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
2. What you need to know before you use **REMSIMA**
3. How **REMSIMA** will be given
4. Possible side effects
5. How to store **REMSIMA**
6. Contents of the pack and other information

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
Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand, 1685
Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in
20 December 2024

Registration number
52/30.1/0309

SKEDULERINGSTATUS:

S4

REMSIMA 100 mg/flessie, poeier vir konsentraat vir oplossing vir infusie
Infliksimab
Bevat suiker: 500 mg sukrose per flessie (50 mg sukrose per ml na hersamestelling)

Lees hierdie hele biljet noukeurig deur voordat u REMSIMA begin gebruik.
- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.

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

1. Wat REMSIMA is en waarvoor dit gebruik word
REMSIMA bevat die aktiewe bestanddeel infliksimab. Infliksimab is 'n monoklonale teenliggaam – 'n tipe proteïen wat aan 'n spesifieke teiken in die liggaam heg, wat TNF (tumor-nekrosefaktor) alfa genoem word.

REMSIMA is deel van die tumor-nekrosefaktor groep medisyne, "die TNF-blokkers". **REMSIMA** word by volwassenes gebruik vir die behandeling van die volgende inflammatoriese siektes:
- Rumatoïede artritis
- Psoriatiese artritis
- Ankiloserende spondilitis
- Psoriase.

REMSIMA word ook gebruik by volwassenes en kinders van 6 jaar of ouer vir:
- Crohn se siekte
- Ulseratiewe kolitis.

REMSIMA werk deur die werking van 'n proteïen genaamd TNF-α (tumor-nekrosefaktor alfa) te blokkeer. Hierdie proteïen is betrokke by inflammatoriese prosesse van die liggaam en deur dit te blokkeer, kan die inflammasie in u liggaam verminder word.

2. Wat u moet weet voordat u REMSIMA gebruik
REMSIMA moet nie aan u toegedien word nie indien:
- U hipersensitief (allergies) is vir **REMSIMA** of enige van die ander bestanddele van **REMSIMA** (gelys in afdeling 6).
- U allergies is vir proteïene wat van muise kom.
- U tuberkulose (TB) het of enige ander ernstige infeksie soos longontsteking of sepsis (ernstige bakteriële infeksie van die bloed).
- U matige of ernstige hartversaking het.
- U anakinra neem (word gebruik om rumatoïede artritis te behandel, wat pyn en inflammasie in die gewrigte veroorsaak).
- U lewendige entstowwe ontvang (sien **Wees veral versigtig met REMSIMA**).

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met REMSIMA:
U sal 'n pasiëntwaarskuwingskaart van u dokter ontvang. Hierdie kaart bevat belangrike veiligheidsinligting waarvan u bewus moet wees voor en tydens u behandeling met **REMSIMA**.

Raadpleeg u dokter voordat u REMSIMA kry indien u:
Voorheen behandeling gehad het met enige medisyne wat dieselfde aktiewe bestanddeel (infliksimab) bevat.
- Lig u dokter in indien u voorheen behandel is met 'n medisyne wat infliksimab bevat, of indien u in die verlede met **REMSIMA** behandel is en nou weer met **REMSIMA** behandeling begin.
- Indien u 'n onderbreking gehad het en u behandeling met infliksimab vir meer as 16 weke gestaak het, is daar 'n groter risiko vir allergiese reaksies wanneer u weer met die behandeling begin.

Infeksies
- Indien u 'n infeksie het, selfs al is dit 'n baie geringe een, moet u die dokter inlig voordat **REMSIMA** aan u toegedien word.
- Indien u in 'n gebied gewoon of gereis het waar infeksies genaamd histoplasmose, koksidioidomikose of blastomikose algemeen voorkom, moet u die dokter in kennis stel voordat **REMSIMA** aan u gegee word**.** Hierdie infeksies word veroorsaak deur spesifieke soorte swamme wat die longe of ander dele van u liggaam kan beïnvloed.
- Wanneer u met **REMSIMA** behandel word, kan u makliker infeksies kry. U het ook 'n groter risiko indien u 65 jaar of ouer is.
- Hierdie infeksies kan ernstig wees en sluit in tuberkulose, infeksies wat veroorsaak word deur virusse, swamme of bakterieë, of ander opportunistiese infeksies en sepsis wat lewensbedreigend kan wees.

