REMICADE®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using REMICADE?

REMICADE contains the active ingredient infliximab. REMICADE is used to reduce the signs and symptoms of rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, ulcerative colitis, psoriasis and Crohn's disease.

For more information, see Section 1. Why am I using REMICADE? in the full CMI.

2. What should I know before I use REMICADE?

Do not use if you have ever had an allergic reaction to infliximab, to other murine (mouse) proteins or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions (including, but not limited to infections or heart failure), take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section 2. What should I know before I use REMICADE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with REMICADE and affect how it works, or cannot be taken simultaneously. Discuss with your doctor if any of the other medications you take impact your treatment with REMICADE. Also tell your doctor if you have had any recent vaccinations or are planning to be vaccinated.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How REMICADE is given?

- REMICADE is given in a drip into a vein (called an infusion) over at least 2 hours.
- If you were able to tolerate the first 3 two-hour infusions, your doctor may decide to give your next REMICADE infusions over a period of not less than 1 hour.
- For children and adolescents (6-17 years) the infusion is given over at least 2 hours.
- A period of observation follows treatment.

More instructions can be found in Section 4. How REMICADE is given? in the full CMI.

5. What should I know while using REMICADE?

Things you should do	• Remind any doctor, nurse, dentist or pharmacist you visit that you are using REMICADE before you undergo any surgical procedures or receive any vaccinations. • Tell your doctor, nurse or pharmacist if you do not feel well, the medicine starts to upset you or your symptoms become worse. • Tell your doctor immediately if symptoms of tuberculosis, hepatitis B or any other infection appears. • Tell your doctor if you are receiving therapeutic infectious agents for the treatment of cancer. Continue to take adequate contraceptive measures to avoid falling pregnant. Tell your doctor if you are

	planning to become pregnant.
Things you should be careful of	• Tell your doctor if you think you have an infection. • Tell your doctor immediately if you develop a skin rash or hives. • If you suffer from congestive heart failure, tell your doctor immediately if your condition worsens.
Driving or using machines	• REMICADE is unlikely to make you drowsy. If you are tired, do not drive a car or work with machinery.

For more information, see Section 5. What should I know while using REMICADE? in the full CMI.

6. Are there any side effects?

REMICADE may cause side effects, including but not limited to propensity to viral infections, fever, headache, dizziness, flushing, bronchitis, pneumonia, difficulty to breathe, sinusitis, nausea, diarrhoea, abdominal pain, rash, urticaria, increased sweating, dry skin, fatigue, chest pain and infusion-related reactions.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

REMICADE®

Active ingredient(s): *Infliximab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using REMICADE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using REMICADE.**

Where to find information in this leaflet:

1. Why am I using REMICADE?
2. What should I know before I use REMICADE?
3. What if I am taking other medicines?
4. How REMICADE is given?
5. What should I know while using REMICADE?
6. Are there any side effects?
7. Product details

1. Why am I using REMICADE?

REMICADE contains the active ingredient infliximab. Infliximab is a monoclonal antibody (proteins that recognize and bind to other proteins) that is produced from human and mouse proteins

Infliximab acts by binding to a special protein in the body called tumour necrosis factor alpha (TNF α). In people with diseases such as, Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and psoriasis, the body produces too much TNF α , which can cause the body's immune system to attack healthy tissue and result in inflammation. Blocking TNF α with REMICADE can reduce inflammation, but can also reduce your immune system's ability to fight off infections.

REMICADE is used to:

- Reduce the signs and symptoms of rheumatoid arthritis (an inflammatory disease of the joints) and to prevent damage to the joints and improve your physical function. REMICADE will also be given with a disease-modifying medicine called methotrexate.
- Reduce the signs and symptoms of ankylosing spondylitis (an inflammatory disease of the spine) improve the physical function and the quality of life if you have not responded to other medicines.
- Reduce the signs and symptoms of psoriatic arthritis (an inflammatory disease of the joints usually accompanied by psoriasis) including reduction of pain and swelling in and around your joints and improve the physical function and quality of life if you have not responded to other medications.
- Reduce the signs and symptoms and improve the quality of life in patients with moderate to severe plaque psoriasis (an inflammatory disease of the skin) who have not responded well enough to treatments such as phototherapy or conventional

systemic treatments, or when these treatments are not appropriate.

