PATIENT INFORMATION LEAFLET FOR

REMIFLIX

SCHEDULING STATUS: S4

REMIFLIX 100 mg, Lyophilised powder for concentrate for solution for infusion

Infliximab

Contains sugar (sucrose 500 mg per vial).

Read all of this leaflet carefully before you are given REMIFLIX

- 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.
- REMIFLIX 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 REMIFLIX is and what it is used for
2. What you need to know before you are given REMIFLIX
3. How to use REMIFLIX
4. Possible side effects
5. How to store REMIFLIX
6. Contents of the pack and other information

1. What REMIFLIX is and what it is used for

REMIFLIX (Infliximab) is a monoclonal antibody, it belongs to a group of medicines called 'TNF (tumour necrosis factor) blockers. Infliximab works by selectively attaching to TNF alpha (TNFα) and blocking its action. TNFα is involved in inflammatory processes of the body so blocking it can

reduce the inflammation in your body.

REMIFLIX is used in adults for the following inflammatory diseases:

- **Rheumatoid arthritis**
- **Ankylosing spondylitis**
- **Psoriatic arthritis**
- **Psoriasis**

REMIFLIX is also used in adults and children 6 years of age or older for:

- **Crohn's disease**
- **Ulcerative colitis**

2. What you need to know before you are given REMIFLIX

You should not be administered REMIFLIX if:

- you are hypersensitive (allergic) to infliximab or to any of the other ingredients in REMIFLIX (listed in **section 6**)
- you are allergic (hypersensitive) to proteins that come from mice
- you have heart failure that is moderate or severe
- you have tuberculosis (TB) or any other serious infection like pneumonia or sepsis (serious bacterial infection of the blood)
- you are taking anakinra (used to treat rheumatoid arthritis, which causes pain and inflammation in the joints)
- you are receiving live vaccines (see **Take special care with REMIFLIX**).

Do not use REMIFLIX if any of the above applies to you. If you are not sure, talk to your doctor before you are given REMIFLIX.

Warnings and precautions

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

Had treatment with any medicine containing the same active ingredient (infliximab) before.

- You have been treated with REMIFLIX in the past and are now re-starting treatment again.
- If you have had a break and stopped your treatment with infliximab for more than 16 weeks, there is a higher risk for allergic reactions when you start the treatment again.

Infections

- You have an infection even if it is a very minor one.
- You have ever lived in or travelled to an area where fungal associated infections (histoplasmosis, coccidioidomycosis, or blastomycosis) are common. These infections are caused by specific types of fungi that can affect the lungs or other parts of your body.
- You are 65 or older, as you may get infections more easily. These infections may be serious and include tuberculosis, infections caused by viruses, fungi, bacteria, or other organisms in the environment and sepsis that may be life-threatening.

Tell your doctor straight away if you get signs of infection during treatment with REMIFLIX (regardless of your age). Signs include fever, cough, flu-like signs, feeling unwell, red or hot skin, wounds or dental problems. Your doctor may recommend temporarily stopping REMIFLIX.

Tuberculosis (TB)

- You have ever had tuberculosis (TB) or if you have been in close contact with someone who has had or has TB.
- Your doctor will test you to see if you have TB. Cases of TB have been reported in patients treated with REMIFLIX, even in patients who have already been treated with medicines for TB.
- If your doctor feels that you are at risk for TB, you may be treated with medicines for TB before you are given REMIFLIX.

Tell your doctor straight away if you get signs of TB during treatment with REMIFLIX. Signs include persistent cough, weight loss, feeling tired, fever, night sweats.

Hepatitis B virus (HBV)

- You are a carrier of hepatitis B or have ever had it. Tell your doctor if you think you might be at risk of contracting hepatitis B. Your doctor should test you for hepatitis B virus. Treatment with TNF blockers such as REMIFLIX may result in reactivation of hepatitis B virus in patients who carry this virus, which can be life-threatening in some cases.

Heart problems

- You have any heart problems, such as mild heart failure. Your doctor will want to closely monitor your heart.

Tell your doctor straight away if you get new or worsening signs of heart failure during treatment with REMIFLIX. Signs include shortness of breath or swelling of your feet.

