volwasse leukemie. CLL beïnvloed B-limfosiete, wat in die beenmurg ontstaan en in die limfknope ontwikkel. Pasiënte met CLL het te veel abnormale limfosiete, wat hoofsaaklik in die beenmurg en bloed ophoop.
  Die verspreiding van hierdie abnormale B-limfosiete is die oorsaak van simptome wat u mag hê. **BLITZIMA** gebruik in kombinasie met chemoterapie vernietig hierdie selle.
- *Rumatoïede artritis (RA)*
  BLITZIMA word gebruik vir die behandeling van rumatoïede artritis. Rumatoïede artritis is 'n siekte van die gewrigte. B-limfosiete is betrokke by die oorsaak van sommige van die simptome wat u ervaar. **BLITZIMA** word gebruik om rumatoïede artritis te behandel by mense wat reeds ander medisyne probeer het wat óf opgehou het om te werk óf nie goed genoeg gewerk het nie. **BLITZIMA** word gewoonlik saam met 'n ander medisyne genaamd metotreksaat geneem.
  BLITZIMA vertraag die skade aan u gewrigte wat veroorsaak word deur rumatoïede artritis en verbeter u vermoë om normale daaglikse aktiwiteite uit te voer.
- *Granulomatose met poli-angiitis (GPA) of mikroskopiese poli-angitis (MPA)*
  BLITZIMA word gebruik vir die bewerkstelling van remissie in granulomatose met poli-angitis (voorheen genoem Wegener se granulomatose) of mikroskopiese poli-angitis, geneem in kombinasie met kortikosteroïede. Granulomatose met poli-angitis en mikroskopiese poli-angitis is twee vorme van inflammasie van die bloedvate wat hoofsaaklik die longe en niere beïnvloed, maar ook ander organe kan beïnvloed. B-limfosiete is betrokke by die oorsaak van hierdie toestande.
- *Pemphigus vulgaris (PV)*
  BLITZIMA word gebruik vir die behandeling van pasiënte met matige tot ernstige *pemphigus vulgaris* (PV). PV is 'n outo-immuun toestand wat pynlike blase op die vel en voering van die mond, neus, keel en geslagsdele veroorsaak.

2. Wat u moet weet voordat u BLITZIMA gebruik
BLITZIMA moet nie aan u toegedien word nie indien:
- u is hipersensitief (allergies) vir rituximab is, ander proteïene wat soos rituximab is, of vir enige van die

ander bestanddele van **BLITZIMA** (gelys in afdeling 6).
- u tans 'n ernstige aktiewe infeksie het, ‘n infeksie met tuberkulose (TB) het, of onlangs in noue kontak was met iemand wat 'n tuberkulose (TB) infeksie het.
- u 'n swak immuunstelsel het.
- u ernstige hartversaking of ernstige onbeheerde hartsiektes én rumatoïede artritis het, granulomatose met poli-angitis of mikroskopiese poli-angitis.

Moenie **BLITZIMA** gebruik indien enige van die bogenoemde op u van toepassing is nie. Indien u nie seker is nie, raadpleeg u dokter, apteker of verpleegkundige voordat u **BLITZIMA** gebruik.

Waarskuwings en voorsorgmaatreëls
Raadpleeg u dokter, apteker of verpleegkundige voordat u **BLITZIMA** gebruik indien:
- u al ooit gediagnoseer is met, of dalk tans 'n tuberkulose (TB) infeksie het. Dit is omdat **BLITZIMA** kan veroorsaak dat die tuberkulose-infeksie weer aktief word. Om hierdie rede kan u dokter u vir tuberkulose toets en voorstel dat u voorkomende behandeling vir tuberkulose-infeksie benodig voordat u **BLITZIMA** gebruik. Indien die toets negatief is, kan u dokter u monitor en met tussenposes vir TB-infeksie toets tydens u behandeling met **BLITZIMA**.
- u besmet is met MIV.
- u al ooit 'n hepatitis-infeksie gehad het, of nou kan hê. Dit is omdat **BLITZIMA** in enkele gevalle kan veroorsaak dat hepatitis B weer aktief word, wat in baie seldsame gevalle dodelik kan wees. Pasiënte wat al ooit hepatitis B-infeksie gehad het sal noukeurig deur hul dokter ondersoek word vir tekens van hierdie infeksie.
- u al ooit hartprobleme gehad het (soos angina, hartkloppings of hartversaking) of asemhalingsprobleme.
- u behandeling neem vir hoë bloeddruk. U kan gevra word om nie u medisyne vir 12 uur vóór u infusie met **BLITZIMA** te neem nie. Sommige mense ervaar 'n daling in hul bloeddruk tydens die infusie.