- Treat active moderate to severe Crohn's disease (a chronic inflammatory disease of the bowel) in adult patients and in children and adolescent patients (6 to 17 years old) who have not responded well enough to other treatments. REMICADE will reduce the symptoms and improves the quality of life. It can also reduce the number of draining fistulas, a common complication of Crohn's disease.
- Treat moderate to severe active ulcerative colitis (an inflammatory disease of the bowel) in adult patients and in children and adolescent patients (6 to 17 years old) who have not responded well enough to other treatments.

Your doctor, however, may have prescribed REMICADE for another purpose.

Children and adolescents

Do not give REMICADE to children with Crohn's disease or ulcerative colitis who are younger than 6 years.

Do not give REMICADE to children and adolescents with any other disease.

2. What should I know before I use REMICADE?

Warnings

Do not use REMICADE if:

- **you have an allergy to murine (mouse) proteins or any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction to REMICADE may include skin rash, hives, fatigue, wheezing, difficulty in breathing, and/or low blood pressure.

- **you have an infection that you are being treated for. If you have or think you may have an infection, ask your doctor if it is the kind of infection that could put you at risk for serious side effects from REMICADE.**
- **you are already taking another medicine for arthritis, which contains the substance called anakinra.**
- **you have congestive heart failure. you may not be a candidate for treatment with REMICADE. Your doctor will decide if you should receive REMICADE.**

Check with your doctor if you:

- **have an infection that won't go away or a history of infection that keeps coming back.**

- **have had tuberculosis (TB), or if you have recently been with anyone who might have TB. Your doctor will evaluate you for TB and perform a skin test. If your doctor feels that you are at risk for TB, he or she may start treating you for TB before you begin REMICADE therapy.**
- **have ever had or had been in close contact with hepatitis B**

Reactivation of hepatitis B have been reported in people treated with TNF blockers. However, these reports are very rare.

- **have lived in or travelled to an area where fungal infections called histoplasmosis, coccidioidomycosis, or blastomycosis are common.**
  Ask your doctor if you don't know if these infections are common in the area in which you have lived in or travelled to.

These infections are caused by fungus that can affect the lungs or other parts of your body.

- **have had cancer**

A type of blood cancer called lymphoma has been reported in patients receiving TNF-blockers. The reports are rare but are more frequent than expected for people in general. Cancers, other than lymphoma, have also been reported.

- **have moderate to severe chronic obstructive pulmonary disease (COPD)**

Lung, head, neck and other cancers have been reported in patients with a history of heavy smoking.

- **have a long history of Crohn's disease rheumatoid arthritis, ankylosing spondylitis or psoriatic arthritis, especially if you have a highly active disease and/or have been taking medicine that reduces the activity of the body's natural defences.**

You may be more likely to develop infections and lymphomas than people in general, even without receiving TNF-blockers such as REMICADE.

- **have or have had a disease that affects the nervous system such as multiple sclerosis and seizures, or if you experience any numbness, weakness, tingling, or sight disturbances.**
- **suffer from congestive heart failure.**

Steps must be taken to monitor any changes to your condition during treatment with REMICADE.

- **have ongoing blood disorders or a history of blood disorders.**
- **have recently received or are scheduled to receive any vaccines**

Patients receiving REMICADE should not receive live vaccines. If possible, you should have all of your vaccines brought up to date before starting treatment with REMICADE.

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

Your doctor may delay treatment with REMICADE

- **have an allergy to alpha-gal or have been diagnosed with alpha-gal syndrome (a type of food allergy to certain meats or meat products) .**

Your doctor will discuss with you the benefits of using REMICADE against the potential risks.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you:

• are pregnant or intend to become pregnant.

Treatment with REMICADE is not recommended while you are pregnant.

You must use adequate contraception to avoid falling pregnant during REMICADE treatment and for at least 6 months after the last infusion.

• are breast-feeding

REMICADE passes into breastmilk. Talk to your doctor about the best way to feed your baby.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work.