Lig u dokter onmiddellik in indien u tekens van infeksie ervaar terwyl u met **REMSIMA** behandel word. Tekens van infeksie kan insluit koors, hoes, griepagtige tekens, 'n gevoel van ongesteldheid, rooi of warm vel, wonde of tandprobleme. U dokter kan die tydelike staking van **REMSIMA** aanbeveel.

Tuberkulose (TB)
- Dit is uiters belangrik dat u die dokter inlig indien u al ooit tuberkulose (TB) gehad het of indien u in noue kontak was met iemand wat TB gehad het, of tans het.
- U dokter sal u toets om te sien of u TB het. Gevalle van TB is aangemeld by pasiënte wat met **REMSIMA** behandel is, selfs by pasiënte wat met medikasie vir TB behandel is. U dokter sal hierdie toetse op u pasiëntwaarskuwingskaart aanteken.
- Indien u dokter voel dat u 'n risiko het om TB te kry, kan u met medisyne vir TB behandel word voordat **REMSIMA** aan u gegee word**.**

Lig u dokter onmiddellik in indien u tekens van TB ervaar terwyl u met **REMSIMA** behandel word. Tekens van TB sluit in aanhoudende hoes, gewigsverlies, moegheid, koors, nagsweet.

Hepatitis B-virus (HBV)
- Lig u dokter in indien u 'n draer is, of indien u hepatitis B het, of in die verlede gehad het, voordat **REMSIMA** aan u gegee word.

Hartprobleme
- Lig u dokter in indien u enige hartprobleme het, soos ligte hartversaking.
- U dokter sal u hartfunksie noukeurig wil monitor.

Lig u dokter onmiddellik in indien u nuwe tekens, of tekens van verergering van hartversaking

ervaar terwyl u met **REMSIMA** behandel word**.** Tekens van hartversaking sluit in kortasem of swelling van u voete.

Kanker en limfoom
- Lig u dokter in indien u limfoom ('n tipe bloedkanker) of enige ander kanker het, of ooit gehad het, voordat u **REMSIMA** ontvang**.**

Longsiekte of hewige rook
- Lig u dokter in indien u 'n longsiekte genaamd chroniese obstruktiewe longsiekte (COPD) het of indien u 'n swaar roker is, voordat **REMSIMA** aan u gegee word.

Senuweestelsel siekte
- Lig u dokter in indien u 'n probleem het, of al ooit gehad het, wat u senuweestelsel beïnvloed, voordat **REMSIMA** aan u gegee word. Dit sluit siektes in soos veelvuldige sklerose en Guillain-Barré-sindroom. U moet ook u dokter in kennis stel indien u aan stuipaanvalle ly of met optiese neuritis gediagnoseer is.
- Lig u dokter onmiddellik in indien u simptome van 'n senuweesiekte ervaar terwyl u behandeling met **REMSIMA** ontvang. Hierdie tekens kan veranderinge in u visie, swakheid in u arms of bene, gevoelloosheid of tinteling in enige deel van u liggaam insluit.

Inentings
Stel u dokter in kennis indien u onlangs 'n inenting gehad het of gaan hê.
- U moet nie lewendige entstowwe ontvang terwyl u **REMSIMA** gebruik nie (sien **Moenie REMSIMA gebruik nie**).
- Sekere inentings kan infeksies veroorsaak. Indien u **REMSIMA** ontvang het terwyl u swanger was, kan u baba 'n groter risiko hê om so 'n infeksie te kry vir tot ses maande na geboorte. Dit is belangrik dat u baba se dokters en ander gesondheidsorgverskaffers ingelig is van u gebruik van **REMSIMA**, sodat hulle kan besluit wanneer u baba enige entstof moet ontvang, insluitend lewende entstowwe soos BCG (wat gebruik word om tuberkulose te voorkom). Sien **Swangerskap en borsvoeding**.

Operasies of tandheelkundige prosedures
- Stel u dokter in kennis indien u enige operasies of tandheelkundige prosedures gaan ondergaan.
- Lig die chirurg of tandarts in wat die prosedure gaan uitvoer dat u behandel word met **REMSIMA** deur vir hulle u pasiëntwaarskuwingskaart te wys.

Indien u nie seker is of enige van die bogenoemde op u van toepassing is nie, raadpleeg u dokter voordat **REMSIMA** aan u gegee word**.**

Kinders en adolessente
REMSIMA moet slegs by kinders gebruik word indien hulle vir Crohn se siekte of ulseratiewe kolitis behandel word. Hierdie kinders moet 6 jaar of ouer wees.
REMSIMA is nie getoets by kinders met Crohn se siekte was jonger as 6 jaar is, of by kinders met jeugdige rumatiese artritis nie.

