

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 Cimzia®?

Cimzia® contains the active ingredient certolizumab pegol. Cimzia® is used to treat several inflammatory diseases.

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

2. What should I know before I use Cimzia®?

Do not use if you have ever had an allergic reaction to certolizumab pegol or any of the ingredients listed at the end of the CMI.

Do not use if you have tuberculosis or a severe infection or are taking another drug called Anakinra.

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 Cimzia®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cimzia® 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 Cimzia®?

- Follow all directions given to you by your doctor and other health professionals carefully including:
 - how many injections to take (the initial dose is usually 2 injections every 2 weeks, then 1 injection every 2 weeks)

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

5. What should I know while using Cimzia®?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Cimzia®.
Things you should not do	<ul style="list-style-type: none">Do not inject yourself with this medicine unless you have been trained by a healthcare professional.Do not use this medicine after the expiry date which is stated on the label and carton after EXP.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how Cimzia® affects you.
Looking after your medicine	<ul style="list-style-type: none">Keep this medicine out of the sight and reach of children.Store in a refrigerator between 2°C – 8°C. Do not freeze.Keep the pre-filled syringe or pen in the outer carton in order to protect from light.If needed, Cimzia® may be stored at room temperature up to a maximum of 25°C for a single period of up to 10 days with protection from light. Once Cimzia® has been stored at room temperature, it should not be placed back into the refrigerator and should be discarded if not used within the 10-day period.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common and serious side effects are infections, nausea, weakness, rash or itching, headache, dizziness, or a bump or open sore that doesn't heal.

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.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cimzia®. **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 Cimzia®.**

Where to find information in this leaflet:

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

1. Why am I using Cimzia®?

Cimzia® contains the active certolizumab pegol. Cimzia® is a human antibody fragment. Antibodies are proteins that specifically recognise and bind to other proteins. Cimzia binds to a specific protein called tumour necrosis factor α (TNF α), thereby blocking the activity of TNF α . Cimzia® can prevent the harmful effects of TNF α , thereby reducing the signs and symptoms of inflammatory diseases such as joint pain, tenderness, swelling and stiffness.

Cimzia® is used to treat inflammatory diseases such as:

rheumatoid arthritis (joint pain, tenderness, swelling and stiffness) It may be used together with another medicine called methotrexate

plaque psoriasis (red, itchy and inflamed skin)

psoriatic arthritis (similar symptoms to rheumatoid arthritis and plaque psoriasis)

ankylosing spondylitis and non-radiographic axial spondyloarthritis (back pain and morning stiffness)

2. What should I know before I use Cimzia®?

Warnings

Do not use Cimzia® if:

- you are allergic to certolizumab pegol or any of the ingredients listed at the end of this leaflet
- you have a severe infection, including tuberculosis or ongoing or recurring infections (symptoms include fever, wounds, feeling tired, dental problems)
- you have moderate to severe heart failure
- you are already using anakinra, another medicine for rheumatoid arthritis

- the packaging is torn or shows signs of tampering or if the syringe or pen does not look quite right
- the expiry date (EXP) printed on the pack is past.

Check with your doctor if you:

- have any other medical conditions such as symptoms of infection, including fever, cough, any flu-like symptoms, open cuts or sores on your body
- have a history of recurrent infections or other conditions that increase the risk of infections
- have a nervous system disorder such as multiple sclerosis and other demyelinating disease
- have congestive heart failure
- have cancer (such as lymphoma and skin cancer)
- have symptoms of lupus (persistent rash, fever, joint pain, and tiredness)
- experience allergic reactions such as chest tightness, wheezing, dizziness, swelling or rash
- have airway disease such as emphysema or chronic obstructive pulmonary disease
- have a blood disorder or symptoms of a blood disorder such as persistent bruising, bleeding, paleness or fever
- have tuberculosis, or if you have been in close contact with someone who has had tuberculosis
- are scheduled for any vaccines
- are scheduled for any surgery or dental procedures.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Cimzia can be used during breastfeeding.

Children and adolescents

Cimzia® is not recommended for children and young people under 18 years of age. This is because it has not been studied in this age group.

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 Cimzia® and affect how it works.

Taking other biologic medicines while on anti-TNF therapy 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 Cimzia®.

4. How do I use Cimzia®?

How much to take / use

- The starting dose is 400 mg CIMZIA (as 2 injections in one day) given at weeks 0, 2 and 4.
- This is followed by a maintenance dose of 200 mg every other week starting at week 6. Alternatively, your doctor may decide that you should receive a monthly dose of 400 mg Cimzia®.
- The maintenance dose may be higher or lower depending on your response to the treatment which will be determined by your doctor.
- Follow the instructions provided and use Cimzia® until your doctor tells you to stop.

When to take / use Cimzia®

- Cimzia® should be used as instructed by your doctor.

