SIMPONI® and SIMPONI® IV

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 SIMPONI/SIMPONI IV?

SIMPONI® / SIMPONI® IV contains the active ingredient golimumab (rmc). SIMPONI is used to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis and ulcerative colitis. SIMPONI IV is used to treat rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis.
For more information, see Section 1. Why am I using SIMPONI/SIMPONI IV? in the full CMI.

2. What should I know before I use SIMPONI/SIMPONI IV?

Do not use if you have ever had an allergic reaction to golimumab (rmc) 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 SIMPONI/SIMPONI IV? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SIMPONI/SIMPONI IV 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 SIMPONI/SIMPONI IV?

- **SIMPONI** is for injection under the skin (subcutaneous use) using a pre-filled syringe or a SmartJect injector pen.
- **SIMPONI IV** is for infusion into a vein usually in the arm (intravenous infusion).
- Your doctor will determine the correct dose of SIMPONI/SIMPONI IV for you and how often you should receive it.

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

5. What should I know while using SIMPONI/SIMPONI IV?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using SIMPONI/SIMPONI IV. • Use appropriate contraception to avoid becoming pregnant while using SIMPONI/SIMPONI IV and for at least 6 months after the last dose. • Tell your doctor if you are scheduled for any vaccines. • Keep all of your doctor's appointments so that your progress can be checked. • Tell your doctor if you develop an infection or you notice any changes in the appearance of the skin or growths on the skin occur during or after therapy.
Things you should not do	• Do not stop using SIMPONI/SIMPONI IV because you are feeling better, unless your doctor tells you to.
Driving or using machines	• Be careful before you drive or use any machines until you know how SIMPONI/SIMPONI IV affects you
Looking after your medicine	• Keep SIMPONI/SIMPONI IV in a refrigerator where the temperature stays between 2°C and 8°C. Do not freeze. Do not shake. • Keep SIMPONI/SIMPONI IV in the outer carton until it is time to use it. This helps protect it from light.

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

6. Are there any side effects?

Side effects that require urgent medical attention include infections, kidney infection, allergic reaction, new or worsening **congestive** heart failure**, neurological disease, blood disorders and** liver problems**.**
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.

SIMPONI® and SIMPONI® IV

Active ingredient(s): golimumab (rmc)

Consumer Medicine Information (CMI)

This leaflet provides important information about using SIMPONI/SIMPONI IV. **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 SIMPONI/SIMPONI IV.**

Where to find information in this leaflet:

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

1. Why am I using SIMPONI/SIMPONI IV?

SIMPONI/SIMPONI IV contains the active ingredient golimumab (rmc) which is a human monoclonal antibody that is produced by recombinant technology. Monoclonal antibodies are proteins that recognise and bind to other specific proteins in the body. Golimumab works by binding to a specific protein in the body called tumour necrosis factor (TNF) alpha.

SIMPONI/SIMPONI IV is used to adult patients with:

- **Rheumatoid arthritis**, an inflammatory disease of the joints.

  If you have active rheumatoid arthritis, you will be given SIMPONI/SIMPONI IV, which you will take in combination with methotrexate.

- **Psoriatic arthritis**, 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.

  If you have active psoriatic arthritis, you will be given SIMPONI/SIMPONI IV alone or in combination with methotrexate.

- **Ankylosing spondylitis**, an inflammatory disease of the spine.

SIMPONI is also used to treat adult patients with:

- **Non-radiographic axial spondyloarthritis**, an inflammatory disease of the spine.
- **Ulcerative colitis**, an inflammatory disease of the bowel.
- If you have moderate to severe ulcerative colitis that is active and has not responded to other medications, you will be given SIMPONI.

In these diseases, the body produces too much TNF. Too much of this substance causes your body's immune system to attack healthy tissue and results in inflammation. Blocking TNF-alpha with SIMPONI/SIMPONI IV can reduce the signs and symptoms of your disease by reducing the inflammation associated with these diseases, but it can also reduce your immune system's ability to fight off infections.

2. What should I know before I use SIMPONI/SIMPONI IV?

Warnings

Do not use SIMPONI/SIMPONI IV if:

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

  Always check the ingredients to make sure you can use this medicine.

- you have a severe infection including tuberculosis, infection of the bloodstream (sepsis), and other infections that can occur when the body's natural defences are lowered.

