Ixifi®

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 IXIFI?

IXIFI contains the active ingredient infliximab. It is used in people with diseases such as Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and psoriasis.

IXIFI blocks the damage caused by too much TNFα, a chemical produced by the body in people with certain diseases, causing the body' immune system to attack normal healthy parts of the body.

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

2. What should I know before I use IXIFI?

Do not use if you have ever had an allergic reaction to infliximab, history of allergies to some 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 IXIFI? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with IXIFI 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 IXIFI?

- IXIFI is given by a healthcare professional through a needle placed in a vein in your arm via a drip (called an infusion) over at least 2 hours (may be less based on previous use).
- Your doctor may ask you to take other medicines along with IXIFI.

More instructions can be found in Section 4. How do I use IXIFI? in the full CMI.

5. What should I know while using IXIFI?

Things you should do	• Contact your doctor immediately if you develop new or worsening symptoms. • Tell your doctor or dentist that you are being treated with IXIFI before you undergo any surgical procedures. • You should continue to take adequate contraceptive measures to avoid pregnancy. • Tell your doctor that you are taking IXIFI before receiving any vaccinations.
Driving or using machines	• IXIFI is unlikely to make you drowsy. If you are tired, do not drive a car or work with machinery.
Looking after your medicine	• IXIFI will be is stored in its original package in the refrigerator at 2° to 8° Celsius (Refrigerate. Do not Freeze) before use. • Unopened IXIFI can also be stored in the original carton outside of the refrigerator up to a maximum of 30°C for a single period of up to 6 months; but not beyond the expiration date.

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

6. Are there any side effects?

Fever or chills, itchiness or hives on the skin, upset stomach or diarrhoea, symptoms of a cold or aches and pains. More serious side effects include severe allergic reactions, impacts on the liver or nervous system, infections or some cancers; new or worsening autoimmune or inflammatory conditions

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

Ixifi®

Active ingredient(s): *Infliximab*)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using IXIFI?

IXIFI contains the active ingredient infliximab.

Infliximab is a monoclonal antibody - a type of protein that recognises and binds to certain special proteins 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. IXIFI can block the damage caused by too much TNFα.

IXIFI is a biosimilar medicine.

IXIFI is a medicine used in people with the following diseases:

- Rheumatoid arthritis: an inflammatory disease of the joints. IXIFI is used to reduce the signs and symptoms of rheumatoid arthritis and to prevent damage to the joints. You will also be given with IXIFI a disease-modifying medicine called methotrexate.
- Ankylosing Spondylitis: an inflammatory disease of the spine. IXIFI can reduce the signs and symptoms of ankylosing spondylitis, thereby improving physical function.
- Psoriatic arthritis: an inflammatory disease of the joints in which psoriasis (inflammatory disease of the skin) usually occurs in association with arthritis. Often the fingers and toes are affected, although it may occur in other parts of the body. IXIFI 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). IXIFI may be given alone in this case, or in combination with methotrexate.
- Psoriasis: an inflammatory disease of the skin. IXIFI is used to treat patients with moderate to severe psoriasis who have not responded well enough to treatments such as phototherapy (treatment with ultraviolet light or sunlight along with a medicine to make your skin sensitive to light) or conventional treatments, or when these treatments are not appropriate.
- Crohn's disease: a chronic inflammatory disease of the bowel. It may also affect any part of the gut. IXIFI 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. IXIFI 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: an inflammatory disease of the bowel. IXIFI 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.

IXIFI is not to be given to children with Crohn's disease or ulcerative colitis who are younger than 6 years.

Use in children and adolescents is reserved only for Crohn's disease or ulcerative colitis in those aged 6 to 17 years old, who have not responded well enough to other treatments.

IXIFI is not to be given to children and adolescents with any other disease.

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

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

IXIFI is a medicine that affects your immune system.