How to inject Cimzia®

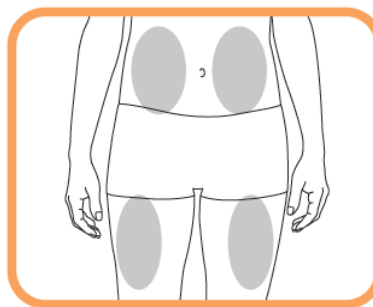
- Cimzia® is injected under the skin (subcutaneous use). The injection can be self-administered or given by another person, for example a family member or friend after proper training in injection technique, by your doctor or a nurse.
- The following instructions explain how to inject Cimzia®. Read the instructions carefully and follow them step by step.
- Do not attempt to self-inject until you are sure that you understand how to prepare and give the injection.

1. Setting up

- Take the carton containing Cimzia® out of the refrigerator.
- Wash your hands thoroughly.
- Set up the following items on a clean surface.
 - One pre-filled syringe or pen of Cimzia®
 - One alcohol pad
- Look at the expiry date on the syringe/pen. Do not use the product after the month and year shown.
- Allow Cimzia® to reach room temperature. This will take about 30 minutes for the pre-filled syringe and 30-45 minutes for the pre-filled pen minutes.
- Do not try to warm up the syringe/pen.

2. Choosing and preparing an injection site.

- Choose a site on your thigh or stomach.



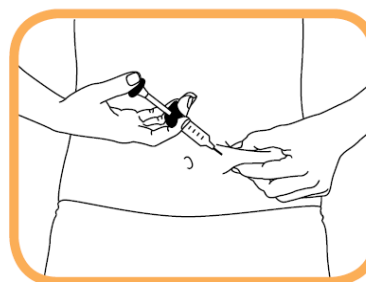
Each new injection should be given on a separate site from the last injection site.

- Do not inject in an area where the skin is tender, reddened, bruised, or hard.
- Wipe the injection site with the enclosed alcohol pad, using a circular motion.
- Do not touch the site again before injecting.

3. Injecting Cimzia®

Pre-filled syringe

- Do NOT shake the syringe.
- Check the medicine in the barrel of the syringe is clear to pale yellow and free from particles. Do not use the pre-filled syringe if the solution is discoloured, cloudy or if you can see particles in it. You may see an air bubble. This is normal. There is no need to remove air bubbles before injection. Injecting the solution subcutaneously with air bubbles is harmless.
- Remove the cap from needle syringe by pulling off the plastic ring in a straight line, being careful not to touch the needle or let the needle touch any surface. Do not bend the needle.
- Hold the syringe with the needle facing down.
- With one hand, gently grasp the cleaned areas of skin and hold firmly.



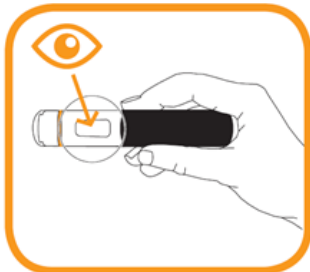
- With the other hand, hold syringe at a 45 degree angle to skin.
- With one quick, short motion, push the needle all the way into the skin.
- Push the plunger to inject solution- it can take up to 10 seconds to empty the syringe.



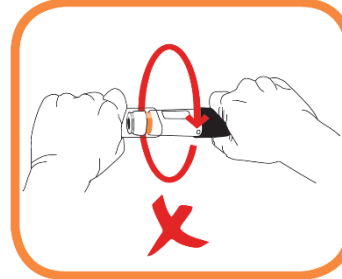
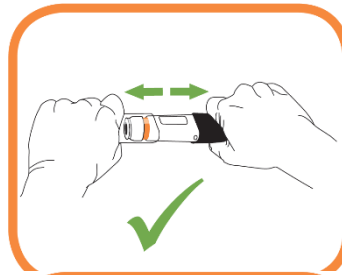
- When the syringe is empty, carefully remove the needle from the skin at the same angle at which it was inserted.
- Release the skin with the first hand.
- Using your thumb or a piece of gauze, apply pressure over the injection site for a few seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

Pre-filled pen

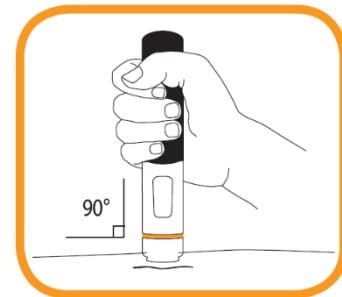
- The pre-filled pen is designed to work accurately and safely. However, if any of the following steps go wrong and/or if you feel unsure about the injection process, contact your doctor or pharmacist.
- Do NOT shake the pre-filled pen.
- Check the medicine in the pre-filled pen (through the viewing window) is clear to pale yellow and free from particles. Do not use the pre-filled pen if the solution is discoloured, cloudy or if you can see particles in it. You may see air bubbles. This is normal. There is no need to remove air bubbles before injection. Injecting the solution subcutaneously with air bubbles is harmless.



- Hold the pre-filled pen firmly with one hand around the black handle.
- Grasp the clear cap with the other hand and remove it. **Do not twist the cap off as this may jam the internal mechanism.**



- Inject within 5 minutes of removing the cap. **Do not replace the cap.**
- Although hidden from view the needle tip is now uncovered. Do not try to touch the needle as it could activate the pre-filled pen.
- Hold the pre-filled pen straight (at a 90 degree angle) against the skin that previously has been cleaned (the "injection site").