Cancer and lymphoma

- You have or have ever had lymphoma (a type of blood cancer) or any other cancer. Patients with severe rheumatoid arthritis, who have had the disease for a long time may be at higher risk of developing lymphoma. Children and adults receiving REMIFLIX may have an increased risk of developing lymphoma or another cancer. Some patients who have received TNF-blockers, including infliximab have developed a rare type of cancer called hepatosplenic T-cell lymphoma. Of these patients, most were teenage boys or young men and most had either Crohn’s disease [a type of inflammatory bowel disease (IBD) that may affect any part of the gastrointestinal tract from mouth to anus] or ulcerative colitis. This type of cancer has usually resulted in death. Almost all patients had also received medicines containing azathioprine or 6-mercaptopurine in addition to TNF-blockers. Some patients treated with infliximab, as in REMIFLIX, have developed certain kinds of skin cancer. If there

are any changes in your skin or growths on the skin during or after therapy, tell your doctor.

- Some women being treated for rheumatoid arthritis with infliximab have developed cervical cancer. For women taking infliximab, as in REMIFLIX, including those over 60 years of age, your doctor may recommend regular screening for cervical cancer.

Lung disease or heavy smoking

- You have a lung disease called Chronic Obstructive Pulmonary Disease (COPD) or if you are a heavy smoker. Patients with COPD and patients who are heavy smokers may have a higher risk of developing cancer with infliximab, as in REMIFLIX, treatment.

Nervous system disease

- You have or have ever had a problem that affects your nervous system (multiple sclerosis or Guillain-Barre syndrome) before you are given REMIFLIX. This includes if you have fits or have been diagnosed with ‘optic neuritis’.
- Tell your doctor straight away if you get symptoms of a nerve disease during treatment with REMIFLIX. Signs include changes in your vision, weakness in your arms or legs, numbness or tingling in any part of your body.
- You have any abnormal skin openings (fistulae) before you are given REMIFLIX.

Vaccinations

- You recently have had or are due to have a vaccine. You should receive recommended
- vaccinations before starting infliximab treatment. You may receive some vaccines during
- treatment with infliximab, as in REMIFLIX, but you should not receive live vaccines (vaccines that contain a living but weakened infectious agent) while using REMIFLIX because they may cause infections.
- If you received REMIFLIX while you were pregnant, your baby may also be at higher risk for getting an infection with live vaccines for up to six months after birth. It is important that

you tell your baby's doctors and other healthcare professionals about your infliximab use so they can decide when your baby should receive any vaccine, including live vaccines such as BCG (used to prevent tuberculosis). For more information see section on **Pregnancy and breast-feeding.**

- You have recently received or are scheduled to receive treatment with a therapeutic infectious agent (such as BCG instillation used for the treatment of cancer).

Operations or dental procedures

- You are going to have any operations or dental procedures tell your surgeon or dentist that
- you are having treatment with infliximab, as in REMIFLIX.

Children and adolescents

The information above also applies to children and adolescents. In addition:

- REMIFLIX should only be used in children if they are being treated for Crohn's disease or ulcerative colitis. These children must be 6 years of age or older.
- REMIFLIX has not been studied in children with Crohn's disease less than 6 years of age or in children with juvenile rheumatic arthritis.
- Some children and teenage patients who have received TNF-blockers such as infliximab, as in REMIFLIX, have developed cancers, including unusual types, which sometimes resulted in death.
- More children taking infliximab, as in REMIFLIX, developed infections as compared to adults.
- Children should receive recommended vaccinations before starting REMIFLIX treatment. Children may receive some vaccines during treatment with REMIFLIX but should not receive live vaccines while using infliximab.

If you are not sure if any of the above apply to you, talk to your doctor before you are given

REMIFLIX.

Other medicines and REMIFLIX

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

Patients who have inflammatory diseases already take medicines to treat their problem. These medicines may cause side effects. Your doctor will advise you what other medicines you must keep using while you are using infliximab, as in REMIFLIX.

Tell your doctor if you are using or have recently used any other medicines, including any other medicines to treat Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis or psoriasis or medicines obtained without a prescription, such as vitamins and herbal medicines.