2. What should I know before I use IXIFI?

Warnings

Do not use IXIFI if:

- You are allergic to infliximab, or any of the ingredients listed at the end of this leaflet, or if you have a history of allergies to mouse proteins (what infliximab may be made of).
  Some of the symptoms of an allergic reaction may include skin rash, hives, fatigue, wheezing, difficulty in breathing, and/or low blood pressure.
  Always check the ingredients to make sure you can use this medicine.
- You have a severe infection, such as tuberculosis and infected abscesses (infection commonly found in the lungs), sepsis (an infection in the bloodstream), a repeating infection, or you have had repeating infections in the past.
- You have heart failure that is moderate or severe.

- You are already taking another medicine for arthritis, which contains the substance called anakinra.

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. IXIFI may affect the normal immune response. You might get infections more easily. Some cases of serious infections, including tuberculosis and sepsis have been reported in patients treated with IXIFI.
- Ever had or been in close contact with Tuberculosis, even if you were treated for it.
- Have ever had or had been in close contact with hepatitis B. Reactivation of hepatitis B has 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 moderate to severe chronic obstructive pulmonary disease (COPD). Lung, head, neck and other cancers have been reported in patients with COPD 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 defenses. You may be more likely to develop infections and lymphomas than people in general, even without receiving TNF blockers such as IXIFI.
- Are pregnant or plan to become pregnant. IXIFI is not recommended in pregnancy. Please see Section 2 - Pregnancy and breastfeeding
- Are breast-feeding. IXIFI is not recommended while breastfeeding. Please see Section 2 - Pregnancy and breastfeeding.
- Have or have had a disease that affects the nervous system such as multiple sclerosis, Guillain-Barré syndrome 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 IXIFI.
- Have ongoing blood disorders or a history of blood disorders.
- Have recently received or are scheduled to receive any vaccines. Patients receiving IXIFI should not receive 'live' vaccines. If possible, you should have all of your vaccines brought up to date before starting treatment with IXIFI.
- have recently received or are scheduled to receive treatment with a therapeutic infectious agent (such as BCG instillation used for the treatment of cancer).
- Take any medicines for any other condition
- Have a planned surgical procedure as treatment with INFLECTRA may be delayed.

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.

If you are being treated with IXIFI, you must avoid becoming pregnant by using adequate contraception during your treatment and for at least 6 months after your last IXIFI injection.

It is not known if IXIFI can affect your ability to have children in the future.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Breast feeding is not recommended during treatment and for 6 months after the last dose of IXIFI. Your doctor will help you decide whether or not to use IXIFI.

Severely decreased numbers of white blood cells have also been reported in infants born to women treated with infliximab for injection during pregnancy. If your baby has continual fevers or infections, contact your baby's doctor immediately.

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 interfere with IXIFI and affect how it works.

- Tell your doctor if you take a medicine for arthritis containing the ingredient anakinra. IXIFI should not be taken together with anakinra.
- Tell your doctor if you are already taking another medicine for arthritis, which contains the substance called abatacept.
- Tell your doctor about all medicines that you have recently taken or are taking during your treatment with IXIFI. These include any other medicines to treat rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis (such as phototherapy or other treatments), Crohn's disease, ulcerative colitis.
- Tell your doctor if you take medicines to prevent rejection in organ transplantation.

Tell your doctor you are taking IXIFI before receiving any vaccinations. While using IXIFI you should not receive live vaccines. If possible, you should have all of your vaccines brought up to date before starting treatment with IXIFI.

Live vaccines should not be given to your baby while you are breast-feeding unless your baby's doctor recommends otherwise. If you have a baby or if you are breast-feeding while you are using IXIFI, tell your baby's doctor about your IXIFI use before the baby receives any vaccines, including live vaccines such as the BCG vaccine (used to prevent tuberculosis) and rotavirus vaccine.

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

4. How do I use IXIFI?

How IXIFI will be given to you

- IXIFI is only available on prescription.
- IXIFI is given by a healthcare professional through a needle placed in a vein in your arm via a drip (called an infusion) over at least 2 hours.

When IXIFI will be given to you

- If you were able to tolerate the first 3 two-hour infusions, your doctor may decide to give your next IXIFI infusions over a period of not less than 1 hour.
- For children and adolescents (6-17 years) with Crohn's disease or ulcerative colitis, the infusion is given over a period of not less than 2 hours.
- A period of observation to watch for any reactions to the medicine follows treatment.

