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EPAR summary for the public

Amgevita

adalimumab

This is a summary of the European public assessment report (EPAR) for Amgevita. 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 Amgevita.

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

What is Amgevita and what is it used for?

Amgevita 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 there is no damage on X-ray but 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 chronic 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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Amgevita 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 Amgevita in all conditions, including when it can be used in children, see the summary of product characteristics (also part of the EPAR).

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

How is Amgevita used?

Amgevita can only be obtained with a prescription and treatment should be started and supervised by specialist doctors experienced in the diagnosis and treatment of the conditions for which it is authorised. Doctors treating uveitis should also take advice from doctors who have experience of using Amgevita.

The medicine is available as a solution for injection under the skin in a pre-filled syringe or pen. The dose depends on the condition to be treated and in children is usually calculated according to the child's weight and height. After the starting dose, Amgevita is most often given every two weeks, but it may be given every week in certain situations. After training, patients or their carers may inject Amgevita if their doctor considers it appropriate. Patients may be given other medicines during treatment with Amgevita, such as methotrexate or corticosteroids (other anti-inflammatory medicines).

For information on the doses to be used for each condition and other information on the use of Amgevita, see the package leaflet.

How does Amgevita work?

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

What benefits of Amgevita have been shown in studies?

Extensive laboratory studies comparing Amgevita with Humira have shown that adalimumab in Amgevita is highly similar to adalimumab in Humira in terms of chemical structure, purity and biological activity.

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

The medicine has been shown to have similar effects to Humira in one main study involving 526 patients with moderate to severe rheumatoid arthritis that had not responded adequately to methotrexate, and in another main study in 350 patients with moderate to severe psoriasis.

In the rheumatoid arthritis study, response was measured as a 20% or more improvement in symptom score after 24 weeks of treatment: 75% of those given Amgevita responded, compared with 72% of those given Humira. In the psoriasis study, which looked at the degree of improvement after 16

weeks, there was an 81% improvement in symptom score with Amgevita compared with an 83% improvement with Humira.

What are the risks associated with Amgevita?

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

Amgevita and other medicines of its class may also 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 (seen in between 1 in 10,000 and 1 in 1,000 patients) 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).

Amgevita 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 restrictions with Amgevita, see the package leaflet.

Why is Amgevita approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that, in accordance with EU requirements for biosimilar medicines, Amgevita has a highly similar structure, purity and biological activity to Humira and is distributed in the body in the same way.

In addition, studies in rheumatoid arthritis and psoriasis have shown that the effects of the medicine are equivalent to those of Humira in these conditions. All these data were considered sufficient to conclude that Amgevita will behave in the same way as Humira in terms of effectiveness and safety in its approved indications. Therefore, the CHMP's view was that, as for Humira, the benefit outweighs the identified risk. The Committee recommended that Amgevita be given marketing authorisation.

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

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

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

Other information about Amgevita

The European Commission granted a marketing authorisation valid throughout the European Union for Amgevita on 22 March 2017.

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

This summary was last updated in 03-2017.