  SIMPONI/SIMPONI IV can affect your body's ability to fight a serious infection. If you are not sure whether you have a serious infection, check with your doctor.

- you are already taking another medicine for arthritis, which contains either of the substances called anakinra (Kineret) or abatacept (Orencia).
- you have moderate to severe heart failure.

Check with your doctor if you:

- have any kind of infection even if it is very minor, or have an infection that won't go away, or a history of infection that keeps coming back.

  SIMPONI/SIMPONI IV is a medicine that affects your immune system. SIMPONI/SIMPONI IV can lower the ability of your immune system to fight infections. Some patients have had serious infections while receiving SIMPONI/SIMPONI IV, including tuberculosis, and systemic bacterial and fungal infections. Some patients have died from these serious infections.

- have had TB (tuberculosis) or have recently been near anyone who might have TB. Your doctor will evaluate you for TB and perform a skin or a blood test. If your doctor feels that you are at risk for TB, he or she may start treating you for TB before you begin SIMPONI/SIMPONI IV therapy.
- have lived in or travelled to an area where infections called histoplasmosis, coccidioidomycosis, or blastomycosis are common. These infections are caused by a fungus that can affect the lungs or other parts of your body. Ask your doctor if you don't know whether these infections are common in the area in which you have lived or travelled.

- have or have had a hepatitis B infection, or have been in contact with someone who has this condition. Treatment with TNF-blocking agents such as SIMPONI/SIMPONI IV may result in reactivation of hepatitis B in patients who carry this virus. If you know or suspect you may be a carrier of the hepatitis B virus, be sure to tell your doctor about this as this may impact the decision to start or continue treatment with SIMPONI/SIMPONI IV. Your doctor should do a blood test for the hepatitis B virus before you start treatment with SIMPONI/SIMPONI IV .
- have heart failure, or if you previously had or currently have any heart condition. If you develop new or worsening symptoms of heart failure, such as shortness of breath or swelling of your feet, you must notify your doctor.
- have or have had a condition that affects your nervous system, such as multiple sclerosis or Guillain-Barre syndrome. You should tell your doctor if you experience any weakness in your arms or legs, numbness, tingling, or visual disturbances.
- have or have had any type of cancer. A type of blood cancer called lymphoma has been reported in patients receiving TNF alpha blockers. The reports are rare but more frequent than expected for people in general. Cancers, other than lymphoma, have also been reported.
- have recently received or are scheduled to receive a vaccine. Patients receiving SIMPONI/SIMPONI IV should not receive some type of vaccines.
- have recently received or are scheduled to receive treatment with a therapeutic infectious agent (such as BCG instillation used for the treatment of cancer).
- have a latex allergy. The needle cover on the pre-filled syringe and the injector pen contains dry natural rubber.
- have an allergy to alpha-gal or have been diagnosed with alpha-gal syndrome (a type of food allergy to certain meats or meat products).
- blood disorders, or a history of blood disorders.
- You have ever received other TNF alpha antagonist treatments such as infliximab (REMICADE) or adalimumab (HUMIRA)
- take any medicines for any other condition.

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?

Cancer

- In clinical studies, reports of blood cancer called lymphoma were more frequent in patients on SIMPONI/SIMPONI IV than for people in general. People who have been treated for rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis for a long time, particularly those with highly active disease may be more prone to develop lymphoma.
- Cancers, other than lymphoma, have also been reported in patients treated with SIMPONI/SIMPONI IV or other TNF blockers. In a study of SIMPONI/SIMPONI IV in patients with severe persistent asthma, cancers occurred in SIMPONI/SIMPONI IV-treated patients, but not in control-treated patients. If you have severe persistent asthma, you should discuss with your doctor whether SIMPONI/SIMPONI IV is appropriate for you.
- There have been cases of cancers, including unusual types, in children and teenage patients taking TNF-blocking agents, which sometimes resulted in death. For children and adults taking TNF blocker medicines, the chances of getting lymphoma or others cancers may increase.
- On rare occasions, a specific and severe type of lymphoma called hepatosplenic T-cell lymphoma has been observed in patients taking other TNF blockers. Most of these patients were adolescent or young adult males. This type of cancer has usually resulted in death. Almost all of these patients had also received drugs known as azathioprine or 6-mercaptopurine. Tell your doctor if you are taking azathioprine or 6-mercaptopurine with SIMPONI/SIMPONI IV. Talk to your doctor if you are concerned about this.
- Some patients treated with SIMPONI/SIMPONI IV have developed certain kinds of skin cancer like melanoma.