Do not use REMICADE if you are already taking another medicine for arthritis, which contains the substance anakinra.

Tell your doctor if you are already taking another medicine for arthritis which contains the substance abatacept.

Tell your doctor if you are receiving other treatments:

- **for rheumatoid arthritis**
- **for ankylosing spondylitis**
- **for psoriatic arthritis**
- **for psoriasis, such as phototherapy or other treatments**
- **for Crohn's disease**
- **for ulcerative colitis**
- **to prevent rejection in organ transplantation.**

Tell your doctor you are taking REMICADE before receiving any vaccinations.

While using REMICADE you should not receive live vaccines. If possible, you should have all of your vaccines brought up to date before starting treatment with REMICADE. If you have a baby or if you are breast-feeding while you are using REMICADE, tell your baby's doctor about your REMICADE use before the baby receives any vaccines, including live vaccines such as the BCG vaccine (used to prevent tuberculosis) and rotavirus vaccine. Live vaccines should not be given to your baby while you are breast-feeding unless your baby doctor recommends otherwise.

Your doctor or pharmacist will be able to tell you what to do when being given REMICADE with other medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect REMICADE.

4. How REMICADE is given?

How much is given

REMICADE is only available on prescription and given in a drip into a vein (called an infusion) over at least 2 hours.

If you were able to tolerate the first 3 two-hour infusions, your doctor may decide to give your next REMICADE infusion over a period of not less than 1 hour.

For children and adolescents (6-17 years) the infusion is given over at least 2 hours.

A period of observation follows treatment.

Your doctor may delay treatment with REMICADE if you have any surgery planned.

Rheumatoid arthritis

The recommended starting dose is an infusion of 3 mg/kg. You will get additional doses of 3 mg/kg at 2 and 6 weeks after your first infusion and then every 8 weeks after that.

If, after 12 weeks of treatment, your arthritis does not respond well enough to the 3 mg/kg dose, your doctor may decide to gradually increase your dose to a maximum of 7.5 mg/kg every 8 weeks.

You will also be taking methotrexate as part of your treatment.

Ankylosing Spondylitis

The recommended starting dose is an infusion of 5 mg/kg. You will get additional doses of 5 mg/kg at 2 and 6 weeks after your first infusion and then every 6 weeks after that.

Psoriatic arthritis

The recommended starting dose is an infusion of 5 mg/kg. You will receive additional doses of 5 mg/kg at 2 and 6 weeks after your first infusion and then every 8 weeks after that.

REMICADE may be given alone or in combination with methotrexate.

Psoriasis

The recommended starting dose is an infusion of 5 mg/kg. You will get additional doses of 5 mg/kg at 2 and 6 weeks after your first infusion, and then every 8 weeks after that.

Crohn’s disease

The recommended starting dose for Crohn's disease in adults and in children and adolescents (6 to 17 years); and for closure of fistula in adult patients is an initial infusion of 5 mg/kg followed by additional doses of 5 mg/kg at 2 and 6 weeks after your first infusion, and then every 8 weeks after that. In some cases, your doctor may decide to increase your dose up to 10 mg/kg.

Ulcerative colitis

The recommended starting dose for ulcerative colitis in adults and in children and adolescents (6 to 17 years) is an infusion of 5 mg/kg. You will get additional doses of 5 mg/kg at 2 and 6 weeks after your first infusion, and then every 8 weeks after that. Your doctor will monitor your response to REMICADE and may adjust your dose.

If you miss a dose

As REMICADE is given under the supervision of your doctor, you are unlikely to miss a dose. However, if you forget or miss your appointment to receive REMICADE, make another appointment as soon as possible.

Your doctor will decide when and how much your next dose of REMICADE will be.

If you are given too much REMICADE

As REMICADE is given to you under the supervision of your doctor it is very unlikely you will receive too much. **If you think you or anybody else has been given too much REMICADE, you may need urgent medical attention.**

You should immediately:

- phone the Poisons Information Centre (in Australia telephone **13 11 26**. In New Zealand telephone **0800 POISON** or **0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using REMICADE?

Things you should do

Tell your doctor, nurse or pharmacist if the medicine starts to upset you or your symptoms become worse.

