SCHEDULING STATUS:

S4

REMSIMA 100 mg/vial , powder for concentrate for solution for infusion

Infliximab

Contains sugar: 500 mg sucrose per vial (50 mg sucrose per ml after reconstitution)

Read all of this leaflet carefully before you start using REMSIMA.

- 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.

What is in this leaflet

1. What REMSIMA is and what it is used for

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

REMSIMA is part of the tumour necrosis factor group of medicines, “the TNF blockers”. **REMSIMA** is used in adults for the treatment of the following inflammatory diseases:

- Rheumatoid arthritis
- Psoriatic arthritis
- Ankylosing spondylitis
- Psoriasis.

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

- Crohn's disease
- Ulcerative colitis.

REMSIMA works by blocking the action of a protein called TNF α (tumour necrosis factor alpha). This protein is involved in inflammatory processes of the body and by blocking it the inflammation in your body can be reduced.

2. What you need to know before you use REMSIMA

REMSIMA should not be administered to you:

- You are hypersensitive (allergic) to REMSIMA or any of the other ingredients of REMSIMA (listed in section 6).
- You are allergic to proteins that come from mice.
- You have tuberculosis (TB) or any other serious infection like pneumonia or sepsis (serious bacterial infection of the blood).
- You have moderate or severe heart failure.
- 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 REMSIMA**).

Warnings and precautions

Take special care with REMSIMA:

You will receive a patient alert card from your doctor. This card contains important safety information that you need to be aware of before and during your treatment with **REMSIMA**.

Talk to your doctor before you are given REMSIMA if you have:

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

- Tell your doctor if you have been treated with a medicine containing infliximab before or if you have been treated with **REMSIMA** in the past and are now starting **REMSIMA** 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

- If you have an infection, even if it is a very minor one, you should tell your doctor before you are given **REMSIMA**.
- If you have lived in or travelled to an area where infections called histoplasmosis, coccidioidomycosis or blastomycosis are common, you should tell your doctor before you are given **REMSIMA**. These infections are caused by specific types of fungi that can affect the lungs or other parts of your body.
- When you are being treated with **REMSIMA**, you may get infections more easily. You also have a greater risk if you are 65 years of age or older.
- These infections may be serious and include tuberculosis, infections caused by viruses, fungi or bacteria, or other opportunistic infections and sepsis that may be life-threatening.

Tell your doctor immediately if you experience signs of infection while you are being treated with **REMSIMA**. Signs of infection may include fever, cough, flu-like signs, a feeling of being unwell, red or hot skin, wounds or dental problems. Your doctor may recommend temporary discontinuation of **REMSIMA**.

Tuberculosis (TB)

- It is extremely important that you tell your doctor if you have ever had tuberculosis (TB) or if you have been in close contact with someone who has had or currently has TB.
- Your doctor will test you to see if you have TB. Cases of TB have been reported in patients treated with **REMSIMA**, even in patients who have been treated with medications for TB. Your doctor will record these tests on your patient alert card.
- If your doctor feels that you are at risk for TB, you may be treated with medicines for TB before you are given **REMSIMA**.

Tell your doctor immediately if you experience signs of TB while you are being treated with **REMSIMA**. Signs of TB include persistent cough, weight loss, feeling tired, fever, night sweats.

Hepatitis B virus (HBV)

- Tell your doctor if you are a carrier or if you have or have had hepatitis B in the past before you are given **REMSIMA**.

Heart problems

- Tell your doctor if you have any heart problems, such as mild heart failure.
- Your doctor will want to closely monitor your heart function.

Tell your doctor immediately if you experience new or worsening signs of heart failure while you are being treated with **REMSIMA**. Signs of heart failure include shortness of breath or swelling of your feet.

Cancer and lymphoma

- Tell your doctor if you have or have ever had lymphoma (a type of blood cancer) or any other cancer before you are given **REMSIMA**.

Lung disease or heavy smoking

- Tell your doctor if you have a lung disease called chronic obstructive pulmonary disease (COPD) or if you are a heavy smoker, before you are given **REMSIMA**.

Nervous system disease

- Tell your doctor if you have or have ever had a problem that affects your nervous system before you are given **REMSIMA**. This includes diseases such as multiple sclerosis and Guillain-Barré syndrome. You should also inform your doctor if you suffer from fits or have been diagnosed with optic neuritis.
- Tell your doctor immediately if you experience symptoms of a nerve disease while you are receiving treatment with **REMSIMA**. These signs may include changes in your vision, weakness in your arms or legs, numbness or tingling in any part of your body.

Vaccinations

Inform your doctor if you recently have had or are going to have a vaccination.

- You should not receive live vaccines while using **REMSIMA** (see **Do not use REMSIMA**).
- Certain vaccinations may cause infections. If you received **REMSIMA** while you were pregnant, your baby may be at higher risk for getting such an infection up to six months after birth. It is important that you tell your baby's doctors and other healthcare providers about your **REMSIMA** use so they can decide when your baby should receive any vaccine, including live vaccines like BCG (used to prevent tuberculosis). See **Pregnancy and breastfeeding**.

Operations or dental procedures

- Inform your doctor if you are going to have any operations or dental procedures.
- Tell the surgeon or dentist who will be performing the procedure that you are having

treatment with **REMSIMA** by showing them your patient alert card.

If you are not sure if any of the above applies to you, talk to your doctor before you are given **REMSIMA**.

Children and adolescents

REMSIMA 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.

REMSIMA has not been studied in children with Crohn's disease less than 6 years of age or in children with juvenile rheumatic arthritis.

Other medicines and REMSIMA

Always tell your healthcare 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 being treated with **REMSIMA**.