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

Pasiënte wat inflammatoriese siektes het, neem reeds medisyne om hul probleem te behandel. Hierdie medisyne kan newe-effekte veroorsaak. U dokter sal u inlig watter ander medisyne u moet aanhou gebruik terwyl u met **REMSIMA** behandel word**.**

Swangerskap en borsvoeding

- Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u **REMSIMA** neem.
- **REMSIMA** word nie aanbeveel vir gebruik tydens swangerskap nie.
- U moet vermy om swanger te raak terwyl u met **REMSIMA** behandel word**,** en vir 6 maande nadat u behandeling daarmee gestaak is. Maak seker dat u voorbehoeding gedurende hierdie tyd gebruik.
- Moenie borsvoed terwyl u met **REMSIMA** behandel word nie, of vir 6 maande na u laaste behandeling met **REMSIMA** nie.
- Indien u **REMSIMA** ontvang het terwyl u swanger was, kan u baba 'n groter risiko hê om 'n infeksie te kry.
- Dit is belangrik dat u baba se dokters en ander gesondheidsorgverskaffers ingelig is van u behandeling met **REMSIMA** voordat u baba enige entstof ontvang. Indien u **REMSIMA** ontvang het terwyl u swanger was, kan die toediening van BCG-entstof (wat gebruik word om tuberkulose te voorkom), binne 6 maande na die geboorte aan u baba, tot infeksie met ernstige komplikasies, insluitend die dood, lei. Lewendige entstowwe soos BCG moet nie aan u baba gegee word binne 12 maande ná geboorte nie. Vir meer inligting, sien afdeling oor inenting.

Daar is berigte van 'n ernstige verlaging in die aantal witbloedselle by babas wat gebore is vanaf vroue wat tydens swangerskap met **REMSIMA** behandel is. Indien u baba aanhoudende koors of infeksies het, kontak u baba se dokter onmiddellik.

Bestuur en gebruik van masjinerie
REMSIMA kan u vermoë om te bestuur of gereedskap of masjinerie te gebruik, beïnvloed. Indien u duiselig voel nadat u **REMSIMA** ontvang het**,** moenie bestuur of enige gereedskap of masjinerie gebruik nie.

REMSIMA bevat natrium
REMSIMA bevat minder indien 1 mmol natrium (23 mg) per dosis, dit wil sê in wese 'natriumvry'. Voordat **REMSIMA** egter aan u gegee word, word dit gemeng met 'n oplossing wat natrium bevat. Raadpleeg u dokter indien u op 'n lae sout dieet is.

REMSIMA bevat sukrose
REMSIMA bevat 'n suiker genaamd sukrose wat 'n uitwerking op die beheer van u bloedsuiker kan hê indien u diabetes mellitus het.
Indien u dokter u ingelig het dat u 'n onverdraagsaamheid teenoor sommige suikers het, raadpleeg u dokter voordat u **REMSIMA** neem.

3. Hoe REMSIMA gegee sal word

- Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.
- Daar sal nie van u verwag word om **REMSIMA** aan uself toe te dien nie.
- **REMSIMA** sal deur u dokter of verpleegkundige deur middel van inspuiting aan u gegee word.
- U dokter of verpleegkundige sal die **REMSIMA**-oplossing vir inspuiting voorberei.
- Die **REMSIMA**-oplossing sal stadig (oor 'n tydperk van 2 uur) in een van u are ingespuit word. Dit sal gewoonlik in u arm wees. Dit word 'n binneaarse infusie of drup genoem. Na die derde behandeling mag u dokter besluit om u **REMSIMA** oor 'n tydperk van 1 uur te gee.
- U sal gemonitor word terwyl u **REMSIMA** kry en ook vir 1 tot 2 uur daarna.

Hoeveel REMSIMA word gegee:

- Die dokter sal besluit watter dosis (in mg) en hoe gereeld u **REMSIMA** sal ontvang**.** Dit sal afhang van u siekte, u gewig en hoe goed u op **REMSIMA** reageer**.**

- Die tabel hieronder toon die algemene dosis van **REMSIMA**.

1ste behandeling	0 weke
2de behandeling	2 weke na u 1ste behandeling
3de behandeling	6 weke na u 1ste behandeling
Verdere behandelings	Elke 6 tot 8 weke, afhangende van u siekte

Rumatoïede artritis:
Die algemene dosis is 3 mg per kg liggaamsgewig.