Indien enige van die bogenoemde op u van toepassing is (of u is nie seker nie), raadpleeg u dokter, apteker of verpleegkundige voordat u **BLITZIMA** gebruik. U dokter sal dalk ekstra versigtig moet wees tydens u behandeling met **BLITZIMA.**

Indien u rumatoïede artritis, granulomatose met poli-angitis, mikroskopiese poli-angitis of *pemphigus vulgaris* het, lig ook u dokter in:
- dat u medisyne soos chemoterapie of immuunonderdrukkende medisyne geneem het, of tans neem, wat u immuunstelsel kan beïnvloed.
- indien u dink u kan 'n infeksie hê, selfs 'n ligte een soos 'n verkoue. Die selle wat deur **BLITZIMA** geraak word, help om infeksie te beveg en u moet wag totdat die infeksie opgeklaar het voordat u **BLITZIMA** gebruik. Lig ook u dokter in indien u in die verlede baie infeksies gehad het of aan ernstige infeksies ly.
- indien u dink u sal dalk enige inentings in die nabye toekoms nodig hê, insluitend inentings vir reis na ander lande. Sommige entstowwe moet nie op dieselfde tyd as **BLITZIMA** gegee word nie, of in die maande nadat u **BLITZIMA** ontvang het. U dokter sal vasstel of u enige entstowwe moet ontvang voordat u **BLITZIMA** gebruik.

Kinders en adolessente
Raadpleeg u dokter, apteker of verpleegkundige voordat u hierdie medisyne ontvang indien u, of u kind, jonger as 18 jaar oud is. Dit is omdat daar nie veel inligting oor die gebruik van **BLITZIMA** by kinders en jongmense is nie.

Ander medisyne en BLITZIMA
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Lig u dokter of apteker in indien u tans die volgende gebruik:
- indien u medisyne vir hoë bloeddruk neem. U kan gevra word om nie hierdie ander medisyne te neem vir 12 ure voordat u **BLITZIMA** gegee word nie. Dit is omdat sommige mense 'n daling in hul bloeddruk ervaar terwyl hulle **BLITZIMA** ontvang.
- indien u al ooit medisyne geneem het wat u immuunstelsel beïnvloed, soos chemoterapie of immuunonderdrukkende medisyne.

Swangerskap en borsvoeding
Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies voordat u **BLITZIMA** neem**.**

U moet u dokter of verpleegkundige inlig indien u swanger is, dink dat u dalk swanger is of van plan is om swanger te raak. Dit is omdat **BLITZIMA** deur die plasenta oorgedra kan word en u baba kan beïnvloed.

Indien u swanger kan raak, moet u en u maat 'n effektiewe metode van voorbehoeding gebruik terwyl u **BLITZIMA** gebruik. U moet dit ook vir 12 maande ná u laaste behandeling met **BLITZIMA** volhou.

Moenie borsvoed terwyl u met **BLITZIMA** behandel word nie. Moet ook nie borsvoed vir 12 maande ná u laaste behandeling met **BLITZIMA** nie. Dit is omdat **BLITZIMA** in borsmelk uitgeskei kan word.

Bestuur en gebruik van masjinerie
BLITZIMA kan u vermoë om 'n voertuig te bestuur of masjinerie te gebruik, benadeel. Wees veral versigtig voordat u take uitvoer wat u aandag verg, totdat u weet hoe **BLITZIMA** u sal beïnvloed.

