

RENFLEXIS®

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 RENFLEXIS?

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

For more information, see Section [1. Why am I using RENFLEXIS?](#) in the full CMI.

2. What should I know before I use RENFLEXIS?

Do not use if you have ever had an allergic reaction to 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, 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 RENFLEXIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RENFLEXIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use RENFLEXIS®?

- RENFLEXIS 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 RENFLEXIS 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.

More instructions can be found in Section [4. How do I use RENFLEXIS?](#) in the full CMI.

5. What should I know while using RENFLEXIS®?

Things you must do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using RENFLEXIS.• 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 RENFLEXIS before you undergo any surgical procedures.• Call your doctor straight away if you have symptoms of TB (persistent cough, weight loss, listlessness, fever), or any other infection appear, 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.• You should continue to take adequate contraceptive measures to avoid pregnancy.
Things to be careful of	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• RENFLEXIS 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 RENFLEXIS?](#) in the full CMI.

6. Are there any side effects?

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.

RENFLEXIS®

Active ingredient(s): *infliximab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using RENFLEXIS. **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 RENFLEXIS.**

Where to find information in this leaflet:

- [1. Why am I using RENFLEXIS?](#)
- [2. What should I know before I use RENFLEXIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use RENFLEXIS?](#)
- [5. What should I know while using RENFLEXIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using RENFLEXIS?

RENFLEXIS contains the active ingredient infliximab. RENFLEXIS is a biosimilar medicine. Comparability in safety, efficacy and quality between RENFLEXIS and the reference product has been established.

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 (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 normal healthy parts of the body. RENFLEXIS can block the damage caused by too much TNF α .

Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory disease of the joints. RENFLEXIS 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. RENFLEXIS 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. RENFLEXIS 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). RENFLEXIS may be given alone or in combination with methotrexate.

Psoriasis

Psoriasis is an inflammatory disease of the skin. RENFLEXIS 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. RENFLEXIS 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.

RENFLEXIS 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. RENFLEXIS 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 RENFLEXIS to children with Crohn's disease or ulcerative colitis who are younger than 6 years.

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

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

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

2. What should I know before I use RENFLEXIS?

Warnings

Do not use RENFLEXIS if:

- you are allergic to mouse proteins, or any of the ingredients listed at the end of this leaflet.**

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

- you have severe infections such as tuberculosis and infected abscesses, a repeating infection or have had repeating infections.**
- you are already taking another medicine for arthritis, which contains the substance called anakinra.**

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

Check with your doctor if you:

- currently have an infection, or if you are prone to infections, or if you have a history of infections**

RENFLEXIS 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 infliximab.

- **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 TNF α 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 RENFLEXIS.

- **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 RENFLEXIS.

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

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

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

Your doctor will discuss with you the benefits of using RENFLEXIS 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 plan to become pregnant**

Like most medicines, RENFLEXIS is not recommended while breast-feeding. It is not known whether RENFLEXIS passes into breastmilk.

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

- **are breastfeeding**

Infliximab 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 RENFLEXIS if 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 RENFLEXIS before receiving any vaccinations. While using RENFLEXIS you should not receive live vaccines. If possible, you should have all of your vaccines brought up to date before starting treatment with RENFLEXIS. If you have a baby or if you are breast-feeding while you are using RENFLEXIS, tell your baby's doctor about your RENFLEXIS use before the baby receives any vaccines, **including live vaccines such as 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 RENFLEXIS 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 RENFLEXIS.

4. How do I use RENFLEXIS?

How RENFLEXIS is given

RENFLEXIS is only available on prescription. RENFLEXIS 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 RENFLEXIS 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.

You will be observed for at least 1 to 2 hours after your infusion is finished.

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. RENFLEXIS 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.

If you receive too much? (overdose)

As RENFLEXIS 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 RENFLEXIS, you should immediately:

- contact your doctor, pharmacist or

- phone the Poisons Information Centre (by calling 13 11 26), 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 RENFLEXIS?

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 RENFLEXIS 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 RENFLEXIS before receiving any vaccinations.

Live vaccines should not be given while you are being treated with RENFLEXIS.

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 RENFLEXIS, tell your baby's doctor about your RENFLEXIS 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 infliximab during pregnancy. If your baby has continual fevers or infections, contact your baby's doctor immediately.

Things to be careful of

Tell your doctor if you think you have an infection.

RENFLEXIS 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 RENFLEXIS 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

RENFLEXIS 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 RENFLEXIS.

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.

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

Side effects

Side effects	What to do
<ul style="list-style-type: none"> • headache • nausea or vomiting • dizziness and light-headedness • fatigue • fever • rash • hives • itching • sore throat • coughing • hoarseness • Respiratory infections (such as bronchitis, sinus infections, cold) • 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 	<p>Tell your doctor or nurse as soon as possible if you notice any of these side effects.</p>

Side effects	What to do
<ul style="list-style-type: none"> • 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. 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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. <p>There have been very rare cases where people taking infliximab have developed liver problems. Signs that you could be having a problem include:</p> <ul style="list-style-type: none"> • jaundice (skin and eyes turning yellow) • dark-brown coloured urine • right-sided abdominal pain • fever • severe fatigue (tiredness). 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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 infliximab, 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 infliximab. All of these patients were also receiving

drugs known as azathioprine or 6-mercaptopurine. No cases of HSTCL have been reported in patients receiving infliximab only. HSTCL often results in death. The role of TNF blockers in the development of cancers in children and adolescents remains 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 infliximab.

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 RENFLEXIS. Periodic screening of women treated with RENFLEXIS 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 RENFLEXIS.

After RENFLEXIS 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 RENFLEXIS.
 - 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 RENFLEXIS treatment.

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

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 RENFLEXIS contains

Active ingredient (main ingredient)	Infliximab 100 mg per vial
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• monobasic sodium phosphate monohydrate• sucrose

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|--|
| <ul style="list-style-type: none">• polysorbate 80• dibasic sodium phosphate (heptahydrate) |
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Do not take this medicine if you are allergic to any of these ingredients.

What RENFLEXIS looks like

RENFLEXIS comes as a white powder in a glass vial (Aust R 260410).

Storage

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

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

Who distributes RENFLEXIS

RENFLEXIS is supplied by:

Australian Sponsor:

SAMSUNG BIOEPIS AU PTY LTD

Level 16, 201 Elizabeth Street,

Sydney NSW 2000, Australia

Distributor:

Organon Pharma Pty Limited

Building A, 26 Talavera Road, Macquarie Park, NSW 2113, Australia

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Tel: 1 800 023 135

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