Psoriatiese artritis, ankiloserende spondilitis, psoriase, ulseratiewe kolitis en Fistulerende Crohn se siekte:
Die algemene dosis is 5 mg per kg liggaamsgewig.

Gebruik by kinders en adolessente
By kinders (6 jaar of ouer) wat vir Crohn se siekte of ulseratiewe kolitis behandel word, is die aanbevole dosis dieselfde as vir volwassenes.

Indien u te veel REMSIMA ontvang:
Aangesien **REMSIMA** deur u dokter of verpleegkundige toegedien word, is dit onwaarskynlik dat u te veel gegee sal word. Daar is geen bekende newe-effekte van die ontvangs van te veel **REMSIMA** nie.

Indien u die REMSIMA-infusie vergeet of mis:
Aangesien 'n gesondheidsorgverskaffer **REMSIMA** sal toedien**,** is dit onwaarskynlik dat die dosis gemis sal word.
Indien u 'n afspraak vergeet of mis om **REMSIMA** te ontvang**,** maak so gou moontlik 'n ander afspraak.

4. Moontlike newe-effekte
REMSIMA kan newe-effekte hê.
Nie alle newe-effekte wat vir **REMSIMA** aangemeld word, is by hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u **REMSIMA** neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van **REMSIMA** en lig u dokter onmiddellik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- Tekens van 'n allergiese reaksie soos swelling van u gesig, lippe, mond of keel wat probleme kan veroorsaak om te sluk of asem te haal, veluitslag, galbulte, swelling van die hande, voete of enkels. 'n Allergiese reaksie kan binne 2 uur ná u inspuiting of later plaasvind.
- Meer tekens van 'n allergiese reaksie kan tot 12 dae na u inspuiting voorkom, wat pyn in die spiere, koors, gewrigs- of kakebeenpyn, seer keel of hoofpyn insluit.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige allergiese reaksie op **REMSIMA** gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:
- Tekens van 'n hartprobleem soos ongemak of pyn op die bors, armpyn, kortasem, angs, lighoofdigheid, duiseligheid, floute, sweet, naarheid, braking, fladdering of dawering in u bors, 'n vinnige of 'n stadige hartklop en/of swelling van u voete.
- Tekens van infeksie (insluitend TB) soos koors, moegheid, (aanhoudende) hoes, kortasem, griepagtige simptome, gewigsverlies, nagsweet, geswelde limfknope of brandende sensasie tydens urinering.

- Tekens van 'n longprobleem soos hoes, asemhalingsprobleme, opbouing van vloeistof in die longe of benoudheid op die bors.
- Tekens van 'n senuweestelselprobleem (insluitend oogprobleme) soos aanvalle, tinteling of gevoelloosheid in enige deel van u liggaam, swakheid in arms of bene, veranderinge in sig soos dubbelvisie of ander oogprobleme.
- Tekens van 'n lewerprobleem soos vergeling van die vel of oë, donkerbruin-gekleurde urien of pyn in die regter boonste kant van die maagarea, koors.
- Meningitis (erge hoofpyn, koors en stywe nek).
- Inflammasie van u pankreas (pankreatitis)
- Tekens van 'n immuunstelselversteuring genaamd lupus, soos gewrigspyn of 'n uitslag op die wange of arms wat sensitief is vir die son.
- Ernstige velprobleme (pynlike veluitslag, blaasvorming en afskilfering, met koors en veluitslag).
- Tekens van 'n lae bloedtelling soos aanhoudende koors, bloeding of makliker kneusing of bleekheid.

Hierdie is alles ernstige newe-effekte. U mag dalk dringend mediese hulp nodig hê.

Lig u dokter so gou as moontlik in indien u enige van die volgende opmerk:
Gereelde:
- Maagpyn, sleg voel (naarheid), hardlywigheid, diarree, spysvertering, sooibrand.
- Virale infeksies (soos herpes of griep) of bakteriële infeksies (soos ‘n abses of infeksie van die vel (sellulitis)).
- Boonste respiratoriese infeksies soos sinusitis.
- Hoofpyn.
- Pyn.
- Bloeding in die maag of ingewande (swart, teeragtige stoelgang of bloed in die stoelgang).
- Galbulte, jeukerige uitslag of droë vel, pitsere.
- Sirkulasieprobleme soos lae of hoë bloeddruk.
- Voel moeg of swak.
- Depressie, probleme om te slaap.
- Oogprobleme, insluitend rooi oë en infeksies, versteurde of verminderde visie.
- Pyn in die gewrigte, spiere of rug.
- Haarverlies.
- Reaksies by die inspuitplek soos pyn, swelling, rooiheid of jeukerigheid.
- Kouekoors, 'n opbou van vloeistof onder die vel wat swelling veroorsaak.

