REMICADE®

Infliximab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about REMICADE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using REMICADE against the benefits it is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What REMICADE is used for

REMICADE contains the active ingredient, infliximab. Infliximab is a monoclonal antibody that is produced from human and mouse proteins by recombinant technology. Monoclonal antibodies are proteins that recognise and bind to certain special proteins in the body.

Infliximab acts by binding to a special protein in the body called tumour necrosis factor alpha (TNFα). In people with diseases such as Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and psoriasis, the body produces too much TNFα, which can cause the body's immune system to attack normal healthy parts of the body. REMICADE can block the damage caused by too much TNFα.

Rheumatoid arthritis
Rheumatoid arthritis is an inflammatory disease of the joints. REMICADE is used to reduce the signs and symptoms of rheumatoid arthritis and to prevent damage to the joints. You will also be given a disease-modifying medicine called methotrexate.

Ankylosing Spondylitis
Ankylosing spondylitis is an inflammatory disease of the spine. REMICADE can reduce the signs and symptoms of ankylosing spondylitis, thereby improving physical function.

Psoriatic arthritis
Psoriatic arthritis is an inflammatory disease of the joints in which psoriasis usually occurs in association with arthritis. Often the fingers and toes are affected, although it may occur in other parts of the body. REMICADE is used to reduce the signs and symptoms of psoriatic arthritis and improve the physical function in adults who have not responded well enough to previous treatments with other disease-modifying anti-rheumatic drugs (DMARDS). REMICADE may be given alone or in combination with methotrexate.

Psoriasis
Psoriasis is an inflammatory disease of the skin. REMICADE is used to treat patients with moderate to severe psoriasis who have not responded well enough to treatments such as phototherapy or conventional systemic treatments, or when these treatments are not appropriate.

Crohn's disease
Crohn's disease is a chronic inflammatory disease of the bowel. It may also affect any part of the gut. REMICADE is used to treat moderate to severe Crohn's disease in adult patients and in children and adolescent patients (6 to 17 years old) who have not responded well enough to other treatments.

REMICADE can also reduce the number of abnormal openings from the bowel through the skin (called draining enterocutaneous fistula), a common complication of Crohn's disease.

Ulcerative Colitis
Ulcerative colitis is an inflammatory disease of the bowel. REMICADE is used to treat the signs and symptoms of ulcerative colitis in adult patients and in children and adolescent patients (6 to 17 years old) who have not responded well enough to other treatments.

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.

Your doctor, however, may prescribe REMICADE for another purpose.

Ask your doctor if you have any questions about why REMICADE has been prescribed for you.

Before you are given REMICADE

When you must not be given it

Do not use REMICADE if you have an allergy to 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.

Do not use REMICADE if you have severe infections such as tuberculosis and infected abscesses, a repeating infection or have had repeating infections.

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

If you have never been given REMICADE and have congestive heart failure, you should not use it.

Before you are given it

Tell your doctor if you:

- **currently have an infection, or if you are prone to infections, or if you have a history of infections**
  REMICADE may affect the normal immune response. You might get infections more easily. Some cases of serious infections, including tuberculosis (TB) and sepsis have been reported in patients treated with REMICADE.
- **have ever had or been in close contact with TB, even if you were treated for it.**
- **have ever had or had been in close contact with hepatitis B**
  Reactivation of hepatitis B have been reported in people treated with TNFα 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 a long history of Crohn's disease rheumatoid arthritis, ankylosing spondilitis 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.
- **are pregnant or plan to become pregnant**
  Like most medicines, REMICADE is not recommended in pregnancy. **You must use adequate contraception to avoid falling pregnant.**
- **are breast-feeding**
  Like most medicines, REMICADE is not recommended while breast-feeding. It is not known whether REMICADE passes into breastmilk.
- **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.**
- **are scheduled to receive any vaccines**
  Patients receiving REMICADE should not receive some types of vaccines.

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

Taking or being given other medicines

Tell your doctor if you are taking any other medicines, including any 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 is you are already taking another medicine for arthritis, which contains the substance called anakinra.

Tell your doctor if you are already taking another medicine for arthritis, which contains the substance called 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. Some vaccinations should not be given while you are on REMICADE.

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

How REMICADE is given

REMICADE is only available on prescription. 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 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.

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, 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.

What do I do if I receive too much? (overdose):

As REMICADE is being 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, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do, or go to Accident and Emergency at your nearest hospital.

Poisons Information Centre telephone numbers:

Australia: 13 11 26

New Zealand: (03) 474 7000

Keep these telephone numbers handy.

While you are being given REMICADE

Things you must do

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

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

Tell your doctor:

- **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.**
  Some vaccinations should not be given while you are being treated with REMICADE.

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

Your doctor will also advise you not to breastfeed.

Things to 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.

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

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. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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.

Ask your doctor or pharmacist to answer any questions you may have.

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.

Tell your doctor immediately if you notice any of the following:

- pain or tenderness in chest, muscles, joints or jaw
- 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.

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

- headache
- nausea or vomiting
- dizziness and light-headedness
- fatigue
- fever
- rash
- hives
- itching
- sore throat
- coughing
- hoarseness
- shortness of breath
- chest pain
- back pain
- muscle pain
- abdominal pain
- indigestion
- diarrhoea
- weight loss, muscle wasting
- 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.

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
- right-sided abdominal pain
- fever
- severe fatigue (tiredness).

You should contact your doctor immediately if you develop any of these symptoms.

Tell your doctor if you notice any other effects.

Most of the side effects are mild to moderate in severity. Other side effects not listed above may also occur in some patients. 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 (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.** 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.

Your doctor will advise you not to breastfeed for at least 6 months after your last infusion of REMICADE.

Tell your doctor if you notice any other effects.

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.

Product description

What it looks like

REMICADE comes as a white powder in a glass vial.

Ingredients

Active ingredient:

Infliximab (recombinant) 100 mg per vial

Inactive ingredients:

- sodium phosphate monobasic monohydrate
- sodium phosphate dibasic dihydrate
- sucrose
- polysorbate 80

Supplier

JANSSEN-CILAG Pty Ltd
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Australian Registration Number

AUST R 73827

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