

PATIENT INFORMATION ON CERTOLIZUMAB

[Sir-toe-LIZ-you-mab]

Brand name: Cimzia

This information sheet was written by the Australian Rheumatology Association to help you understand certolizumab. It includes important information about:

- **how you should take your medication**
- **what are the possible side effects**
- **what tests you will have to watch your condition**
- **other precautions you should take while you are taking certolizumab.**

Please read it carefully and discuss any concerns with your rheumatologist.

IMPORTANT THINGS TO REMEMBER

- You must see your rheumatologist regularly to make sure the treatment is working and check for possible side effects.
- You should have regular blood tests as suggested by your rheumatologist
- It is important to tell your rheumatologist if you have a new serious illness such as a serious infection, cancer, heart failure etc.
- If you are worried about any side effects, you should contact your rheumatologist as soon as possible.
- If you stop certolizumab for any reason, you must contact your rheumatologist. Failure to do so may mean that your treatment may no longer be funded.
- If you plan to become pregnant, you must discuss the timing with your rheumatologist.

For more information about RHEUMATOID ARTHRITIS and other inflammatory conditions see Arthritis Australia's website: www.arthritisaustralia.com.au

What is certolizumab?

Certolizumab belongs to a class of medications called **biological disease modifying antirheumatic drugs (biological DMARDs or bDMARDs)**. Specifically, it is a TNF inhibitor.

bDMARDs have now been given to over a million people worldwide since their first use in the late 1990s. These medications block substances, produced by arthritic tissues, called cytokines.

These cytokines are found in excessive amounts in the blood and joints of people with rheumatoid arthritis, psoriatic arthritis, juvenile arthritis and ankylosing spondylitis.

They cause inflammation, which results in symptoms of pain, joint swelling and stiffness, and can lead to joint damage.

By blocking the cytokine called Tumour Necrosis Factor (TNF), certolizumab lessens inflammation, pain symptoms and helps stop further joint damage.

What benefit can you expect from your treatment?

You may notice lessening of joint swelling, pain and stiffness, often within the first 8 weeks of starting.

Stopping certolizumab

If you stop or delay your certolizumab treatment, you may worsen again. Keep on your treatment, unless told by your rheumatologist to stop or unless side effects occur (see Side effects).

If you stop certolizumab for any reason, you must contact your rheumatologist.

Failure to do so may mean that your treatment may no longer be funded.

How will you be checked while on certolizumab?

- Medications like certolizumab are very expensive and highly funded by Medicare. Certain conditions must be met to receive it.
- Certolizumab will only be given if your disease is active and if standard treatments have not worked.
- It will only be kept going if it helps your condition. This must be checked between 12 and 16 weeks after the start of treatment.

- Blood tests are needed during your treatment to watch for side effects and decide if the treatment is working.
- How often you have blood tests will depend on what other medications you are taking and what other illnesses you might have. Your rheumatologist will advise on this.

How is certolizumab given?

Certolizumab is injected under the skin of the abdomen or thigh. It comes in a pen or a syringe injection.

It can be injected by your doctor, nurse, carer or by you. If injecting yourself, be sure to follow the detailed instructions carefully to ensure the best response. It is particularly important to change where you inject each time.

What is the dosage?

The usual dose for adults with arthritis is 400mg given in two injections on the same day every two weeks for the first 3 doses. Then either a 200mg injection may be given every two weeks or two 200mg injections every 4 weeks.

Can other medications be taken with certolizumab?

Certolizumab may be used with other arthritis medications including:

- other DMARDs such as methotrexate
- steroid medications such as prednisolone or cortisone injections into the joint
- anti-inflammatory medications (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen, Nurofen)
- simple pain medications such as paracetamol.

Certolizumab cannot be used with other bDMARDs.

There are separate information sheets for the medications mentioned above.

Are there any side effects?

You might experience side effects with your treatment. Contact your rheumatologist if you have any concerns about possible side effects. Many side effects disappear when certolizumab treatment is stopped.

Most common possible side effects

- Mild pain, swelling or itching at the site of the injection are very common (up to 20% of patients) but can be reduced by applying ice and antihistamine/steroid creams to the injection site and/or leaving it out of the refrigerator for 30 minutes before injecting.

