INFLECTRA®

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 INFLECTRA?

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

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

2. What should I know before I use INFLECTRA?

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 INFLECTRA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INFLECTRA 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 INFLECTRA?

INFLECTRA 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 INFLECTRA 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 INFLECTRA? in the full CMI.

5. What should I know while using INFLECTRA?

Things you should do	• Remind any doctor, nurse, dentist or pharmacist you visit that you are using INFLECTRA before you undergo any surgical procedures or receive any vaccinations. • Tell your doctor, nurse or pharmacist if the medicine starts to upset you or your symptoms become worse. • Tell your doctor 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 pregnancy.
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	• INFLECTRA 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 INFLECTRA? in the full CMI.

6. Are there any side effects?

INFLECTRA 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.

INFLECTRA®

Active ingredient: *Infliximab*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I using INFLECTRA?

INFLECTRA contains the active ingredient infliximab.

INFLECTRA is an approved biosimilar medicine. Comparability in safety, efficacy and quality between INFLECTRA 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 (TNFα).

In people with diseases such as, 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.

INFLECTRA can block the damage caused by too much TNFα.

Rheumatoid arthritis

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

Psoriasis

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

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

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

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

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

2. What should I know before I use INFLECTRA?

Warnings

Do not use INFLECTRA 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 INFLECTRA 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 INFLECTRA 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

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

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

Your doctor will discuss with you the benefits of using INFLECTRA 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 INFLECTRA is not recommended while you are pregnant. INFLECTRA crosses the placenta and has been detected in the bloodstream of infants for up to 12 months following birth.

You must use adequate contraception for at least 6 months after receiving the last INFLECTRA infusion to avoid falling pregnant.

- **are breast-feeding**

INFLECTRA has been detected in breast milk. Your doctor will discuss with you if the benefit of INFLECTRA treatment for you outweighs the potential risk to your infant while breast feeding.

3. What if I am taking other medicines?

Tell your doctor 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 INFLECTRA 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 or ulcerative colitis
- to prevent rejection in organ transplantation**.**

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

Some vaccinations should not be given while you are being treated with INFLECTRA.

Your doctor or pharmacist will be able to tell you what to do when being given INFLECTRA 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 INFLECTRA.

4. How do I use INFLECTRA?

How INFLECTRA is given

INFLECTRA 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 INFLECTRA 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.

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.

INFLECTRA 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 miss a dose

As INFLECTRA 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 INFLECTRA, make another appointment as soon as possible.

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

If you are given too much

As INFLECTRA 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 INFLECTRA, you should immediately:

- tell your doctor, 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 INFLECTRA?

Things you should do

Tell your doctor or nurse straight away if:

- **the medicine starts to upset you or your symptoms** become worse.
- you are being treated with INFLECTRA before you undergo any surgical procedures.
- you have symptoms of TB (persistent cough, weight loss, listlessness, fever), or any other infection appear. Do this immediately.
- you have symptoms of hepatitis B (upset stomach, loss of appetite, vomiting, tiredness, dark yellow or brown urine, and yellow eyes or skin) appear. Do this immediately.
- you are taking INFLECTRA before receiving any vaccinations.

  Some vaccinations should not be given while you are being treated with INFLECTRA.

- If you are receiving therapeutic infectious agents for the treatment of cancer.

  Patients receiving INFLECTRA 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.

Your doctor will also advise you not to breastfeed.

If you have a baby while you are using INFLECTRA, tell your doctor about your INFLECTRA use before your baby receives any vaccinations. A 12-month waiting period is

recommended before administering live vaccines to your baby.

Things you should be careful of

Tell your doctor if you think you have an infection.

INFLECTRA 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 INFLECTRA 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

INFLECTRA 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 INFLECTRA.

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 INFLECTRA 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
Skin related symptoms: • rash • hives • itching • flushing • dry skin or increased sweating • new onset of psoriasis, mainly on the soles of the feet and on palms **Gastrointestinal symptoms:** • nausea or vomiting • abdominal pain • indigestion • diarrhoea • fluid retention **Pain and alertness** • fatigue • headache • dizziness and light-headedness • chest pain • back pain • muscle pain **Cough and cold like symptoms:** • fever • sore throat • coughing • hoarseness • shortness of breath **Other:** • weight loss (or gain), muscle wasting • problems with urination • changes in the way your heart beats, for example, if you notice it beating faster • worsening of rheumatoid arthritis.	**Tell your doctor or nurse as soon as possible if you notice any of these side effects**

Serious side effects

Serious side effects	What to do
Aches and pains: • pain or tenderness in chest, muscles, joints or jaw • muscle pains • joint pains **Skin related symptoms:** • rash • itching **Swelling or numbness:**	**Tell your doctor or nurse immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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 • numbness or paralysis in the face, leg, or arm, most likely on just one side of the body • blurred or darkened vision **Heart and chest related symptoms:** • abnormal chest sounds • symptoms that may indicate heart failure, e.g. shortness of breath, especially with exercise or lying down, or swelling of your feet. **Other:** • fever • tiredness **Liver related symptoms:** There have been very rare cases where people taking INFLECTRA 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).	

Tell your doctor or nurse 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 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 INFLECTRA, 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 INFLECTRA. All of these patients were also receiving drugs known as azathioprine or 6-mercaptopurine. No cases of HSTCL have been reported in patients receiving INFLECTRA 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, Merkel cell carcinoma, basal cell carcinoma, mycosis fungoides and squamous cell carcinoma) have been reported rarely in patients treated with TNF-blockers, including INFLECTRA.

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 INFLECTRA. Periodic screening of women treated with INFLECTRA 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 INFLECTRA.

After INFLECTRA 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 INFLECTRA.**
    - 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 INFLECTRA treatment.

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

Tell your doctor if you wish to breastfeed your infant after your last INFLECTRA treatment.

Your doctor will discuss the risks and benefits with you.

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 INFLECTRA contains

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

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

What INFLECTRA looks like

INFLECTRA comes as a white powder in a glass vial

(AUST R 217066).

Storage

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

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

Who distributes INFLECTRA

INFLECTRA is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in April 2024.