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EPAR summary for the public

Cyltezo

adalimumab

This is a summary of the European public assessment report (EPAR) for Cyltezo. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Cyltezo.

For practical information about using Cyltezo, patients should read the package leaflet or contact their doctor or pharmacist.

What is Cyltezo and what is it used for?

Cyltezo is a medicine that acts on the immune system and is used to treat the following conditions:

- plaque psoriasis (a disease causing red, scaly patches on the skin);
- psoriatic arthritis (a disease causing red, scaly patches on the skin with inflammation of the joints);
- rheumatoid arthritis (a disease causing inflammation of the joints);
- axial spondyloarthritis (inflammation of the spine causing back pain), including ankylosing spondylitis and when X-ray does not show disease but there are clear signs of inflammation;
- Crohn's disease (a disease causing inflammation of the gut);
- ulcerative colitis (a disease causing inflammation and ulcers in the lining of the gut);
- polyarticular juvenile idiopathic arthritis and active enthesitis-related arthritis (both rare diseases causing inflammation in the joints);
- hidradenitis suppurativa (acne inversa), a long-term skin disease that causes lumps, abscesses (collections of pus) and scarring on the skin;
- non-infectious uveitis (inflammation of the layer beneath the white of the eyeball).

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Cyltezo is mostly used in adults when their conditions are severe, moderately severe or getting worse, or when patients cannot use other treatments. For detailed information on the use of Cyltezo in all conditions, including when it can be used in children, see the summary of product characteristics.

Cyltezo contains the active substance adalimumab and is a 'biosimilar medicine'. This means that Cyltezo is highly similar to a biological medicine (the 'reference medicine') that is already authorised in the European Union (EU). The reference medicine for Cyltezo is Humira. For more information on biosimilar medicines, see here.

How is Cyltezo used?

Cyltezo is available as a solution for injection under the skin in a pre-filled syringe or pen and is usually given every 2 weeks. The dose and frequency of injection depends on the condition to be treated and the dose for a child is calculated according to the child's weight and height. After training, patients or their carers may inject Cyltezo if their doctor considers it appropriate.

Treatment with Cyltezo must be started and supervised by a doctor who has experience in the treatment of the diseases for which Cyltezo is used. Doctors treating uveitis should also take advice from doctors who have experience of using Cyltezo.

Cyltezo can only be obtained by prescription. For further information, see the package leaflet.

How does Cyltezo work?

The active substance in Cyltezo, adalimumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a substance in the body called tumour necrosis factor (TNF). TNF is involved in causing inflammation and is found at high levels in patients with the diseases that Cyltezo is used to treat. By attaching to TNF, adalimumab blocks its activity, thereby reducing inflammation and other symptoms of the diseases.

What benefits of Cyltezo have been shown in studies?

Laboratory studies comparing Cyltezo with Humira have shown that the active substance in Cyltezo is highly similar to that in Humira in terms of structure, purity and biological activity. Studies have also shown that giving Cyltezo produces similar levels of the active substance in the body to giving Humira.

In addition, a study involving 645 patients with moderate or severe rheumatoid arthritis who were also taking methotrexate confirmed that Cyltezo and Humira have similar effectiveness. Treatment response was measured as a 20% or more improvement in symptom score, which was seen after 12 and 24 weeks of treatment in 67% and 69% respectively of those given Cyltezo. This compared with 61% and 65% of those given Humira. Comparable benefit continued to be seen with longer term treatment for 48 weeks.

Because Cyltezo is a biosimilar medicine, the studies on effectiveness and safety of adalimumab carried out with Humira do not all need to be repeated for Cyltezo.

What are the risks associated with Cyltezo?

The most common side effects with adalimumab (seen in more than 1 patient in 10) are infections (including in the nose, throat and sinuses), injection site reactions (redness, itching, bleeding, pain or swelling), headache and muscle and bone pain.

Like other medicines of its class, Cyltezo may affect the ability of the immune system to fight off infections and cancer, and there have been some cases of serious infections and blood cancers in patients using adalimumab.

Other rare serious side effects (which may affect up to 1 in 1,000 people) include failure of bone marrow to produce blood cells, disorder of the nerves, lupus and lupus-like conditions (where the immune system attacks the patient's own tissues, causing inflammation and organ damage), and Stevens-Johnson syndrome (a serious skin condition).

Cyltezo must not be used in patients with active tuberculosis or other severe infections, or in patients with moderate to severe heart failure (an inability of the heart to pump enough blood around the body).

For the full list of side effects and restrictions with Cyltezo, see the package leaflet.

Why is Cyltezo approved?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Cyltezo has a highly similar structure, purity and biological activity to Humira and is distributed in the body in the same way.

In addition, a study in rheumatoid arthritis has shown that the effects of the medicine are equivalent to those of Humira in this condition. All these data were considered sufficient to conclude that Cyltezo will behave in the same way as Humira in terms of effectiveness and safety in its approved uses. Therefore, the Agency's view was that, as for Humira, the benefit outweighs the identified risk, and it recommended that Cyltezo be given marketing authorisation.

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

The company that markets Cyltezo must provide educational packs for doctors who prescribe the medicine. These packs will include information on the safety of the medicine. An alert card will also be given to patients.

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

Other information about Cyltezo

The European Commission granted a marketing authorisation valid throughout the European Union for Cyltezo on 10 November 2017.

The full EPAR for Cyltezo 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 Cyltezo, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2017.