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**EPAR summary for the public**

# Cimzia

certolizumab pegol

This is a summary of the European public assessment report (EPAR) for Cimzia. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Cimzia.

## What is Cimzia?

Cimzia is a solution for injection that contains the active substance certolizumab pegol. It is available in a pre-filled syringe (200 mg/ml).

## What is Cimzia used for?

Cimzia is used in adults to treat the following diseases:

- moderate to severe, active rheumatoid arthritis (a disease causing inflammation of the joints). It is used in combination with another medicine, methotrexate, when the disease has not responded adequately to other treatments called disease-modifying antirheumatic drugs (DMARDs), including methotrexate. Cimzia can also be given alone when treatment with methotrexate is not appropriate.
- severe, active and progressive rheumatoid arthritis that has not been previously treated with methotrexate or other DMARDs. In these patients, Cimzia is given in combination with methotrexate.
- axial spondyloarthritis (a disease causing inflammation and pain in the joints of the spine), including patients with:
  - severe active ankylosing spondylitis who have not responded adequately or are intolerant to anti-inflammatory medicines called non-steroidal anti-inflammatory drugs (NSAIDs);

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  - severe active axial spondyloarthritis without evidence on the X-ray of ankylosing spondylitis but with objective signs of inflammation who have not responded adequately or are intolerant to NSAIDs.
- psoriatic arthritis (a disease causing red, scaly patches on the skin and inflammation of the joints). It is used in combination with methotrexate, when the disease has not responded adequately to DMARDs, including methotrexate. Cimzia can also be given alone when treatment with methotrexate is not appropriate.

The medicine can only be obtained with a prescription.

## How is Cimzia used?

Treatment with Cimzia should only be started by a specialist doctor who has experience in diagnosing and treating the diseases that Cimzia is used to treat.

Cimzia is given by injection under the skin, usually in the thigh or abdomen (tummy). The treatment starts with a 400 mg dose given as two injections, followed by a further 400 mg dose two and four weeks later. After this, patients with rheumatoid arthritis and psoriatic arthritis should be given a maintenance dose of 200 mg given as one injection, every two weeks; once patients respond to this dose, an alternative dose of 400 mg every four weeks can be given. Patients with axial spondyloarthritis should receive either 200 mg every two weeks or 400 mg every four weeks. After training, patients may inject themselves with Cimzia if their doctor agrees.

## How does Cimzia work?

The active substance in Cimzia, certolizumab pegol, is an immunosuppressant medicine, a medicine that reduces the activity of the immune system (the body's natural defences). It is made up of a monoclonal antibody, certolizumab, which has been 'pegylated' (attached to a chemical called polyethylene glycol). A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen) that is found in the body. Certolizumab pegol has been designed to attach to a messenger protein in the body called tumour necrosis factor alpha (TNF-alpha). This messenger is involved in causing inflammation and is found at high levels in patients with the diseases that Cimzia is used to treat. By blocking TNF-alpha, certolizumab pegol reduces the inflammation and other symptoms of the diseases.

Pegylation decreases the rate at which the substance is removed from the body and allows the medicine to be given less often.

## How has Cimzia been studied?

For active rheumatoid arthritis that has not responded adequately to previous treatment with DMARDs, Cimzia has been compared with placebo (a dummy treatment) in two main studies involving 1,601 adults who were receiving methotrexate treatment. An additional study compared Cimzia given alone with placebo in 218 patients whose response to other medicines such as methotrexate had been inadequate. However, the dose of Cimzia used in this study was higher than the normal dose. The main measures of effectiveness were the number of patients who had at least a 20% reduction in the number and severity of symptoms after 24 weeks and a reduction in the worsening of joint damage as seen on X-rays.

Cimzia was also compared with placebo in 879 adults with active rheumatoid arthritis who had never received treatment with DMARDs. In this study, all patients also received methotrexate and the main measure of effectiveness was the number of patients who achieved sustained remission (no detectable disease activity) after 52 weeks of treatment.

For axial spondyloarthritis, Cimzia has also been compared with placebo in one main study involving 325 adults. The main measure of effectiveness was the number of patients who had at least a 20% reduction in the number and severity of symptoms after 12 weeks of treatment.

For psoriatic arthritis, Cimzia has been compared with placebo in one main study involving 409 adults who were also receiving other treatments for this condition. The main measures of effectiveness were the number of patients who had at least a 20% reduction in the number and severity of symptoms after 12 weeks and a reduction in the worsening of joint damage after 24weeks.

## What benefit has Cimzia shown during the studies?

In rheumatoid arthritis, Cimzia with methotrexate was more effective than placebo with methotrexate. In the first main study, 57% of patients receiving Cimzia (141 out of 246) achieved 20% reductions compared with 9% of patients receiving placebo (11 out of 127). In the other main study, the results were similar with 59% of patients who received Cimzia (228 out of 388) achieving 20% reductions compared with 14% of patients receiving placebo (27 out of 198). This study also showed that patients who received Cimzia had a greater reduction in the worsening of joint damage as seen on X-rays. In the additional study of Cimzia used on its own, more patients who received Cimzia achieved 20% reductions compared with those who received placebo. In the last study in patients who had never received treatment with DMARDs, almost 29% of patients (189 out of 655) treated with Cimzia in combination with methotrexate were in sustained remission after 52 weeks of treatment, compared with 15% (32 out of 213) of patients receiving placebo with methotrexate.

In the main study in axial spondyloarthritis, 58% of patients receiving Cimzia 200 mg every 2 weeks and 64% of patients receiving Cimzia 400 mg every 4 weeks achieved at least a 20% reduction compared with 38% of patients receiving placebo.

In the psoriatic arthritis study, 58% of patients receiving Cimzia 200 mg every two weeks and 52% of patients receiving Cimzia 400 mg every four weeks achieved at least 20% reductions compared with 24% of patients receiving placebo. However, no significant difference between Cimzia and placebo was seen regarding a reduction in the worsening of joint damage.

## What is the risk associated with Cimzia?

The most common side effects with Cimzia (seen in between 1 and 10 patients in 100) are bacterial infections including abscesses (cavities containing pus), viral infections (including herpes, papillomavirus, and influenza), eosinophilic disorders (disorders of eosinophils, a type of white blood cell), leucopenia (low white blood cell counts including low levels of neutrophils and lymphocytes), nausea (feeling sick), headaches (including migraine), sensory abnormalities (such as numbness, tingling, burning sensation), hypertension (high blood pressure), hepatitis (liver inflammation) including increased levels of liver enzymes, rash, fever, pain, asthenia (weakness), pruritus (itching) and reactions at the injection site. For the full list of all side effects reported with Cimzia, see the package leaflet.

Cimzia must not be used in patients with active tuberculosis, other severe infections, or moderate to severe heart failure (an inability of the heart to pump enough blood around the body). For the full list of restrictions, see the package leaflet.

## Why has Cimzia been approved?

The CHMP decided that Cimzia's benefits are greater than its risks and recommended that it be given marketing authorisation.

## What measures are being taken to ensure the safe and effective use of Cimzia?

A risk management plan has been developed to ensure that Cimzia is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Cimzia, including the appropriate precautions to be followed by healthcare professionals and patients.

The company that markets Cimzia will also provide educational packs for doctors who will prescribe Cimzia. These packs will include information on the safety of the medicine. Patients will be given a special patient alert card with safety information that patients should carry on them.

## Other information about Cimzia

The European Commission granted a marketing authorisation valid throughout the European Union for Cimzia on 1 October 2009.

The full EPAR for Cimzia can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Cimzia, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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