Tell your doctor, nurse or dentist that you are being treated with REMICADE before you undergo any surgical procedures.

Tell your doctor or nurse:

- **if symptoms of TB (persistent cough, weight loss, listlessness, fever), or any other infection appear.**

  Do this immediately.
- **if symptoms of hepatitis B (upset stomach, loss of appetite, vomiting, tiredness, dark yellow or brown urine, and yellow eyes or skin) appear.**
  You must do this immediately.
- **that you are taking REMICADE before receiving any vaccinations.**
  Live vaccines should not be given while you are being treated with REMICADE.
- **if you are receiving therapeutic infectious agents for the treatment of cancer.**
  Patients receiving REMICADE should not receive some medicines, such as live attenuated bacteria used for the treatment of cancer.

You should continue to take adequate contraceptive measures to avoid pregnancy.

If you have a baby or if you are breast-feeding while you are using REMICADE, tell your baby's doctor about your REMICADE use before the baby receives any vaccines, including live vaccines. Live vaccines should not be given to your baby while you are breast-feeding unless your baby doctor recommends otherwise.

Severely decreased numbers of white blood cells have also been reported in infants born to women treated with REMICADE during pregnancy. If your baby has

continual fevers or infections, contact your baby's doctor immediately.

Things you should be careful of

Tell your doctor if you think you have an infection. REMICADE may affect the normal immune response.

There is a possibility that you may be more prone to infections. You will be watched closely for signs of infection.

Tell your doctor immediately if you develop a skin rash or hives.

Your doctor may discontinue REMICADE until the symptoms go away and then begin giving the medicine again. Symptoms will resolve with appropriate treatment.

If you suffer from congestive heart failure, tell your doctor immediately if your condition worsens.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how REMICADE affects you.

REMICADE is unlikely to make you drowsy. If you are tired, do not drive a car or work with machinery.

6. Are there any side effects?

Tell your doctor, nurse, or pharmacist as soon as possible if you do not feel well while you are being given REMICADE.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Generally, patients with rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, or psoriasis already take several medicines to treat their disease. These medicines may themselves cause side effects.

If you get additional side effects or any new symptoms, please tell your doctor.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

During the infusion of REMICADE the following reactions may occur:

- fever or chills
- itchiness or hives
- chest pain
- low blood pressure
- high blood pressure
- shortness of breath.

These reactions are more likely to occur during the first and second infusion but may also appear up to six months after the last infusion.

Less serious side effects

Less serious side effects	What to do
• headache • nausea or vomiting • dizziness and light-headedness • fatigue • fever • rash • hives • itching • sore throat • coughing • respiratory infections (such as bronchitis, sinus infections, cold) • hoarseness • shortness of breath • chest pain • back pain • muscle pain • abdominal pain • indigestion • diarrhoea • weight loss, muscle wasting	**Tell your doctor or nurse as soon as possible if you notice any of these side effects.**

Less serious side effects	What to do
• problems with urination • changes in the way your heart beats, for example, if you notice it beating faster • flushing • dry skin or increased sweating • fluid retention • new onset of psoriasis, mainly on the soles of the feet and on palms • worsening of rheumatoid arthritis. Lichenoid reactions (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes) or other skin rashes, including redness, itching, skin peeling and blistering, that could be serious. small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalized exanthematous pustulosis), have	

Less serious side effects	What to do
been reported in some patients. • Autoimmune disorders such as: - lupus like symptoms: symptoms may include prolonged chest discomfort or pain, shortness of breath, joint pain, or a rash on the cheeks or arms that is sensitive to the sun - paradoxical drug induced immune disorder: New appearance of inflammatory symptoms in the skin and/or other organs which is opposite to what is expected with the medicine.	