BLITZIMA bevat natrium
BLITZIMA bevat 2,3 mmol (of 52,6 mg) natrium per 10 mL flessie en 11,5 mmol (of 263,2 mg) natrium per 50 mL flessie, gelykstaande aan 2,6 % (vir 10 mL flessie) en 13,2 % (vir 50 mL flessie) van die WGO se aanbevole maksimum daaglikse inname van 2 g natrium vir 'n volwassene. Dit moet in ag geneem word by pasiënte op 'n natrium-beheerde dieet.

3. Hoe om BLITZIMA te gebruik
Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.
Neem altyd **BLITZIMA** presies soos u dokter u opdrag gegee het.
U moet met u dokter of apteker bevestig indien u onseker is.

Hoe dit gegee word
BLITZIMA sal aan u gegee word deur 'n dokter of verpleegkundige wat ervare is in die gebruik van hierdie behandeling. Hulle sal u fyn dophou terwyl u hierdie medisyne ontvang. Dit is ingeval u enige newe-effekte kry. U sal altyd **BLITZIMA** met 'n drup (binneaarse infusie) gegee word.

Medisyne wat voor elke BLITZIMA-toediening gegee word
Voordat u **BLITZIMA** gegee word, sal u ander medisyne (premedikasie) ontvang om moontlike newe-effekte te voorkom of te verminder.

Hoeveel en hoe gereeld u die behandeling sal ontvang

a) Indien u behandel word vir non-Hodgkin se Limfoom

- *Indien u **BLITZIMA** as enkelterapie ontvang*
  BLITZIMA sal een keer per week vir 4 weke aan u gegee word. Herhaalde behandelingskursusse met **BLITZIMA** is moontlik.
- *Indien u **BLITZIMA** saam met chemoterapie kry*
  BLITZIMA sal op dieselfde dag as u chemoterapie aan u gegee word. Dit word gewoonlik elke 3 weke gegee, vir tot 8 keer.
- Indien u goed reageer op behandeling, kan u **BLITZIMA** vir twee jaar ontvang, toegedien elke 2 of 3 maande. U dokter kan dit verander, afhangende van hoe u op die medisyne reageer.

b) Indien u vir chroniese limfositiese leukemie behandel word
Wanneer u met **BLITZIMA** in kombinasie met chemoterapie behandel word, sal u **BLITZIMA** elke 28 dae ontvang, totdat u 6 dosisse ontvang het. Die chemoterapie moet ná die infusie met **BLITZIMA** gegee word. U dokter sal besluit of u terselfdertyd ander behandeling moet ontvang.

c) Indien u vir rumatoïede artritis behandel word
Elke behandelingskursus bestaan uit twee afsonderlike infusies wat 2 weke uitmekaar gegee word. Herhaalde behandelingskursusse met **BLITZIMA** is moontlik. Afhangende van die tekens en simptome van u siekte, sal u dokter besluit wanneer u meer **BLITZIMA** moet ontvang. Dit kan maande ná die vorige dosis wees.

d) Indien u behandel word vir granulomatose met poli-angitis of mikroskopiese poli-angitis
Behandeling met **BLITZIMA** gebruik vier afsonderlike infusies wat met weeklikse tussenposes gegee word. 'n Kortikosteroïed-medisyne sal gewoonlik via inspuiting gegee word voor die aanvang van behandeling met **BLITZIMA**. Kortikosteroïed-medisyne wat per mond gegee word, kan te eniger tyd

deur u dokter begin word om u toestand te behandel.

e) Indien u behandel word vir *Pemphigus vulgaris* (PV)
Elke behandelingskursus bestaan uit twee afsonderlike infusies wat 2 weke uitmekaar gegee word. Indien u goed reageer op die behandeling, kan u **BLITZIMA** as 'n onderhoudsbehandeling ontvang. Dit sal ná 1 jaar, en weer 18 maande ná die aanvanklike behandeling toegedien word, en dan elke 6 maande soos nodig, of u dokter kan dit verander, afhangende van hoe u op die medisyne reageer.

Indien u meer BLITZIMA ontvang as wat u moes
Aangesien **BLITZIMA** deur u dokter of verpleegkundige toegedien word, is dit onwaarskynlik dat te veel toegedien sal word. Daar is geen bekende newe-effekte van die toediening van te veel **BLITZIMA** nie.