How much will be given

Your doctor may ask you to take other medicines along with IXIFI.

Rheumatoid Arthritis:

- The recommended dose of IXIFI is 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 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 5mg/kg at 2 and 6 weeks after your first infusion, then every 8 weeks after that.
- IXIFI may be given alone or in combination with methotrexate.

Psoriasis:

- The recommended 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.

Crohn's Disease and Fistulising 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 forget to use IXIFI

- If you forget or miss an appointment to receive IXIFI, make another appointment as soon as possible to find out when to receive your next dose.

If you use too much IXIFI

As IXIFI 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 IXIFI, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling Australia: 13 11 26, or New Zealand: 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 IXIFI?

Things you should do

- Contact your doctor immediately if you develop new or worsening symptoms.

- Tell your doctor or dentist that you are being treated with IXIFI before you undergo any surgical procedures.
- You should continue to take adequate contraceptive measures to avoid pregnancy.
- Be watchful for signs of immediate allergic reaction such as hives, difficulty breathing, chest pain or low blood pressure, or delayed allergic reaction (up to 12 days after injection) such as muscle or joint pain with fever or rash.
- Tell your doctor:
    - That you are taking IXIFI before receiving any vaccinations. Some vaccinations should not be given while you are being treated with IXIFI.
    - If you are receiving other medicines for the treatment of cancer. Patients receiving IXIFI should not receive some medicines used for the treatment of cancer.
    - If you think you have an infection. IXIFI 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.
    - If you have had phototherapy for psoriasis.
    - If you have a baby or if you are breastfeeding while you are using IXIFI 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's doctor recommends otherwise.
    - If your baby has continual fevers or infections. Severely decreased numbers of white blood cells have been reported in infants born to women treated with IXIFI during pregnancy.

Call your doctor straight away if you:

- Develop symptoms of Tuberculosis (persistent cough, weight loss, loss of interest in doing anything, fever), or any other infection appear. Do this immediately.
- Develop symptoms of hepatitis B (upset stomach, loss of appetite, vomiting, tiredness, dark yellow or brown urine, and yellow eyes or skin). You must do this immediately.
- Develop a skin rash or hives. Your doctor may discontinue IXIFI until the symptoms go away and then begin giving the medicine again. Symptoms will resolve with appropriate treatment.
- Suffer from congestive heart failure and your condition worsens.
- Notice symptoms signal liver injury such as jaundice (skin and eyes turning yellow), dark brown-colored urine, right-sided abdominal pain, fever, and severe fatigue (tiredness).
- You have symptoms of a stroke 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.

After IXIFI is stopped

Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment:

- skin rash or hives
- frequent infections
- symptoms of Tuberculosis or any other infection (persistent cough, weight loss, listlessness, fever).
- symptoms of hepatitis B (upset stomach, loss of appetite, vomiting, tiredness, dark yellow or brown urine, and yellow eyes or skin).

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

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

Driving or using machines

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

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

Looking after your medicine

IXIFI will be is stored in its original package in the refrigerator at 2° to 8° Celsius (Refrigerate. Do not Freeze) before use.

If removed from the fridge, store unopened IXIFI in its original carton up to a single period of 6 months at a maximum temperature of 30°C; but not more than the expiration date already shown on the carton. The new expiry date should now be written on the carton and IXIFI cannot be returned to the fridge.

It will be kept where young children cannot reach it.

Discard this medicine if not used by the new expiry date or the expiry date printed on the carton, whichever is earlier.

The vial must be kept sealed. Only a healthcare professional should prepare the medicine before use and administer it to you. IXIFI vials are for single use only. Any unused portion should be discarded.

Getting rid of any unwanted medicine

The practice where IXIFI is kept will safely dispose of this medicine per local guidelines and regulations.

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 IXIFI.

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.

