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Cimzia (*certolizumab pegol*)

An overview of Cimzia and why it is authorised in the EU

What is Cimzia and what is it used for?

Cimzia is a medicine that is used in adults to treat the following diseases:

- active rheumatoid arthritis (a disease causing inflammation of the joints) when it is used in combination with another medicine, methotrexate, or given alone when treatment with methotrexate is not appropriate.
- axial spondyloarthritis (a disease causing inflammation and pain in the joints of the spine), including ankylosing spondylitis and when the X-ray does not show disease but there are clear signs of inflammation.
- psoriatic arthritis (a disease causing red, scaly patches on the skin and inflammation of the joints) when it is used in combination with methotrexate or given alone when treatment with methotrexate is not appropriate.
- plaque psoriasis, a disease causing red, scaly patches on the skin.

Cimzia is mostly used for conditions that are severe, moderately severe or getting worse, or when patients cannot use other treatments. For detailed information on the use of Cimzia in all conditions, see the summary of product characteristics.

Cimzia contains the active substance certolizumab pegol.

How is Cimzia used?

Cimzia can only be obtained with a prescription and treatment 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 available as pre-filled syringes, prefilled pens and dose-dispenser cartridge. It is given by injection under the skin, usually in the thigh or abdomen (belly). Treatment starts with a 400-mg dose given as two injections, followed by a further 400-mg dose 2 and 4 weeks later. After this, depending on the condition being treated, patients should continue with 200 mg or 400 mg, given as one or two injections every 2 or 4 weeks. After training, patients may inject Cimzia themselves if their doctor agrees.

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For more information about using Cimzia, see the package leaflet or contact your doctor or pharmacist.

How does Cimzia work?

The active substance in Cimzia, certolizumab pegol, reduces the activity of the immune system (the body's 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 a protein that has been designed to recognise and attach to a specific structure 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 for. By blocking TNF-alpha, certolizumab pegol reduces 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.

What benefits of Cimzia have been shown in studies?

Nine main studies involving over 3,000 patients have found Cimzia effective for reducing symptoms of inflammatory conditions. The studies included adults with active rheumatoid arthritis, axial spondyloarthritis, psoriatic arthritis and moderate to severe plaque psoriasis:

- For active rheumatoid arthritis that had not improved adequately with disease-modifying antirheumatic drug (DMARD) treatment, two main studies found Cimzia effective when used with methotrexate when compared with placebo (dummy treatment). In the first study, symptoms were reduced by at least 20% in 57% of patients who received Cimzia (141 out of 246) compared with 9% of patients who received placebo (11 out of 127). In the other main study, symptoms were reduced by at least 20% in 59% of patients who received Cimzia (228 out of 388) compared with 14% of patients who received placebo (27 out of 198). Also, X-rays showed that joint damage worsened to a lesser extent in patients who received Cimzia.

  Similar results were seen in a study with patients who had not adequately responded to other medicines such as methotrexate. However, the dose of Cimzia used in this study was higher than the usual dose.

  In patients with active rheumatoid arthritis who had never received DMARDs, treatment with Cimzia led to sustained remission (no detectable disease activity) after 52 weeks of treatment. In a study in 879 patients who had never received DMARDs, treatment with Cimzia and methotrexate led to remission in almost 29% of patients (189 out of 655), compared with 15% (32 out of 213) of patients receiving placebo with methotrexate.
- A study in patients with axial spondyloarthritis showed that symptoms improved by at least 20% after 12 weeks in around 60% of patients treated with Cimzia compared with around 40% of patients receiving placebo.
- For psoriatic arthritis, symptoms improved by at least 20% in 58% of patients treated with Cimzia 200 mg every two weeks compared with 24% of patients receiving placebo. For patients receiving Cimzia 400 mg every four weeks 52% saw an improvement.
- In the treatment of moderate to severe plaque psoriasis, Cimzia was compared with placebo in two main studies. The main measure of effectiveness was the number of patients who responded to treatment after 16 weeks, meaning that symptom scores improved by 75% or more. Treatment with Cimzia 200 mg every two weeks in the two studies led to 66.5% and 52.6% of patients

responding compared with 6.5% and 4.5% of patients receiving placebo. Patients on Cimzia 400 mg every two weeks led to 75.8% and 55.4% of patients responding.

A third study compared Cimzia with placebo as well as another medicine called etanercept. After 12 weeks of treatment, Cimzia 200 mg every two weeks led to 61% of patients responding and 67% responding with Cimzia 400 mg every two weeks compared with 53% of patients receiving etanercept and 5% of patients receiving placebo.

What are the risks associated with Cimzia?

The most common side effects with Cimzia (affecting up to 1 in 10 people) are bacterial infections including abscesses (a swollen area where pus has collected), viral infections (including herpes, papillomavirus and influenza), eosinophilic disorders (disorders of eosinophils, a type of white blood cell), leucopenia (low white blood cell counts), nausea (feeling sick), headaches (including migraine), sensory abnormalities (such as numbness, tingling and burning sensation), high blood pressure, hepatitis (liver inflammation) including increased levels of liver enzymes, rash, fever, pain, weakness, itching and reactions at the injection site. For the full list of side effects of Cimzia, see the package leaflet.

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

Why is Cimzia authorised in the EU?

The European Medicines Agency decided that Cimzia's benefits are greater than its risks and that it can be authorised for use in the EU.

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

The company that markets Cimzia will 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 reminder card with safety information that they should carry with them.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Cimzia have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Cimzia are continuously monitored. Side effects reported with Cimzia are carefully evaluated and any necessary action taken to protect patients.

Other information about Cimzia

Cimzia received a marketing authorisation valid throughout the EU on 1 October 2009.

Further information on Cimzia can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/cimzia.

This overview was last updated in 07-2019.