Indien u die BLITZIMA-infusie vergeet of mis
Indien u 'n afspraak om **BLITZIMA** te ontvang vergeet of mis, maak so gou moontlik 'n ander afspraak.

4. Moontlike newe-effekte
BLITZIMA kan newe-effekte hê.
Nie alle newe-effekte wat vir **BLITZIMA** aangemeld is, word in hierdie biljet ingesluit nie.
Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u **BLITZIMA** neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies.

Infusie-reaksies
Tydens of binne die eerste 2 uur van die eerste infusie kan u koors, kouekoors en bewing ontwikkel. Minder gereeld kan sommige pasiënte pyn op die infusie-area kry, blase, jeukerigheid, naarheid, moegheid, hoofpyn, asemhalingsprobleme, swelling van tong of keel, jeukerige of loopneus, braking, blosing of hartkloppings, hartaanval of lae aantal bloedplaatjies. Indien u hartsiektes of angina het, kan hierdie infusie-reaksies erger word. **Lig die persoon wat u die infusie gee onmiddellik in** indien u enige van hierdie simptome ontwikkel, aangesien die infusie dalk vertraag of gestaak moet word. U kan addisionele behandeling soos 'n antihistamien of parasetamol benodig. Wanneer hierdie simptome verdwyn, of verbeter, kan die infusie voortgesit word. Hierdie reaksies is minder geneig om na die tweede infusie voor te kom.
U dokter kan besluit om u **BLITZIMA**-behandeling te staak indien hierdie reaksies ernstig is.

Infeksies
Lig u dokter dadelik in indien u tekens van 'n infeksie kry, insluitend:
- koors, hoes, seer keel, brandpyn wanneer u urineer, of swak of oor die algemeen sleg voel
- geheueverlies, probleme om te dink, probleme om te loop of sigverlies – hierdie kan wees as gevolg van 'n baie seldsame, ernstige breininfeksie wat al dodelik was (progressiewe multifokale leukoensefalopatie of PML)

U kan makliker infeksies kry tydens u behandeling met **BLITZIMA.** Hierdie is dikwels verkoues, maar daar was gevalle van longontsteking of blaasinfeksies.

Indien u behandel word vir rumatoïede artritis, granulomatose met poli-angitis of mikroskopiese poli-angitis, sal u ook hierdie inligting vind in die Pasiënt Waarskuwingskaart, wat u van u dokter ontvang het. Dit is belangrik dat u hierdie Waarskuwingskaart hou en dit aan u lewensmaat of versorger wys.

Velreaksies
Baie selde kan ernstige blaasvormende veltoestande, wat lewensgevaarlik kan wees, voorkom. Rooiheid, wat dikwels met blase geassosieer word, kan op die vel of op slymvliese voorkom, soos binne-in die mond, die geslagsdele of die ooglede, en koors kan teenwoordig wees. **Lig u dokter dadelik in indien u enige van hierdie simptome ervaar.**

Lig u dokter so gou as moontlik in indien u enige van die volgende opmerk:
a) Indien u behandel word vir non-Hodgkin se Limfoom of chroniese limfositiese leukemie
Baie algemene newe-effekte (kan meer as 1 uit 10 mense beïnvloed):
- bakteriële of virale infeksies, bronchitis
- lae aantal witbloedselle soms met koors, of 'n lae aantal bloedselle wat "bloedplaatjies" genoem word
- naar voel (naarheid)
- bleskolle op die kopvel, kouekoors, hoofpyn
- laer immuniteit – as gevolg van laer vlakke van teenliggaampies genaamd "immunoglobuliene" (IgG) in die bloed wat u help beskerm teen infeksie