Reactions more likely to occur during the first and second infusion (but may also appear up to six months after the last infusion):

- Fever or chills
- Itchiness or hives
- Chest pain
- Low blood pressure
- High blood pressure
- Shortness of breath

More common side effects

More common side effects	What to do
Gastrointestinal related symptoms: • Sore throat • Stomach pain or Upset stomach • Diarrhea • Nausea or vomiting • Urinary tract infections **Infections and related symptoms:** • Developing a cold • Upper respiratory infections (such as bronchitis, sinusitis) • Coughing • Fever **Other:** • Dizziness • Fatigue • Itchiness • Headache • Back pain	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Some patients had side effects that caused them to stop infliximab for injection treatment. The most common reasons were shortness of breath, rash, and headache.

Serious side effects	What to do
Allergic Reaction symptoms: • Hives (red, raised, itchy patches of skin) • Difficulty breathing • Chest pain • High or low blood pressure • Fever • Rash • Muscle or joint pain • Swelling such as in lips or throat, hands, feet or ankles • Difficulty swallowing **Signs of impacts on the liver (rare):** • Jaundice (yellowing of the skin and eyes • Dark brown-coloured urine • Right sided abdominal pain • Fever • Severe fatigue **Symptoms signaling impacts on the nervous system:** • Changes in your vision (including blindness) • Seizures • Weakness in your arms and/or legs or one side of the body • Numbness or tingling in any part of your body including face **Signs of impacts on the heart:** • New, or worsening symptoms for existing heart conditions including shortness of breath (specially with exercise or when lying down) or swelling of your ankles or feet • Changes in the way your heart beats, for example, if you notice it beating faster • If you have a heart problem called congestive heart failure, you will need to be closely monitored by your doctor **Infection related symptoms, and Symptoms signaling impacts on the lungs:** • Fever • Hoarseness • Feeling very tired • Cough or other flu like symptoms • Respiratory infections (such as bronchitis, sinus infections, cold) • Abnormal chest sounds • New or worsening shortness of breath **Skin related symptoms:** • Rashes • Redness • Itching • Skin peeling and blistering • Dry skin or increased sweating • Small pus-filled bumps that can spread over the body, sometimes with a fever • Itchy reddish-purple skin rash and/or threadlike white-grey inside the nose or mouth • New onset of psoriasis, mainly on the soles of the feet and on palms	**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.**

Serious side effects	What to do
Symptoms signaling impacts on the blood: • Bruising or bleeding very easily • Looking very pale **Symptoms related to cancer:** • Possible development of cancers such as skin or lung cancer **Other** • Weight loss (or gain), muscle wasting • Problems with urination • unexpected development of new or worsening autoimmune or inflammatory conditions including lupus, psoriasis, rheumatoid arthritis or inflammatory bowel disease (IBD).	

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

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 IXIFI, 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 in adolescents and young adults with Crohn's disease or ulcerative colitis who have received IXIFI. All of these patients were also receiving drugs known as azathioprine or 6-mercaptopurine. No cases of HSTCL have been reported in patients receiving IXIFI 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 in patients treated with TNF-blockers, including IXIFI. Tell your doctor if you notice any new skin changes during or after therapy or if existing skin marks change appearance.
- Some women being treated for rheumatoid arthritis with infliximab for injection have developed cervical cancer. For women taking IXIFI, including those over 60 years of age, your doctor may recommend that you continue to be regularly screened for cervical cancer.
- Patients with a lung disease called Chronic Obstructive Pulmonary Disease (COPD) and who have a history of heavy smoking may have an increased risk for getting cancer while being treated with IXIFI.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to TGA at www.tga.gov.au/safety/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 IXIFI contains

Active ingredient (main ingredient)	Infliximab
Other ingredients (inactive ingredients)	Disodium succinate hexahydrate, succinic acid, sucrose, polysorbate 80.

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

IXIFI does not contain any preservative.

What IXIFI looks like

IXIFI is supplied as a powder for intravenous infusion, in single-use vials containing 100 mg of infliximab (AUST R 422316).

Who distributes IXIFI

Pfizer Australia Pty Ltd

Level 17, 151 Clarence Street

Sydney NSW 2000

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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