You should also tell your doctor if you have had or develop lymphoma or other cancers while you are taking SIMPONI/SIMPONI IV. Whether you decide to use SIMPONI/SIMPONI IV or not, you should discuss with your doctor the cancer screening measures and impact of the life style choices on the risk of developing cancer.

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.

The use of this medicine in pregnant women is not recommended. SIMPONI/SIMPONI IV should only be used during pregnancy if clearly needed.

Use appropriate contraception to avoid becoming pregnant while using SIMPONI/SIMPONI IV and for at least 6 months after the last dose.

If you received SIMPONI/SIMPONI IV while you were pregnant your baby may be at higher risk of getting an infection for up to approximately six months after the last dose you received during pregnancy. It is important to tell your baby's doctor and other health care professionals about your SIMPONI/SIMPONI IV use before the baby receives any vaccine as certain vaccines may put your baby at higher risk for infections.

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

It is not known whether SIMPONI/SIMPONI IV passes into breast milk. If you are breastfeeding, your doctor may advise you to stop breastfeeding while you are using this medicine, and for at least 6 months after the last dose.

Children and adolescents

SIMPONI/SIMPONI IV is not recommended for use in children below age 18 due to a lack of data on efficacy and safety.

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 SIMPONI/SIMPONI IV and affect how it works. These include any other medicines to treat

- rheumatoid arthritis
- psoriatic arthritis
- ankylosing spondylitis
- ulcerative colitis

Especially, tell your doctor or pharmacist if you are taking a medicine containing the substance anakinra (Kineret), abatacept (Orencia) or rituximab (Mabthera).

SIMPONI/SIMPONI IV should not be taken together with anakinra or abatacept.

Also, tell your doctor if you are taking other medications that affect your immune system.

Tell your doctor if you are scheduled to receive any vaccines. Patient receiving SIMPONI/SIMPONI IV should not receive some type of vaccines.

Using SIMPONI/SIMPONI IV together with any of these medicines may increase the risk of infection.

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

4. How do I use SIMPONI/SIMPONI IV?

SIMPONI is for injection under the skin (subcutaneous use) using a pre-filled syringe or a SmartJect injector pen.

SIMPONI IV is for infusion into a vein usually in the arm (intravenous infusion).

How much to take / use

Subcutaneous use

For rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis and non-radiographic axial spondyloarthritis:

- the recommended dose is 50 mg given as a single injection under the skin.

For ulcerative colitis:

- The starting dose is 200 mg, followed by a dose of 100 mg 2 weeks later.
- The maintenance dose is 100 mg every 4 weeks.

Intravenous infusion

For rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis

- Your doctor will decide your dose (in mg) based on your weight. The dose is 2 mg for every kilogram (kg) of body weight.

When to take / use SIMPONI/SIMPONI IV

Subcutaneous use

For rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis and non-radiographic axial spondyloarthritis:

- SIMPONI should be injected once a month, on the same date each month.
- If you are being treated for non-radiographic axial spondyloarthritis and SIMPONI has no effect on your condition within 12 - 14 weeks, your doctor may tell you to stop using this medicine.

For ulcerative colitis:

- SIMPONI should be injected at Week 0, then 2 weeks later and every 4 weeks, thereafter.

Follow the instructions provided and use SIMPONI until your doctor tells you to stop.

Do not use SIMPONI more often than prescribed.

Intravenous infusion

For rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis

- The table below shows how often you will usually be given SIMPONI IV.

1st treatment	Initial treatment
2nd treatment	4 weeks after your 1st treatment
Further treatments	Every 8 weeks

How to SIMPONI/SIMPONI IV

SIMPONI:

At the start of your therapy, SIMPONI may be injected by your doctor or nurse. However, you and your doctor can decide that you may inject SIMPONI yourself. If this is the case, you will receive training on how to inject SIMPONI yourself. If you are injecting SIMPONI yourself, follow closely the instructions provided in the instruction leaflet inside your pack.