- Press the pre-filled pen firmly against the skin and hold. The injection begins when a first "click" is heard and the orange band at the bottom of the pre-filled pen disappears.



- Continue to hold the pre-filled pen in place firmly against the skin until a second "click" is heard and the viewing window turns orange. This can take up to 15 seconds. At this time, the injection will be complete. If the viewing window turns orange and you hear a second click this means the injection has been completed. If you feel unsure about the injection process, please contact your doctor or pharmacist. Do not try to repeat the injection without speaking to your doctor or your pharmacist.



- The needle will automatically move back into the empty pen. Do not try to touch the needle.
- You can now remove the used pen by pulling the pen straight up carefully from the skin.
- Use a piece of gauze, apply pressure over the injection site for a few seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

4. Throwing away supplies

- You must NOT re-use or re-cap the Cimzia® syringe/pen. This product is for one dose in one patient only.
- After injecting Cimzia®, immediately throw away the used syringe/pen in a special container as instructed by your doctor, nurse or pharmacist.
- Keep this container out of the reach of children.

If you forget to use Cimzia®

Cimzia® should be used regularly at the same time each 2 or 4 weeks. If you miss your dose at the usual time, you should inject the next dose of CIMZIA as soon as you remember. Then inject your next dose as you would have on your originally scheduled day, had you not forgotten a dose.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

- If you are not sure what to do, ask your doctor or pharmacist.
- If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much Cimzia®

If you think that you have used too much Cimzia®, 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 Cimzia®?

Things you should do

Call your doctor straight away if you:

- if you feel Cimzia® is not helping your condition. Your doctor may need to change your medicine.
- Tell your doctor if, for any reason, you have not used Cimzia® exactly as prescribed. Otherwise, your doctor may change your treatment unnecessarily.

Remind any doctor, dentist or pharmacist you visit that you are using Cimzia®.

Things you should not do

- Do not give Cimzia® to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.
- Do not use Cimzia® to treat any other complaints unless your doctor tells you to.
- Do not use Cimzia® and anakinra together.
- Do not use Cimzia® and abatacept together.
- Do not stop using it unless your doctor tells you to.

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your pre-filled syringe or pen in the pack until it is time to use it.
- Keep Cimzia® in a refrigerator between 2°C and 8°C. Do not freeze. Protect from light.
- If needed, Cimzia® may be stored at room temperature up to a maximum of 25°C for a single period of up to 10 days with protection from light. Once Cimzia® has been stored at room temperature, it should not be placed back into the refrigerator and should be discarded if not used within the 10-day period.

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.

When to discard your medicine

After injecting Cimzia®, immediately throw away the used syringe or pen in a special container as instructed by your doctor, nurse or pharmacist.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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
<ul style="list-style-type: none">• lower respiratory tract infections (such as bronchitis, pneumonia)• upper respiratory infections (such as cold, runny nose, sinus infections)• bacterial infections in any site, including abscess (a collection of pus) or a urinary tract infection• viral infections (including cold sores, shingles, and influenza)• fever• high blood pressure• rash or itching• abdominal symptoms such as abdominal pain, nausea, vomiting, diarrhoea, constipation, pain, distension, heartburn, or indigestion• injection site reactions (including pain, swelling, redness or itching)• feeling weak and generally unwell• headache dizziness.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• persistent cough, weight loss, listlessness, fever• signs of nervous system disorders such as numbness or tingling throughout your body, arm or leg weakness, double vision	Call your doctor straight away, or go straight to the Emergency Department at your nearest

<ul style="list-style-type: none">• a bump or open sore that doesn't heal.• severe rash hives or other signs of allergic reaction• swollen face, hands, feet• trouble breathing, swallowing• shortness of breath with exertion or upon lying down or swelling of the feet• persistent fever, bruising, bleeding, paleness.	hospital if you notice any of these serious side effects.
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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 Cimzia® contains

Active ingredient (main ingredient)	certolizumab pegol
Other ingredients (inactive ingredients)	sodium acetate, sodium chloride, water
Potential allergens	Latex, mouse proteins

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

What Cimzia® looks like

Cimzia® is a clear to opalescent, colourless to yellow, essentially free of visible particles, sterile solution in a syringe or pen.

Cimzia® is supplied in a carton containing:

- Two 1 mL pre-filled syringes or pre-filled pens of Cimzia® (AUST R 154726, AUST R 281317)
- Two alcohol wipes (for cleansing the areas chosen for injection)

Who distributes Cimzia®

UCB Pharma

A division of UCB Australia Pty Ltd

Level 1, 1155 Malvern Road

Malvern VIC 3144, Australia

Everyday Support Program

The Everyday Support Program provides a comprehensive resource to assist patients prescribed Cimzia® and offers:

- home visits from a qualified nurse to provide self-injection education
- educational resources.

**Call 1800-CIMZIA
(1800 246 942)**

This leaflet was prepared in February 2022.