In particular, tell your doctor if you are using any of the following medicines:

- Medicines that affect your immune system.
- Infliximab and anakinra should not be used together.
- Infliximab and abatacept should not be used together.

While using infliximab you should not receive live vaccines. If you were using infliximab during pregnancy, tell your baby's doctor and other healthcare professionals caring for your baby about your infliximab use before the baby receives any vaccines.

If you are not sure if any of the above apply to you, talk to your doctor before using infliximab.

Pregnancy, breastfeeding and fertility

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

- REMIFLIX should only be used during pregnancy. if your doctor feels it is necessary for you.

- You should avoid getting pregnant when you are being treated with REMIFLIX and for 6 months after you stop being treated with it. Discuss the use of contraception during this time with your doctor.
- Do not breastfeed when you are being treated with REMIFLIX or for 6 months after your last treatment with REMIFLIX.
- If you received REMIFLIX during your pregnancy, your baby may have a higher risk for getting an infection.
- It is important that you tell your baby's doctors and other healthcare professionals about your REMIFLIX use before your baby is given any vaccine. If you received REMIFLIX while pregnant, giving BCG vaccine (used to prevent tuberculosis) to your baby within 6 months after birth may result in infection with serious complications, including death. Live vaccines such as BCG should not be given to your baby within 6 months after birth. For more information see section on vaccination.
- Severely decreased numbers of white blood cells have been reported in infants born to women treated with REMIFLIX during pregnancy. If your baby has continual fevers or infections, contact your baby's doctor immediately.

Driving and using machines

REMIFLIX may affect your ability to drive or use tools or machines. If you feel tired, dizzy, or unwell after having REMIFLIX, do not drive or use any tools or machines.

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

REMIFLIX contains sodium

REMIFLIX contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-

free'. However, before REMIFLIX is given to you, it is mixed with a solution that contains sodium. Talk to your doctor if you are on a low salt diet.

REMIFLIX contains sucrose

REMIFLIX contains a sugar called sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking REMIFLIX.

3. How REMIFLIX will be given

- Do not share medicines prescribed for you with any other person.
- You will not be expected to give yourself REMIFLIX.
- REMIFLIX will be given to you by your doctor or nurse.
- Your doctor or nurse will prepare the medicine for infusion.
- The medicine will be given as an infusion (drip) (over 2 hours) into one of your veins, usually in your arm. After the third treatment, your doctor may decide to give your dose of REMIFLIX over 1 hour
- You will be monitored while you are given REMIFLIX and also for 1 to 2 hours afterwards.

How much REMIFLIX is given:

- The doctor will decide your dose and how often you will be given REMIFLIX. This will depend on your disease, weight and how well you respond to REMIFLIX.
- If you have the impression that the effect of REMIFLIX is too strong or too weak, tell your doctor.

The table below shows how often you will usually have this medicine after your first dose.

1st dose	0 weeks
2nd dose	2 weeks after your 1st dose
3rd dose	6 weeks after your 1st dose
Further doses	Every 6 to 8 weeks depending on your disease

Rheumatoid arthritis:

The usual dose is 3 mg per kg of body weight.

Psoriatic arthritis, ankylosing spondylitis, psoriasis, ulcerative colitis and Fistulising Crohn's disease:

The usual dose is 5 mg per kg of body weight.

Use in children and adolescents

REMIFLIX should only be used in children if they are being treated for Crohn's disease or ulcerative colitis. These children must be 6 years of age or older. The recommended dose is the same as for adults.

Your doctor will tell you how long your treatment with REMIFLIX will last. If you have the impression that the effect of REMIFLIX is too strong or too weak, tell your doctor or pharmacist.

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

If you are given too much REMIFLIX

As REMFLIX is being given by your doctor or nurse, it is unlikely that you will be given too much. There are no known side effects of having too much of REMIFLIX.

If you forget or miss a dose of REMIFLIX

Since a healthcare professional will administer REMIFLIX, it is unlikely that the dose will be missed. If you forget or miss an appointment to receive REMIFLIX, make another appointment as soon as possible.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

REMIFLIX can have side effects.