Serious side effects

Serious side effects	What to do
• pain or tenderness in chest, muscles, joints or jaw	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you**

Serious side effects	What to do
• swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing • fever • muscle pains • joint pains • tiredness • abnormal chest sounds • rash • itching • symptoms that may indicate heart failure, e.g. shortness of breath, especially with exercise or lying down, or swelling of your feet. There have been very rare cases where people taking REMICADE have developed liver problems. Signs that you could be having a problem include: • jaundice (skin and eyes turning yellow) • dark-brown coloured urine	**notice any of these serious side effects.**

Serious side effects	What to do
• right-sided abdominal pain • fever • severe fatigue (tiredness). • There have been cases where people taking REMICADE have developed serious nervous system problems that have resulted in inflammation of the nerve of the eye, that may cause changes in vision (including blindness); problems with the nerves behind the eye, which may lead to painful and limited eye movements, loss of feeling in the forehead and vision loss (orbital apex syndrome); numbness or tingling; seizures; weakness in the arms or legs. If you experience any of these symptoms, contact your doctor right away.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Most of the side effects are mild to moderate in severity. Other side effects not listed here may occur in some people. Some side effects may appear up to six months after the last infusion.

Cancers

In clinical studies, more cancers were seen in patients who received TNF-blockers, including REMICADE, than patients who did not receive these treatments.

In children and adults being treated with TNF-blockers, the chances of getting lymphoma or other cancers may increase. It should be noted, however, that patients with longstanding and active rheumatoid arthritis or Crohn's disease may already have a higher risk for developing cancers even without TNF-blockers, making it difficult to estimate the risk of developing cancers in these patients. Nevertheless, the role of TNF-blockers in the development of cancers cannot be excluded.

A rare type of cancer called Hepatosplenic T-cell Lymphoma (HSTCL) has been reported rarely in adolescents and young adults with Crohn's disease or ulcerative colitis who have received REMICADE. All of these patients were also receiving drugs known as azathioprine or 6-mercaptopurine.

No cases of HSTCL have been reported in patients receiving REMICADE only. HSTCL often results in death. The role of TNF blockers in the development of cancers in children and adolescents remain unclear.

Talk to your doctor if you are concerned about this.

Skin cancers (T cell lymphoma, mycosis fungoides, melanoma and Merkel cell carcinoma) have been reported rarely in patients treated with TNF-blockers, including REMICADE.

Tell your doctor if you notice any new skin lesions during or after therapy or if existing lesions change appearance.

Cervical cancer may occur more frequently in women treated with REMICADE. Periodic screening of women treated with REMICADE should continue.

Patients with a lung disease called Chronic Obstructive Pulmonary Disease and who have a history of heavy smoking may have an increased risk for getting cancer while being treated with REMICADE.

After REMICADE has been stopped

Tell your doctor immediately if:

- **you notice any of the following side effects, even if they occur several weeks after stopping treatment with REMICADE.**

  # skin rash or hives

  # frequent infections

- **symptoms of TB (persistent cough, weight loss, listlessness, fever), or any other infection appear.**
- **symptoms of hepatitis B (upset stomach, loss of appetite, vomiting, tiredness, dark yellow or brown urine, and yellow eyes or skin) appear.**

- symptoms of a stroke appear which may include numbness or weakness of the face, arm or leg, especially on one side of the body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes, sudden trouble walking, dizziness, loss of balance or coordination or a sudden, severe headache.

These symptoms may appear several months after your last REMICADE treatment.

You should continue to take adequate contraceptive measures to avoid pregnancy for at least 6 months after the last infusion of REMICADE.

Tell your doctor if you notice any other effects.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What REMICADE contains

Active ingredient (main ingredient)	• Infliximab (recombinant) 100 mg per vial
Other ingredients (inactive ingredients)	• monobasic sodium phosphate monohydrate • dibasic sodium phosphate dihydrate • sucrose • polysorbate 80

Do not take this medicine if you are allergic to any of these ingredients.

What REMICADE looks like

REMICADE comes as a white powder in a glass vial (AUST R 73827).

Storage

REMICADE should be stored at 2°C to 8°C (Refrigerate.)
Do not use beyond the expiry date.

REMICADE may be stored at temperatures up to a maximum of 30°C for a single period of up to 12 months; but not exceeding the original expiration date. The new expiration date should be written on the carton.

Upon removal from refrigerated storage, REMICADE cannot be returned to refrigerated storage.

REMICADE vials are for single use only. Any unused portion should be discarded.

Who distributes REMICADE?

JANSSEN-CILAG Pty Ltd

17 Khartoum Rd

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

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