Minder gereelde:
- Velprobleme soos vratte, abnormale velverkleuring of pigmentasie, of geswelde lippe.
- Ernstige velprobleme soos toksiese epidermale nekrolise, Stevens-Johnson-sindroom en akute algemene eksantematiese pustulose.
- Ander velprobleme soos veelvormige eriteem, lichenoïede-reaksies (jeukerige rooipers veluitslag en/of draadagtige witgrys lyne op slymvliese), blase en afskilferende vel, of pitsere (furunkulose).
- Wonde neem langer om te genees.
- Voel vergeetagtig, geïrriteerd, verward, senuweeagtig.
- Swaminfeksies soos gisinfeksies, vaginale infeksie, onikomikose (swaminfeksie van die nael).
- Sirkulasieprobleme soos vernouing van 'n bloedvat (abnormaal moeg of swak voel).
- Abnormale weefselswelling of -groei.
- Pyn en swelling van klein bloedvate (vaskulitis).
- Gebrek aan belangstelling of emosie.
- Die gebruik van 'n lewendige entstof kan lei tot 'n infeksie wat veroorsaak word deur die lewendige virusse of bakterieë wat in die entstof voorkom (wanneer u 'n verswakte

immuunstelsel het).
- Veranderinge in cholesterol- en vetvlakke in die bloed.

Nie bekend nie:
- Infeksie as gevolg van 'n lewendige entstof as gevolg van 'n verswakte immuunstelsel.
- 'n Seldsame bloedkanker wat meestal tienerseuns of jong mans affekteer (hepatospleniese T-sel limfoom).
- Kaposi se sarkoom, 'n seldsame kanker wat verband hou met infeksie met menslike herpesvirus 8. Kaposi se sarkoom verskyn meestal as pers letsels op die vel.
- Tydelike verlies van sig tydens of binne 2 uur ná infusie.

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 of apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en elektronies aanmeldingsplatform (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 **REMSIMA** te verskaf**.**
Vir die aanmelding van newe-effekte direk aan die HCR, kontak +27 11 635 0134 of e-pos Adcock.aereports@adcock.com.

5. Hoe om REMSIMA te bêre
Voor hersamestelling:
- Bêre teen 2 °C tot 8 °C.
- **REMSIMA** mag vir 'n enkele tydperk van tot 6 maande by temperature tot 'n maksimum van 25 °C gebêre word, maar mag nie die oorspronklike vervaldatum oorskry nie. Die nuwe vervaldatum moet op die kartonboksie geskryf word. Met verwydering uit verkoelde berging moet **REMSIMA** nie in verkoelde berging teruggesit word nie.

Na hersamestelling:
- Chemiese en fisiese in-gebruik stabiliteit van die hersaamgestelde oplossing is vir 24 uur teen 25 °C bewys. Vanuit 'n mikrobiologiese oogpunt moet die produk so gou as moontlik gebruik word, maar binne 3 uur na hersamestelling en verdunning. Indien dit nie onmiddellik gebruik word nie, is in-gebruik bergingstye en toestande voor gebruik die verantwoordelikheid van die gebruiker en moet dit nie langer as 24 uur teen 2 °C tot 8 °C wees nie.
- **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 REMSIMA bevat
- Die aktiewe bestanddeel is infliksimab. Elke flessie bevat 100 mg infliksimab. Na voorbereiding bevat elke mL 10 mg infliksimab.
- Die ander bestanddele is sukrose, natriumdiwaterstoffosfaatmonohidraat, dinatriumwaterstoffosfaatdihidraat en polisorbaat 80.

Hoe REMSIMA lyk en die inhoud van die verpakking
REMSIMA word voorsien as 'n glasflessie wat 'n poeier vir konsentraat vir oplossing vir infusie bevat. Die poeier is wit.

Houer van Sertifikaat van Registrasie
Adcock Ingram Limited

New Road 1
Erand Gardens
Midrand, 1685
Kliëntediens: 0860 ADCOCK / 232625

Hierdie biljet is mees onlangs hersien op
20 Desember 2024

Registrasienommer
52/30.1/0309

adcock ingram

LM142307-LE002 01/2025