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

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

- Signs of allergic reaction such as swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching, skin pealing and hives,

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to REMIFLIX. You may need urgent medical attention or hospitalisation. An allergic reaction could happen within 2 hours of your injection or later. More signs of an allergic reaction that may happen up to 12 days after your injection include pain in the muscles, fever, joint or jaw pain, sore throat, or headache.

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some patients may experience serious side effects

and may require treatment. Side effects may also occur after your treatment with REMIFLIX has stopped.

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

- **Signs of a heart problem** such as chest discomfort or pain, arm pain, stomach pain, shortness of breath, anxiety, light headedness, dizziness, fainting, sweating, nausea, vomiting, fluttering or pounding in your chest, a fast or a slow heartbeat, and/or swelling of your feet.
- **Signs of infection (including TB)** such as fever, feeling tired, (persistent) cough, shortness of breath, flu-like symptoms, weight loss, night sweats, diarrhoea, wounds, dental problems or burning when urinating.
- **Signs of a lung problem** such as coughing, breathing difficulties or tightness in the chest.
- **Signs of a nervous system problem (including eye problems)** such as fits, tingling or numbness in any part of your body, weakness in arms or legs, changes in eyesight such as double vision or other eye problems.
- **Signs of a liver problem** such as yellowing of the skin or eyes, dark-brown coloured urine or pain in the upper right side of the stomach area, fever.
- Meningitis (severe headache, fever and stiff neck).
- Inflammation of your pancreas (pancreatitis).
- **Signs of an immune system disorder** called lupus such as joint pain or a rash on cheeks or arms that is sensitive to the sun.
- Serious skin problems (painful rash, blistering and peeling, with fever and rash).
- **Signs of a low blood count** such as persistent fever, bleeding or bruising more easily or looking pale.

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

Tell your doctor if you notice any of the following:

Frequent:

- Stomach pain, feeling sick (nausea).
- Viral infections such as herpes or flu.
- Upper respiratory infections such as sinusitis.
- Headache.
- Side effect due to an infusion.
- Pain
- Changes in how your liver works, increase in liver enzymes (shown in blood tests).
- Lung or chest infections such as bronchitis or pneumonia.
- Difficult or painful breathing, chest pain.
- Bleeding in the stomach or intestines (black, tarlike stool or blood in the stool), diarrhoea, indigestion, heartburn, constipation.
- Nettle-type rash (hives), itchy rash or dry skin.
- Balance problems or feeling dizzy.
- Fever, increased sweating.
- Circulation problems such as low or high blood pressure, bruising, hot flush or nosebleed, warm, red skin (flushing).
- Feeling tired or weak.
- Bacterial infections such as blood poisoning, abscess or infection of the skin (cellulitis).
- Blood problems such as anaemia or low white blood cell count.
- Swollen lymph nodes.
- Depression, problems sleeping.
- Eye problems, including red eyes and infections.
- Fast heartbeat (tachycardia) or palpitations.
- Pain in the joints, muscles or back.

- Psoriasis, skin problems such as eczema and hair loss.
- Reactions at the injection site such as pain, swelling, redness or itching.
- Chills, a build-up of fluid under the skin causing swelling.
- Feeling numb or having a tingling feeling.

Less frequent:

- Skin problems such as warts, abnormal skin colouration or pigmentation, or swollen lips.
- Serious skin problems such as toxic epidermal necrolysis, Stevens-Johnson Syndrome and acute generalised exanthematous pustulosis.
- Other skin problems such as erythema multiforme, lichenoid reactions (itchy reddish purple skin rash and/or threadlike white-grey lines on mucous membranes), blisters and peeling skin, or boils (furunculosis).
- Urinary tract infection
- Shortage of blood supply, swelling of a vein.
- Skin problems such as blistering, warts, abnormal skin colouration or pigmentation, or swollen lips.
- Severe allergic reactions (e.g. anaphylaxis), an immune system disorder called lupus, allergic reactions to foreign proteins.
- Wounds taking longer to heal.
- Swelling of the liver (hepatitis) or gall bladder, liver damage.
- Feeling forgetful, irritable, confused, nervous.
- Eye problems including blurred or reduced vision, puffy eyes or sties.
- New or worsening heart failure, slow heart rate.
- Fainting.
- Convulsions, nerve problems.
- A hole in the bowel or blockage of the intestine, stomach pain or cramps.