Algemene newe-effekte (kan tot 1 uit 10 mense beïnvloed):
- infeksies van die bloed (sepsis), longontsteking, gordelroos, verkoue, infeksies van die bronchiale weë, swaminfeksies, infeksies van onbekende oorsprong, inflammasie van die sinusse, hepatitis B
- lae aantal rooibloedselle (bloedarmoede), lae aantal van alle bloedselle
- allergiese reaksies (hipersensitiwiteit)
- hoë bloedsuikervlak, gewigsverlies, swelling in die gesig en liggaam, hoë vlakke van die ensiem LDH in die bloed, lae kalsiumvlakke in die bloed
- ongewone gevoelens van die vel – soos gevoelloosheid, tinteling, prikkeling, branderigheid, 'n kruipende gevoel op die vel, verminderde aanrakingssintuig
- rusteloos voel, probleme om aan die slaap te raak,
- word baie rooi in die gesig en ander dele van die vel as gevolg van verwyding van die bloedvate
- duiselig of angstig voel
- produseer meer trane, traanbuisprobleme, inflammasie van die oog (konjunktivitis)
- gelui in die ore, oorpyn
- hartprobleme – soos hartaanval en ongelyke of vinnige hartspoed
- hoë of lae bloeddruk (lae bloeddruk veral wanneer u regop staan)
- sametrekking van die spiere in die lugweë wat hygende asemhaling (bronchospasma) veroorsaak, inflammasie, irritasie in die longe, keel of sinusse, kortasem, loopneus
- naar word (braking), diarree, pyn in die maag, irritasie of sere in die keel en mond, probleme om te sluk, hardlywigheid, slegte spysvertering
- eetversteurings: nie genoeg eet nie, wat lei tot gewigsverlies
- galbulte, verhoogde sweet, nagsweet
- spierprobleme – soos stywe spiere, gewrigs- of spierpyn, rug- en nekpyn
- algemene ongemak, of voel ongemaklik of moeg, bewerasies, tekens van griep
- meervoudige orgaanversaking.

Minder algemene newe-effekte (kan tot 1 uit 100 mense beïnvloed):
- bloedstollingsprobleme, afname in rooibloedselproduksie en toename in rooibloedselvernietiging (aplastiese hemolitiese anemie), geswelde of vergrote limfknope
- voel terneergedruk en verlies aan belangstelling of genot om dinge te doen, senuweeagtig voel
- probleme met smaak – soos veranderinge in die manier waarop dinge smaak
- hartprobleme – soos verlaagde hartklop of borspyn (angina)
- asma, te min suurstof bereik die liggaamsorgane
- swelling van die maag

Baie seldsame newe-effekte (kan tot 1 uit 10 000 mense beïnvloed):
- korttermyn toename in die hoeveelheid van sommige soorte teenliggaampies in die bloed (genoem immunoglobuliene - IgM), chemiese versteurings in die bloed wat veroorsaak word deur die afbraak van sterwende kankerselle
- senuweeskade in arms en bene, verlamde gesig
- hartversaking
- inflammasie van bloedvate, insluitend dié wat lei tot velsimptome
- asemhalingsversaking
- skade aan die dermwand (perforasie)
- ernstige velprobleme wat blase veroorsaak, wat lewensgevaarlik kan wees. Rooiheid, wat dikwels met blase geassosieer word, kan op die vel of op slymvliese voorkom, soos binne-in die mond, die geslagsdele of die ooglede, en koors kan teenwoordig wees
- nierversaking
- erge sigverlies

Frekwensie nie bekend nie:
- 'n vermindering in witbloedselle wat nie dadelik gebeur nie
- verminderde bloedplaatjie-getal net na die infusie - dit kan omgekeer word, maar kan in seldsame gevalle dodelik wees
- gehoorverlies, verlies van ander sintuie

b) Indien u vir rumatoïede artritis behandel word

Baie algemene newe-effekte (kan meer as 1 uit 10 mense beïnvloed):

- infeksies, soos borsinfeksies, urienweginfeksies (pyn wanneer u urineer), verkoue en herpes-infeksies
- allergiese reaksies, wat meer waarskynlik tydens 'n infusie voorkom, maar tot 24 uur ná infusie kan voorkom
- veranderinge in bloeddruk, naarheid, veluitslag, koors, jeukerige gevoel, loopneus of verstopte neus en nies, bewerasies, vinnige hartklop en moegheid
- hoofpyn
- veranderinge in laboratoriumtoetse wat deur u dokter uitgevoer word. Dit sluit in 'n afname in die getal van spesifieke proteïene in die bloed (immunoglobuliene) wat help om u teen infeksie te beskerm.