Inject all the solution in the syringe or injector pen. This ensures that the correct dose is administered.

SIMPONI IV:

Should be diluted before administration. SIMPONI IV is given in a drip into a vein (called an infusion) over a period of about 30 min.

Educational support

The Johnson & Johnson Immunology Patient Support Program is available to patients prescribed SIMPONI. It offers:

- Injection education
- Ongoing medical supplies
- Starter kit
- Reminder service
- Ongoing education

Call 1800 666 845

If you forget to use SIMPONI/SIMPONI IV

SIMPONI/SIMPONI IV should be used regularly at the same time each day (week or month). If you forget to use SIMPONI/SIMPONI IV on your scheduled date, inject a dose as soon as you remember. Inject your next dose at your next regularly scheduled date. This will put you back on your schedule.

Do not take a double dose to make up for the dose you missed.

If you use too much SIMPONI/SIMPONI IV

If you think that you have used too much SIMPONI/SIMPONI IV, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 SIMPONI/SIMPONI IV?

Things you should do

- Continue injecting SIMPONI for as long as your doctor has told you to.
- If you suffer from congestive heart failure, tell your doctor immediately if your condition worsens. See additional information under Congestive heart failure.
- If you are planning to have surgery, tell your doctor or surgeon you are using SIMPONI/SIMPONI IV.
- Use appropriate contraception to avoid becoming pregnant while using SIMPONI/SIMPONI IV and for at least 6 months after the last dose.
- Tell your doctor if you did receive SIMPONI/SIMPONI IV while you were pregnant as your baby may be at higher risk for getting an infection. It is important to tell your baby's doctor and other health care professionals about your SIMPONI/SIMPONI IV use so they can decide when your baby should receive any vaccine.
- Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if:

- symptoms of hepatitis B (upset stomach, loss of appetite, vomiting, tiredness, dark yellow or brown urine, and yellow eyes or skin) appear.
- symptoms of TB (persistent cough, weight loss, listlessness, fever), or any other infection appear
- you have symptoms such as persistent fever, sore throat, bruising, bleeding or paleness. These symptoms may be due to the development of a blood disorder, which may need close monitoring by your doctor.
- if you develop a skin rash or hives. Some patients may get allergic reactions to SIMPONI. Some of these reactions may be serious. If an allergic reaction occurs while getting a SIMPONI infusion or shortly afterwards, your doctor may decide to stop your SIMPONI infusion and/or give you medication to treat the reaction.
- you notice any new skin lesions during or after therapy or if existing lesions change appearance. See additional information under Section 2 What should I know before I use SIMPONI/SIMPONI IV? – Cancer.

Remind any doctor, dentist or pharmacist you visit that you are using SIMPONI/SIMPONI IV.

Things you should not do

- Do not stop using SIMPONI/SIMPONI IV because you are feeling better, unless your doctor tells you to. Your condition may flare up if you stop using SIMPONI/SIMPONI IV.
- Do not shake the solution of SIMPONI.

Congestive heart failure

Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF-blocking agents, including SIMPONI/SIMPONI IV. Some of these patients died. SIMPONI/SIMPONI IV has not been studied in patients with CHF. If you have heart failure and your doctor decides to administer SIMPONI/SIMPONI IV, your condition should be closely monitored during treatment. If you develop new or worsening symptoms of heart failure (such as shortness of breath or swelling of your feet), you should contact your doctor right away.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SIMPONI/SIMPONI IV affects you.

SIMPONI/SIMPONI IV may cause dizziness in some people

Looking after your medicine

- Keep SIMPONI/SIMPONI IV in the outer carton until it is time to use it. This helps protect it from light.
- Keep SIMPONI/SIMPONI IV in a refrigerator where the temperature stays between 2°C and 8°C. Do not freeze. Do not shake.
- If needed, you may store SIMPONI/SIMPONI IV at room temperature up to 25°C for one period of time up to 30 days.
    - Write the date on the carton, on which SIMPONI/SIMPONI IV is removed from the refrigerator.
    - If SIMPONI/SIMPONI IV has reached room temperature, do not put it back in the refrigerator.
    - Throw away SIMPONI/SIMPONI IV if it has been kept at room temperature for 30 days and has not been used.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

After injection, used syringes and SmartJect injector pens should be placed in a puncture-resistant container, like injecting SIMPONI, place the injection device immediately into a sharps container. Do not put the used injection device into your normal household or recycling waste. Dispose of your sharps container according to your state or local regulations. Empty vials, antiseptic wipes, and other supplies can be placed in regular rubbish.