Pregnancy and breastfeeding

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking **REMSIMA**.
- **REMSIMA** is not recommended for use during pregnancy.
- You must avoid getting pregnant when you are being treated with **REMSIMA** and for 6 months after your treatment with it stops. Make sure you use contraception during this time.
- Do not breastfeed when you are being treated with **REMSIMA** or for 6 months after your

last treatment with **REMSIMA**.

- If you received **REMSIMA** while you were pregnant, your baby may be at higher risk of getting an infection.
- It is important that you tell your baby's Doctors and other healthcare providers about your treatment with **REMSIMA** before your baby receives any vaccine. If you received **REMSIMA** while pregnant, administration of 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 like BCG should not be given to your baby within 12 months after birth. For more information see section on vaccination.

There have been reports of severely decreased numbers of white blood cells in infants born to women treated with **REMSIMA** during pregnancy. If your baby has persistent fevers or infections, contact your baby's Doctor immediately.

Driving and using machines

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

REMSIMA contains sodium

REMSIMA contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'. However, before **REMSIMA** 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.

REMSIMA contains sucrose

REMSIMA 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, consult your doctor before taking **REMSIMA**.

3. How REMSIMA will be given

- Do not share medicines prescribed for you with any other person.
- You will not be expected to give yourself **REMSIMA**.
- **REMSIMA** will be given to you by your doctor or nurse by injection.
- Your doctor or nurse will prepare the **REMSIMA** solution for injection.
- The **REMSIMA** solution will be slowly injected (over a 2-hour period) into one of your veins. This will usually be in your arm. This is called an intravenous infusion or drip. After the third treatment, your doctor may decide to give you **REMSIMA** over a 1-hour period.
- You will be monitored while you are given **REMSIMA** and also for 1 to 2 hours after.

How much REMSIMA is given:

- The doctor will decide on what dose you will receive (in mg) and how often you will be given **REMSIMA**. This will depend on your disease, your weight and how well you respond to **REMSIMA**.
- The table below shows the usual dosage of **REMSIMA**.

1st treatment	0 weeks
2nd treatment	2 weeks after your 1st treatment
3rd treatment	6 weeks after your 1st treatment
Further treatments	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

In children (6 years of age or older) treated for Crohn's disease or ulcerative colitis, the recommended dose is the same as for adults.

If you are given too much REMSIMA:

As **REMSIMA** 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 **REMSIMA**.

If you forget or miss your REMSIMA infusion:

Since a health care provider will administer **REMSIMA**, it is unlikely that the dose will be missed. If you forget or miss an appointment to receive **REMSIMA**, make another appointment as soon as possible.

4. Possible side effects

REMSIMA can have side effects.

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

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

- Signs of an allergic reaction such as swelling of your face, lips, mouth or throat which may cause difficulty in swallowing or breathing, skin rash, hives, swelling of the hands, feet or ankles. An allergic reaction could happen within 2 hours of your injection or later.
- More signs of an allergic reaction may happen up to 12 days after your injection which include pain in the muscles, fever, joint or jaw pain, sore throat or headache.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **REMSIMA**. 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:

- Signs of a heart problem such as chest discomfort or pain, arm 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, swollen lymph nodes, or burning sensation when urinating.
- Signs of a lung problem such as coughing, breathing difficulties, build-up of fluid in the lungs, 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 as soon as possible if you notice any of the following:

Frequent:

- Stomach pain, feeling sick (nausea), constipation, diarrhoea, indigestion, heartburn.
- Viral infections (such as herpes or flu) or bacterial infections (such as abscess or infection of the skin (cellulitis)).
- Upper respiratory infections such as sinusitis.
- Headache.
- Pain.
- Bleeding in the stomach or intestines (black, tarlike stool or blood in the stool).
- Hives, itchy rash or dry skin, boils.
- Circulation problems such as low or high blood pressure.
- Feeling tired or weak.
- Depression, problems sleeping.
- Eye problems, including red eyes and infections, blurred or reduced vision.
- Pain in the joints, muscles or back.
- 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.

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).
- Wounds taking longer to heal.

- Feeling forgetful, irritable, confused, nervous.
- Fungal infections such as yeast infections, vaginal infection, onychomycosis (fungal infection of the nail).
- Circulation problems such as narrowing of a blood vessel (feeling abnormally tired or weak).
- Abnormal tissue swelling or growth.
- Pain and swelling of small blood vessels (vasculitis).
- Lack of interest or emotion.
- 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.

Not known:

- Infection due to a live vaccine because of a weakened immune system.
- A rare blood cancer affecting mostly teenage boys or young men (hepatosplenic T-cell lymphoma).
- Kaposi's sarcoma, a rare cancer related to infection with human herpes virus 8. Kaposi's sarcoma most commonly appears as purple lesions on the skin.
- Temporary loss of sight during or within 2 hours of infusion.

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 or 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 **REMSIMA**.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

5. How to store REMSIMA

Before reconstitution:

- Store at 2 °C to 8 °C.
- **REMSIMA** may be stored at temperatures up to a maximum of 25 °C for a single period of up to 6 months, but not exceeding the original expiry date. The new expiry date must be written on the carton. Upon removal from refrigerated storage, **REMSIMA** must not be returned to refrigerated storage.

After reconstitution:

- Chemical and physical in use stability of the reconstituted solution has been demonstrated for 24 hours at 25 °C. From a microbiological point of view, 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 REMSIMA contains

- The active substance is infliximab. Each vial contains 100 mg of infliximab. After preparation each mL contains 10 mg of infliximab.
- The other ingredients are sucrose, sodium dihydrogen phosphate monohydrate, di-sodium hydrogen phosphate dihydrate and polysorbate 80.

What REMSIMA looks like and contents of the pack

REMSIMA is supplied as a glass vial containing a powder for concentrate for solution for infusion.

The powder is white.

Holder of Certificate of Registration

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