Algemene newe-effekte (kan tot 1 uit 10 mense beïnvloed):
- infeksies soos inflammasie van die bronchiale weë (bronchitis)
- 'n gevoel van volheid of 'n kloppende pyn agter die neus, wange en oë (sinusitis)
- swam-voetinfeksie (atleet-voet)
- hoë cholesterolvlakke in die bloed
- abnormale sensasies van die vel, soos gevoelloosheid, tinteling, prikkeling of branderigheid, skiatika, migraine, duiseligheid
- verlies van hare
- angs
- depressie
- slegte spysvertering, diarree, suurrefluks, irritasie en/of ulserasie van die keel en die mond
- pyn op die maag, rug, spiere en/of gewrigte.

Minder algemene newe-effekte (kan tot 1 uit 100 mense beïnvloed):
- oortollige vloeistofretensie in die gesig en liggaam
- inflammasie, irritasie en / of benoudheid van die longe, en keel, hoes
- velreaksies, insluitend galbulte, jeukerigheid en uitslag
- allergiese reaksies, insluitend hygende asemhaling of kortasem, swelling van die gesig en tong, ineenstorting

Baie seldsame newe-effekte (kan tot 1 uit 10.000 mense beïnvloed):
- 'n groep simptome wat binne 'n paar weke ná 'n **BLITZIMA**-infusie voorkom**,** insluitend allergiese reaksies soos veluitslag, jeukerigheid, gewrigspyn, geswelde limfkliere en koors
- ernstige blaasvormende veltoestande wat lewensgevaarlik kan wees. Rooiheid, wat dikwels met blase geassosieer word, kan op die vel of op slymvliese voorkom, soos binne-in die mond, die geslagsdele of die ooglede, en koors kan teenwoordig wees.
- herhaling van 'n vorige hepatitis B-infeksie

Frekwensie nie bekend nie:
- ernstige virusinfeksie

Ander newe-effekte as gevolg van **BLITZIMA,** wat selde aangemeld is, sluit in minder wit selle in die bloed (neutrofiele) wat help om infeksie te beveg. Sommige infeksies kan ernstig wees (sien inligting oor **Infeksies** hierbo).

c) Indien u behandel word vir granulomatose met poli-angitis of mikroskopiese poli-angitis

Baie algemene newe-effekte (kan meer as 1 uit 10 mense beïnvloed):
- infeksies, soos borsinfeksies, urienweginfeksies (pyn wanneer u uineer), verkoue en herpes-infeksies
- allergiese reaksies wat meer waarskynlik tydens 'n infusie voorkom, maar tot 24 uur ná infusie kan voorkom
- diarree
- hoes of kortasem
- neusbloeding
- verhoogde bloeddruk
- pynlike gewrigte of rug
- spiertrekkings of bewerigheid
- voel duiselig
- bewerasies (bewerigheid, dikwels in die hande)
- probleme met slaap (insomnia)
- swelling van die hande of enkels

Algemene newe-effekte (kan tot 1 uit 10 mense beïnvloed):
- slegte spysvertering
- hardlywigheid
- veluitslag, insluitend aknee of puisies
- blosing of rooiheid van die vel
- geblokte neus
- stywe of pynlike spiere
- pyn in die spiere of in die hande of voete
- lae getalle rooibloedselle (bloedarmoede)
- lae getalle bloedplaatjies in die bloed
- 'n toename in die hoeveelheid kalium in die bloed
- veranderinge in die ritme van die hart, of die hart wat vinniger klop as normaal

Baie seldsame newe-effekte (kan tot 1 uit 10 000 mense beïnvloed):
- ernstige blaasvormende veltoestande wat lewensgevaarlik kan wees. Rooiheid, wat dikwels met blase geassosieer word, kan op die vel of op slymvliese voorkom, soos binne-in die mond, die geslagsdele of die ooglede, en koors kan teenwoordig wees.
- herhaling van 'n vorige hepatitis B-infeksie

d) Indien u vir *pemphigus vulgaris* behandel word
Baie algemene newe-effekte (kan meer as 1 uit 10 mense beïnvloed):
- allergiese reaksies wat mees waarskynlik tydens 'n infusie voorkom, maar tot 24 uur ná infusie kan voorkom
- hoofpyn
- infeksies soos borsinfeksies
- langdurige depressie
- verlies van hare