If your doctor tells you to stop taking SIMPONI or has passed its expiry date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

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.

Less serious side effects

Less serious side effects	What to do
Injection site reactions: • mild rash and irritation • swelling, pain or bruising • hives. **Lungs and upper airways:** • flu, cold sores or fever • hoarseness • symptoms of upper respiratory tract infections such as runny nose, blocked sinus or sore throat • lower respiratory tract infections such as bronchitis or pneumonia **Mental, emotional and behavioural:** • difficulty sleeping • depression **Stomach and digestion:** • constipation or indigestion **Skin, nail and hair:** • hair loss • hoarseness	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
• infection of the skin or soft tissue **Heart and blood pressure:** • chest discomfort • high blood pressure **Muscle and joint:** • pain or swelling of the joints • pain or swelling of the elbow or shoulder **Other:** • headache • dizziness • numbness or tingling • feeling weak	

Serious side effects

Serious side effects	What to do
Signs of infection such as: • fever, flu-like symptoms, chills or night sweats • headache, tiredness, persistent cough, blood in your sputum or shortness of breath • weight loss • nausea, vomiting or diarrhoea • redness or swelling of skin or joint • cold sores • tooth pain • burning on urination or a reduction in the amount of urine that is passed • new or worsening of pain in any location **Signs of a kidney infection such as:** • back pain, side pain or severe abdominal pain • fever or chills • tiredness • frequency or burning while passing urine • changes in the colour or smell of urine **Signs of an allergic reaction such as:** • wheezing, shortness of breath, difficulty breathing, or a tight feeling in your chest • swelling of the face, lips, tongue or other parts of the body • rash, itching, hives or flushed red skin	**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
• dizziness or light-headedness **Signs of new or worsening congestive heart failure such as:** • shortness of breath • swelling of your feet **Signs of neurological disease such as:** • changes in your vision • weakness in your arms or legs • numbness or tingling in any part of your body **Signs of blood disorders such as:** • persistent fever • sore throat • bruising or bleeding • paleness **Signs of liver problems such as:** • skin and eyes turning yellow • dark brown-coloured urine or pale stools • stomach pains or severe pain in the right-side of abdomen • severe tiredness or fever • nausea, feeling sick or vomiting	

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.

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 SIMPONI/SIMPONI IV contains

Active ingredient (main ingredient)	golimumab (rmc)
Other ingredients (inactive ingredients)	• sorbitol • histidine • histidine hydrochloride monohydrate • polysorbate 80
	• water for injections

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

What SIMPONI/SIMPONI IV looks like

SIMPONI is a clear to slightly opalescent, colourless to light yellow solution which may contain a few small translucent or white particles. This appearance is not unusual for solutions containing protein.

SIMPONI IV SIMPONI IV solution for intravenous infusion is a colourless to light yellow solution.

Do not use SIMPONI/SIMPONI IV if the solution is discoloured, cloudy, or you can see foreign particles in it.

SIMPONI is available in the following presentations:

For subcutaneous use

- SIMPONI 50 mg pre-filled syringe (AUST R 153767)
- SIMPONI 50mg SmartJect Injector pen (AUST R 153181)
- SIMPONI 100mg pre-filled syringe (AUST R 208278)
- SIMPONI 100mg SmartJect Injector pen (AUST R 208279)

For intravenous infusion

- SIMPONI 50 mg/4 mL concentrate for infusion vial (AUST R 311990)

SIMPONI pre-filled syringes and pre-filled injector pens are supplied in containers of 1 or 3 units.

SIMPONI IV vials are supplied in containers of 1 unit.

For pre-filled syringe and SmartJect autoinjector pen an instruction leaflet explaining how to self-administer the product is included in the pack.

** Not all presentations or pack sizes may be supplied.*

Who distributes SIMPONI/SIMPONI IV

Janssen-Cilag Pty Ltd

17 Khartoum Road,

Macquarie Park, NSW 2113, Australia

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

This leaflet was prepared in 05 Nov 2026.