- Swelling of your pancreas (pancreatitis).
- Fungal infections such as yeast infection.
- Lung problems (such as oedema).
- Fluid around the lungs (pleural effusion).
- Kidney infections.
- Low platelet count, too many white blood cells.
- Infections of the vagina.
- The use of a live vaccine may result in an infection caused by the live viruses or bacteria contained in the vaccine (when you have a weakened immune system).
- Changes in cholesterol and fat levels in the blood.
- A type of blood cancer (lymphoma).
- Your blood not supplying enough oxygen to your body, circulation problems such as narrowing of a blood vessel.
- Inflammation of the lining of the brain (meningitis).
- Infections due to a weakened immune system.
- Hepatitis B infection when you have had hepatitis B in the past.
- Abnormal tissue swelling or growth.
- Swelling of small blood vessels (vasculitis).
- Immune disorders that could affect the lungs, skin and lymph nodes (such as sarcoidosis).
- Lack of interest or emotion.
- Serious skin problems such as toxic epidermal necrolysis, Stevens-Johnson syndrome or erythema multiforme, skin problems such as boils.
- Serious nervous system disorders such as transverse myelitis, multiple sclerosis-like disease, optic neuritis and Guillain-Barré syndrome.
- Fluid in the lining of the heart (pericardial effusion).
- Serious lung problems (such as interstitial lung disease).

- Melanoma (a type of skin cancer).
- Cervical cancer.
- Low blood counts, including a severely decreased number of white blood cells

Side effects with unknown frequency

- Cancer in children and adults.
- A rare blood cancer affecting mostly young people (hepatosplenic T-cell lymphoma).
- Liver failure.
- Merkel cell carcinoma (a type of skin cancer).
- Worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness).
- Temporary loss of sight during or within 2 hours of infusion.
- The use of a ‘live’ vaccine may result in an infection caused by the ‘live’ viruses or bacteria contained in the vaccine (when you have a weakened immune system).

Additional side effects in children and adolescents

Children who took REMIFLIX for Crohn’s disease showed some differences in side effects compared with adults who took infliximab, as in REMIFLIX, for Crohn's disease. The side effects that happened more in children were: low red blood cells (anaemia), blood in stool, low white blood cells (leukopenia), redness or blushing (flushing), viral infections, low neutrophils which are white blood cells that fight infection (neutropenia), bone fracture, bacterial infection and allergic reactions of the breathing tract.

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 the SAHPRA **website,** or to Cipla Medpro (Pty) Ltd. 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 REMIFLIX.

5. How to store REMIFLIX

Before reconstitution:

- REMIFLIX will generally be stored by the healthcare professionals.
- Unopened lyophilised powder: must be refrigerated at 2 ºC to 8 ºC.

After reconstitution:

- In use stability of the reconstituted solution has been demonstrated for 24 hours at 25 °C. The product should be used as soon as possible but within 3 hours of reconstitution and dilution. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2 °C to 8 °C.
- **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 REMIFLIX contains

REMIFLIX contains 100 mg of the active substance infliximab. Infliximab is a monoclonal antibody– a type of protein that attaches to a specific target in the body called TNFα (tumour necrosis factor alpha).

The other ingredients are dibasic sodium phosphate dihydrate, monobasic sodium phosphate -

monohydrate, polysorbate 80, sucrose.

There are no preservatives in this product.

What REMIFLIX looks like and contents of the pack

REMIFLIX is supplied as a sterile, white to pale yellow, lyophilised powder for intravenous infusion.

The reconstituted solution is colourless to straw coloured, clear to opalescent solution, essentially free of visible particles.

REMIFLIX is supplied in a 20 mL 20R glass vial made from Type I glass and bromobutyl rubber stopper and aluminium fill-off seal with white polypropylene flip-off cap packed individually in a carton.

Each single dose vial contains 100 mg of infliximab for final reconstitution volume of 10 mL.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

To access corresponding Professional Information and translated Patient Information Leaflet, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.