Algemene newe-effekte (kan tot 1 uit 10 mense beïnvloed):
- infeksies soos verkoue, herpes-infeksies, ooginfeksie, mondsproei en urienweginfeksies (pyn wanneer u urineer)
- gemoedsversteurings soos prikkelbaarheid en depressie
- velafwykings soos jeukerigheid, galbulte en nie-kwaadaardige knoppe
- moeg of duiselig voel
- koors
- pynlike gewrigte of rug
- pyn op die maag
- pyn in die spiere
- hart klop vinniger as normaal

Frekwensie nie bekend nie (frekwensie kan nie uit die beskikbare data beraam word nie):
- ernstige virusinfeksie

BLITZIMA kan ook veranderinge veroorsaak in laboratoriumtoetse wat deur u dokter uitgevoer word.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **BLITZIMA** te verskaf.
U kan dit ook by Adcock Ingram Limited aanmeld deur die volgende e-posadres te gebruik: Adcock.AEReports@adcock.com.

5. Hoe om BLITZIMA te bêre
Berging van onoopgemaakte flessies

- Bêre flessies in 'n yskas teen 2 °C tot 8 °C.
- Hou die flessie in die buitenste kartonboksie om teen lig te beskerm.

Berging van verdunde produk
- Die voorbereide infusie-oplossing van rituximab is fisies en chemies stabiel vir 24 uur teen 2 °C tot 8 °C, en daarna vir 12 uur by kamertemperatuur (hoogstens 30 °C).
- Vanuit 'n mikrobiologiese oogpunt moet die voorbereide infusie-oplossing onmiddellik gebruik word. Indien dit nie onmiddellik gebruik word nie, is bergingstye en -toestande voor gebruik die verantwoordelikheid van die gebruiker en sal dit normaalweg nie langer as 24 uur teen 2 °C tot 8 °C wees nie, tensy verdunning in beheerde en gevalideerde aseptiese toestande plaasgevind het.
- **BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS.**
- Moenie gebruik ná die vervaldatum wat op die kartonboksie gedruk is nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in afvoerpype en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting
Wat BLITZIMA bevat
Elke flessie **BLITZIMA** 100 bevat 100 mg (in 10 mL) rituximab-konsentraat vir oplossing vir infusie.
Elke flessie **BLITZIMA** 500 bevat 500 mg (in 50 mL) rituximab-konsentraat vir oplossing vir infusie.
Die ander bestanddele is polisorbaat 80, natriumchloried, trinatriumsitraatdihidraat, water vir inspuitings.

Hoe BLITZIMA lyk en die inhoud van die verpakking
BLITZIMA is 'n helder tot opaalagtige, kleurlose tot liggeel oplossing, met pH van 6,3 – 6,8 en osmolaliteit van 342 – 371 mOsmol/kg.
BLITZIMA 100 mg: Helder, kleurlose, tipe I glasflessie met 'n chloorbutiel rubberprop en 'n aluminium seël met 'n geel afwipprop wat 100 mg rituximab in 10 mL bevat. Pak van 2 flessies.

BLITZIMA 500 mg: Helder, kleurlose, tipe I glasflessie met 'n chloorbutiel rubberprop en 'n aluminium seël met 'n donkergrys afwipprop wat 500 mg rituximab in 50 mL bevat. Pak van 1 flessie.

Houer van Sertifikaat van Registrasie
Adcock Ingram Limited
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Erand Gardens
Midrand, 1685
Kliëntediens: 0860 ADCOCK / 232625

Hierdie biljet is mees onlangs hersien op
17 Januarie 2025

Registrasienommer
BLITZIMA 100 mg: 53/26/0506
BLITZIMA 500 mg: 53/26/0507

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