- Headaches, cough, stomach and bowel discomfort may also occur.
- As certolizumab affects the immune system, mild infections, mainly the upper respiratory tract (e.g. colds, sinusitis) may occur more often. Treatment with certolizumab may need to be briefly stopped for a serious infection so contact your rheumatologist for advice.

Less common or rare possible side effects

- Serious infections such as tuberculosis (TB) are seen rarely, and screening for TB is needed before treatment begins.
- Rarely, certolizumab may cause an allergic reaction with itchy, red skin or a rash or a feeling of tightness in the chest and trouble breathing.
- Side effects involving the nerves such as inflammation of the nerve to the eye, may also occur rarely, causing changes in vision or sensation.
- Very rarely 'drug-induced lupus' has occurred with symptoms of rash, fever and increased joint pain.
- Annual skin checks are suggested with any medications that can suppress the immune system as there is a slight increase in risk in skin cancers. To date research and use over 20 years, have not shown an increase in risk of other cancers.

What precautions are necessary?

Infections

- If you have a current infection of any kind treatment with certolizumab should not be given until the infection is treated.
- You will need some blood tests and a chest x-ray to exclude some chronic infections before your first bDMARD.

Precautions with other diseases

Worsening may occur of the following conditions:

- multiple sclerosis
- moderate to severe heart failure.
- systemic lupus erythematosus (lupus/SLE) People with SLE are not often given certolizumab but each case will be assessed whether safe by your rheumatologist

Use with other medications

- Certolizumab can interact with other medications. You should tell all your doctors about all medications you are taking or plan to take. This includes over the counter or herbal/naturopathic medications.

Vaccines

- If you are taking certolizumab you should not be immunised with 'live' vaccines such as MMR (measles, mumps and rubella), Varicella vaccine (Chicken pox) or Zostavax (Varicella Zoster or Shingles), OPV (oral polio virus), BCG (Bacillus Calmette Guerin), Japanese Encephalitis or Yellow Fever. Talk with your rheumatologist before receiving any vaccines.
- Pneumococcal vaccines and the yearly seasonal flu vaccinations are safe and encouraged.

For more information on vaccination including the COVID-19 vaccination go to the ARA website; <https://rheumatology.org.au/> patients, medication information, vaccinations.

Surgery

- If you need surgery for any reason, certolizumab should be stopped before surgery. It can start again after the operation at a time decided by your surgeon and rheumatologist, (often once the wound has healed and there is no infection).

Cancer risk

- Lymphoma, a cancer of lymph glands, is found more commonly in patients with severe active rheumatoid arthritis than in the general population. To date there is no evidence to suggest that certolizumab increases lymphoma.
- If cancer has been previously treated and cured it may be possible for certolizumab to be used safely.
- For general cancer prevention, stopping smoking and taking skin cancer prevention measures are recommended. It is important to use sunscreen and avoid prolonged sun exposure. A yearly skin check is recommended.
- Talk to your doctor if you have any concerns about issues relating to cancer risk.

Use with alcohol

- You may drink alcohol while taking certolizumab. If you are also taking methotrexate, you should be cautious about how much alcohol you drink.

Use in pregnancy and when breastfeeding

- If you plan to become pregnant it is important to discuss this with your doctor as each case is different.

- Certolizumab is not actively transferred across the placenta in the third trimester, therefore there is minimal placental transfer to the infant. Recent data suggests it can be used through conception and continued throughout pregnancy until delivery.
- You should discuss with your rheumatologist regarding breastfeeding. In a study of lactating mothers, minimal transfer of certolizumab from plasma to breast milk was observed. Certolizumab can be used during breastfeeding. You should be supported by your healthcare team if you wish to breastfeed.
- If certolizumab is continued later in pregnancy, the theoretical risk of administration of live or live-attenuated vaccines to infants exposed in utero to certolizumab should be weighed against the benefits.
- The rotavirus vaccine should be given within the first six months of life. Discussion with a neonatologist/paediatrician is recommended. Note: due to lower rates of transfer with certolizumab, this decision may be revised in the future with more data.
- More detailed information can be found at <https://rheumatology.org.au/For-Patients/Pregnancy-Information>

How to store certolizumab

- Certolizumab should normally be kept refrigerated. If needed for example when travelling, it may be stored below 25°C for up to 7 days and then used or discarded.
- Keep all medications out of reach of children.

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

You should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.

The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medications mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medication. It can be reproduced in its entirety but cannot be altered without permission from the ARA. The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.

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